



### May 2022 Update

Serving the NC Life Sciences Industry

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## NCBIO This Month

- NCGA short session priorities
- MDUFA/PDUFA hearing updates
- Congress addressing antimicrobial resistance
- Welcoming new NCBIO members
- OpenDoors seeks partners for workforce diversity
- Register for May 11 Luncheon and Forum

... and more

Lead gifts from Alexandria Real Estate, Biogen, Hatteras push Taylor scholarship fund past \$200,000



The BioWork Lab at Wake Tech's new Lilly Science and Technology Center was named for NCBIO co-founder and president Sam Taylor.

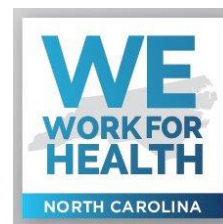
The Samuel M. Taylor Memorial Scholarship Fund created by NCBIO at the North Carolina Community Colleges Foundation Inc. has exceeded \$200,000 in gifts and pledges with leadership gifts coming from **Alexandria Real Estate Equities, Biogen and Hatteras Venture Partners.**

**Grifols, Novo Nordisk, Smith Anderson and Thermo Fisher** have also made significant contributions. Almost 50 companies and individuals have made gifts or pledges to the fund.

Those wanting to contribute to the scholarship fund should make checks payable to the North Carolina Community Colleges Foundation, write Sam Taylor Memorial Scholarship in the memo field or cover letter, and mail them to

NC Community Colleges Foundation  
200 W Jones Street  
Raleigh, NC 27603

## NCBIO Sustaining Members



## NCBIO Supporting Members



[More >>](#)





## STATE UPDATES

### Legislators gear up for short session, NCBIO sets priorities

The NC General Assembly kicks off its short session on May 17. Legislative leaders have expressed a desire to wrap things up by the Fourth of July, but if history is any guide, they're not likely finish before mid July. This is especially true considering law makers will be dealing with approximately \$4 billion in surplus collections and revisiting Medicaid expansion.

In 2021 the legislature and governor enacted a two-year budget that includes \$5 million in the first year for the One NC Small Business Program. For the first time, the program's funding included \$2 million in recurring funds that will be available each year, along with an additional \$3 million appropriated for FY 2022. During the short session, NCBIO will advocate for additional funding for the program.

In 2015, the General Assembly approved the use of biosimilars as substitutes for biologic treatments. The legislation required pharmacists to inform physicians when they substitute an interchangeable biosimilar for a prescribed biologic. However, that notification requirement came with a sunset provision that has since nullified the requirement. NCBIO is working with a coalition of biologics and biosimilars manufacturers to encourage legislators to repeal the sunset provision this session, which will reinstate the notification mandate.

North Carolina's Qualified Business Venture Tax Credit Program provided significant tax benefits to North Carolina taxpayers in connection with their investments in certain types of businesses from 1989 to 2013. Individual investors were entitled to a tax credit equal to 25% of the purchase price paid by the investor for the equity securities or subordinated debt of the Qualified Business purchased by the investor in the calendar year. The maximum credit was \$50,000. NCBIO plans to work with a growing network of angel investors to advocate for the reauthorization for the Qualified Business Venture Tax Credit.

NCBIO's final priority for the 2022 short session of the General Assembly will be to advocate for the NC Biotechnology Center's funding requests.



## NATIONAL UPDATES

### SBIR/STTR programs up for renewal

The Small Business Innovation Research and Small Business Technology Transfer programs are authorized through Sept. 30. The SBIR and STTR programs make competitive awards for small businesses to develop important new technologies.

NCBIO has joined with our national partners in signing a letter to law makers urging Congress to reauthorize this vital program that has provided over 179,000 awards totaling more than \$54.3 billion to U.S. small businesses as of 2019.

### Congress meets on MDUFA, PDUFA, Burr weighs in

The Food and Drug Administration's proposed recommendations for the fifth Medical Device

User Fee Amendments drew a mixed response during meetings with members of Congress. The proposal sets out how much the FDA will collect in fees from medical device companies, as well as its goals for review times and priorities for the next five years.

Sen. Richard Burr took the FDA to task for missing the Jan. 15 deadline for providing Congress with recommendations for a MDUFA agreement and for not publishing minutes of all the meetings with industry that led to the deal.

The senator said the agency was three months late in finalizing the MDUFA V deal because the FDA's Center for Devices and Radiological Health "refused to acknowledge that the agency didn't meet all of its goals from the last round and, now, the FDA wants double the money for mediocre performance improvements and, for certain devices, longer review times."

Other groups raised concerns that the agency relies too much on funding from medical device companies and did not incorporate new provisions to protect people from ineffective or unsafe devices.

Under MDUFA V, the FDA will see a minimum of \$1.78 billion and could see up to \$1.9 billion if it meets certain hiring goals. According to Lauren Roth, associate commissioner for policy at the FDA, the deal could bring in 273 to 387 new hires for the agency.

Members of Congress also weighed in on the Prescription Drug User Fee Act. PDUFA has morphed into a way to provide additional revenue to the agency so it can hire more staff, improve its systems and establish a better managed, more reliable review process to make important drugs available to patients sooner.

During discussions, Burr questioned the need for ever-expanding user fee agreements, which provide for the majority of the FDA's total funding. In 1993, he noted, PDUFA was first authorized and included only about \$35 million for FDA. Today, the agreement is worth more than \$1 billion.

More @ [AdvaMed](#), [Endpoints](#) and [MedTechDive >>](#)

## Congress addresses antimicrobial resistance

Lawmakers continue to consider legislation addressing the challenges of drug-resistant infections.

- The PASTEUR Act would create a new subscription-style model through which the government would pay upfront for access to new antimicrobials rather than linking payment and sales volume, and it would also increase resources for critical antibiotic stewardship programs around the country.
- The DISARM Act would modernize how Medicare reimburses hospitals for appropriate use of innovative antimicrobials and improve patient access to novel treatments.
- The PREVENT Pandemics Act is a compilation of more than a year's work to address lessons learned from COVID-19 and build on investments made during the past two years.

These three policies are complementary and critically needed in the near term to stabilize and sustain the antimicrobials ecosystem and avoid further preventable deaths from antimicrobial-resistant infections.

[More @ BIO >>](#)

## Sandbagging an Alzheimer's Treatment — Wall Street Journal criticizes CMS decision

The editorial board at the Wall Street Journal came out against the early April decision by the Centers for Medicare and Medicaid Services to only cover the Alzheimer's drug Aduhelm for patients enrolled in clinical trials. The Journal writers said that CMS now wants to act as a political check on the safety and efficacy decisions made by the Food and Drug Administration. The editorial states

"This is the first time CMS has restricted drug coverage in such a way. CMS quibbles with the FDA's accelerated approval. Yet the agency also plans to require additional studies even for Alzheimer's treatments that receive traditional FDA approval. The 'rigor' of the study design, CMS says, will be based on 'the strength of evidence in the initial, successful trial.'

In short, CMS bureaucrats will now scrutinize FDA's clinical judgments. CMS says its 'decision facilitates innovation,' but it does the opposite. It creates enormous uncertainty about whether CMS will cover new Alzheimer's treatments as well as other drugs granted accelerated approval."

[More @ Wall Street Journal >>](#)



## Kathi Vidal to lead Patent and Trademark Office

Kathi Vidal, President Joe Biden's pick to lead the U.S. Patent and Trademark Office, was confirmed by the Senate.

Vidal is the second woman to hold the dual roles of under secretary of commerce for intellectual property and USPTO director. She brings experience as a litigator who's been on both sides of patent disputes, most recently as managing partner of Winston & Strawn LLP's Silicon Valley office.

[More @ Bloomberg](#)

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## NCBIO Updates

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### NCBIO welcomes new members

The NCBIO Board of Directors voted unanimously April 29 to accept the following new members into the organization:

- [Bright Path Labs](#) uses a patented AI-powered continuous-flow manufacturing technology to make and scale molecules faster, more efficiently, and less expensively than traditional batch techniques.
- [Hays](#) technology and life science recruiting expertise will enable you to find the best talent in the market whether you are looking for staff in pharmaceuticals, biotechnology, CRO or medical device/technology.
- [JWM Consulting](#) provides employee benefit consulting, alternative funding solutions, compliance guidance, renewal strategies and benefit advice, enrollment support and educational tools.
- [Kaio Therapy's](#) immune activating heat therapy combines immunotherapy with hyperthermia and allows patients a treatment for primary tumor elimination, tumor control and margin reduction with an immunotherapeutic component.
- [Michael Best](#) is a full-service law firm with more than 350 lawyers and technical professionals who work in collaborative, interdisciplinary practices to serve clients around the world.
- [Vectgen Biosciences](#) improves the lives of patients and families living with devastating illnesses, including rare diseases and cancer, by delivering next-generation health care solutions.

### Bryant joins NCBIO in EA role

Tanya Bryant has succeeded Casey Nelson as NCBIO's executive assistant. NCBIO thanks Nelson for her nearly four years of outstanding service.

Bryant has more than 20 years' experience in administrative, human resources and accounting roles. She comes to us from Cisco Systems where she served for three years in an EA role. Prior to Cisco, she held positions at Network Connection and Mercy Diagnostics. In her career, she has also worked for Rex Hospital and the UNC School of Medicine. She holds an associate's degree in business administration.

### Diversity, equity and inclusion resource page launches

NCBIO has created a webpage for members that offers information about our diversity, equity and inclusion initiatives and offerings, as well as a collection of guidance and resources from our DEI partner, The Diversity Movement.

The page at [ncbioscience.net/dei](https://ncbioscience.net/dei) includes highlights from NCBIO's DEI programming and videos and links to webinars, blogs and guides from The Diversity Movement.

[More @ NCBIO](#)

### OpenDoors seeking companies to help increase biotech workforce diversity

OpenDoors, an initiative created by Triangle executives including NCBIO board member and Enzerna President Joseph Ruiz, Ph.D., has launched the OpenDoors Summer Internship program to encourage high-school and community college students to consider the careers in bio-industry.

Program organizers are inviting other local companies to join the initiative by providing a four-to-six-week paid internship to help build the next generation of life science professionals.

The ODSI program (pronounced "odyssey") connects students with opportunities in life sciences organization, including biotechs, biopharmas, CROs and ag-techs. These opportunities do not have to focus on research; internships can be in communications, business development, manufacturing or other areas within the life sciences industry.

The response from high school students has far exceeded their expectations, ODSI organizers said. In this first year of the program, they have received over 40 applications.

OpenDoors Group is a nonprofit organization focused on improving long-term workforce diversity in the biotech and life sciences industry, especially among Blacks, Latines and Native Americans.

For more information, email [diversity@opensdoorgroup.com](mailto:diversity@opensdoorgroup.com) or follow [ODSI on LinkedIn](#).

## NCBIO Member News

*To be included in member news, send information about your organization to [David Etchison](#).*

**BioCryst Pharmaceuticals** announced the European Medicines Agency has granted access to the Priority Medicines scheme for BCX9250, a novel, oral activin receptor-like kinase-2 inhibitor discovered and developed by BioCryst for the treatment of fibrodysplasia ossificans progressiva. [More >>](#)

**Bioventus** has exercised its call option to acquire CartiHeal Ltd. for approximately \$315 million with an additional approximately \$135 million payable contingent on trailing sales. The decision follows the FDA's premarket approval of CartiHeal's Agili-C implant. [More >>](#)

**Chiesi USA** was recognized as a top employer in eight global markets in 2021 and as Top Employer Europe for 10th consecutive year and experienced growth across its global markets with the U.S. up more than 10% and China up 22%. [More >>](#)

**Enzyvant** plans to develop a Good Manufacturing Practice-compliant regenerative medicine manufacturing facility in Morrisville. The development of the 25,972-square-foot facility is expected to begin this summer and take approximately two and a half years to complete. [More >>](#)

**Mycovia** received FDA approval for VIVJOA (oteseconazole capsules), an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis in females with a history of RVVC who are not of reproductive potential. [More >>](#)

**NALA Membranes** has signed a research agreement with Separation Technologies Applied Research and Translation Centre, Singapore to collaborate to scale-up the company's chlorine resistant membrane for pilot testing at municipal water systems. [More >>](#)

**Novartis** announced the FDA has granted commercial licensure approval for its multiproduct gene therapy manufacturing facility in Durham. This approval allows the 170,000 square-foot facility to make, test and release commercial Zolgensma, as well as produce gene therapy product for current and future clinical trials. [More >>](#)

**Novozymes** and **SAS** are collaborating with NC State University at its new Plant Sciences Building, a leading-edge facility at the heart of the university's N.C. Plant Sciences Initiative, an effort that fosters interdisciplinary, team-based work between academia, industry, government, and growers. [More >>](#)

**Opus Genetics** announced a strategic manufacturing services agreement with National Resilience, a technology-focused biomanufacturing company dedicated to broadening access to complex medicines, to support the development and manufacturing of Opus' pipeline. [More >>](#)

**Pfizer** will acquire ReViral, a privately held, clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing novel antiviral therapeutics that target respiratory syncytial virus. ReViral's U.S. headquarters is in Durham. [More >>](#)

**Sage Therapeutics, Inc.** and **Biogen Inc.** initiated a rolling submission of a new drug application to the FDA for zuranolone in the treatment of major depressive disorder. Zuranolone is an investigational two-week, once-daily oral drug being developed for MDD and postpartum depression. [More >>](#)

**Smith Anderson** has added intellectual property attorney Kelsey Nix as co-leader of its IP litigation practice. [More >>](#)

**Syneos Health** announced the appointment of Michelle Keefe as CEO and a member of the company's Board of Directors. Keefe, currently president, medical affairs and commercial solutions, succeeds Alistair Macdonald, who will retire after 20 years at Syneos. [More >>](#)

**Thermo Fisher's PPD** clinical research business and Matrix Clinical Trials, a Matrix Medical Network offering, are collaborating to bring clinical trials to patients with an innovative

mentoring, and considering training opportunities to patients that an innovative decentralized clinical trial solution by deploying state-of-the-art Matrix mobile research sites and expert clinical staff across the U.S. to help recruit and retain trial participants. [More >>](#)

## Events

### NCBIO Luncheon and Forum May 11

The panel discussion is "Regulatory Strategy: Post Pandemic." Join this discussion to learn about recent FDA submissions and regulatory hurdles. You'll be able to get answers to your questions around issues that you have experienced and ways to navigate around them as you look for solutions. The discussion will be moderated by **Robert Rosenthal**, partner, MED1 Ventures, and include

- **Roxy Kozyckyj**, director of state government and regional affairs, AdvaMed;
- **Karl Nobert**, senior counsel, Michael Best;
- **Alessandra Pavesio**, senior vice president and CSO, Bioventus; and
- a representative from the FDA.

Thank you to our forum sponsor, [Michael Best](#). If you are interested in sponsoring this forum, please contact [Natacha Janvier](#), membership director.

**REGISTER NOW**

### NCBIO Legislative Reception June 22

Join NCBIO members and legislators for an evening reception Wednesday, June 22, from 5:30 to 7:30 p.m. at the NC Museum of History highlighting North Carolina'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. Registration is open to all NCBIO member companies and their representatives.

NCBIO thanks premier sponsors **Amgen**, **IQVIA**, **Lilly**, **Pfizer** and **We Work for Health NC** and sponsors **BIO**, **Biogen**, **Bristol Myers Squibb** and **Seqirus** for supporting this event. If you are interested in sponsoring, please contact Membership Director [Natacha Janvier](#).

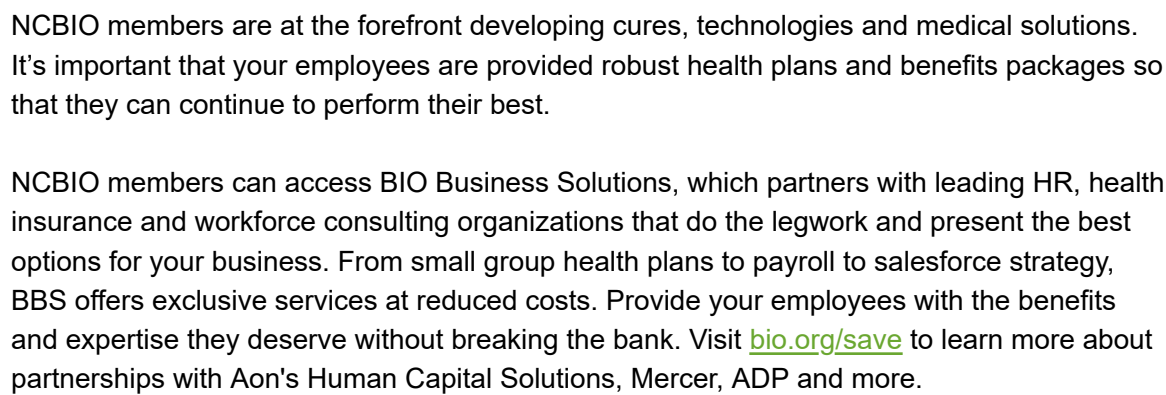
**REGISTER NOW**


[AdvanSE Life Sciences Conference | May 25-27 | Alpharetta, Georgia](#)



For investors and life science entrepreneurs seeking new business opportunities, the Southeast Life Sciences Conference is one the best places to find your next de-risked investment or partnership.

### NCBIO calendar

- [Analytical Methods for Raw Materials Testing](#) hosted by BTEC (5/3/2022 to 5/5/2022)
- [Hands-On cGMP Biomanufacturing Operations](#) hosted by BTEC (5/3/2022 to 5/6/2022)
- [Leading from the Boardroom: Navigating the Life Sciences Boardroom](#) hosted by NACD Research Triangle Chapter (5/4/2022)
- [Informa Markets Engineering South Meet Up](#) (5/5/2022)
- [Clinical Supervision Workshop Series](#) hosted by UNC-Wilmington (5/7/2022)
- [Larger than Life Science: Closing the Deal](#) hosted by LaunchBio (5/10/2022)
- [NCBIO Medical Device Luncheon and Forum](#) (5/11/2022)
- [State of Technology Conference on Future of Cloud](#) hosted by NC TECH (5/12/2022)
- [Chromatography Column Packing: Foundations and Applications](#) hosted by BTEC (5/17/2022 to 5/19/2022)
- [The Way Forward with DE&I: Momentum Through Continued Action](#) hosted by LaunchBio (5/17/2022)
- [Protein Precipitation and Crystallization](#) hosted by BTEC (5/24/2022 to 5/27/2022)
- [Tech Job Expo](#) hosted by NC TECH (6/8/2022)
- [BIO International Convention 2022](#) (6/13/2022 to 6/16/2022)
- [Summer Institute 2022](#) hosted by Duke University Department of Population Health Sciences (6/13/2022 to 6/17/2022)
- [Informa Markets Engineering South](#) (6/14/2022 to 6/16/2022)



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