the ncbio biosciences organization | connections newsletter

April 2022 Update

Serving the NC Life Sciences Industry

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NCBIO This Month

- NCBIO DEI event offers insight, guidance
- One NC Small Business Program guidelines are out
- MDUFA agreement reached
- TRIPS waiver agreement reported
- Wake Tech opens new technology center
- NCBIO Legislative Reception June 22

... and more

NCBIO Roadmap to Diversity event offers guidance for member DEI initiatives

Celeste Warren, vice president, Global Diversity and Inclusion Center at Merck, delivered the event's keynote address. You can watch her talk on the NCBIO YouTube channel.

NCBIO members gathered at the NC Biotechnology Center Wednesday, March 9, to seek inspiration and guidance in pursuing their companies' diversity, equity and inclusion goals.

Some key takeaways from the discussions included the need to weave DEI into everything the company does; it can't stand alone. Success requires DEI champions at the executive level, and it is important to align DEI goals with the organization's business goals so that efforts can be properly resourced, evaluated and valued.

The Roadmap to Diversity event was made possible with the support of NCBIO's partners, AskBio, Biogen, Merck, Novo Nordisk, Precision Biosciences and the Diversity Movement, along with sponsor Aqui Tu.

MORE @ NCBIO >>

NCBIO Sustaining Members

Bio Biotechnology Innovation Organization

Biogen

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WE WORK FOR HEALTH NORTH CAROLINA

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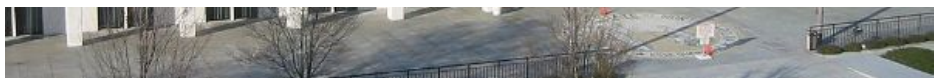


STATE UPDATES

New One NC Small Business Program guidelines published

Updated guidelines for the One North Carolina Small Business Program's SBIR/STTR Phase I Incentive Funds Program and SBIR/STTR Phase I Matching Funds Program are now final and available on the NC Department of Commerce website. Applications for the programs are now being accepted.

The fiscal year 2022 state budget includes $5 million for the One NC Small Business Program. Of that funding, $1 million is allocated to the Incentive Funds Program, and $4 million is allocated to the Matching Funds Program.

Increased funding for the One NC Small Business Program was a high priority for NCBIO last year, and for the first time, the program received recurring funds, which makes it part of the base budget going forward.

The incentive funds program reimburses eligible NC small businesses for a portion of the expenses they incur when preparing Phase I SBIR/STTR applications to federal agencies. The matching funds program awards matching funds to NC businesses who have received a federal SBIR or STTR award.

All eligible businesses are encouraged to apply. The application process is quick, easy, and straightforward, and the post-award reporting requirements are minimal, according to the Commerce Department.

Applicants to the incentive funds program must have received official notification of **receipt** of their Phase I proposal by a federal SBIR/STTR-awarding agency during the Incentive solicitation period (July 1, 2021 to June 30, 2022) to be eligible.

Applicants to the matching funds program must have received official **notification of Phase 1 award** by a federal SBIR/STTR-awarding agency during the same solicitation period to be eligible.

Businesses are eligible to receive one incentive grant and one matching grant during the FY 2021-2022 solicitation period.

Apply at www.nccommerce.com/grants-incentives/technology-funds/one-north-carolina-small-business-program.

NATIONAL UPDATES

FDA reaches MDUFA V agreement with industry

The FDA has "reached an agreement in principle" with industry on a framework for Medical Device User Fee Amendments V. AdvaMed lauded the framework after regulators and industry representatives negotiated updates to the program, which collects fees from applicants to fund FDA review.

The FDA's Center for Devices and Radiological Health and Center for Biologics Evaluation and Research will work with companies submitting products for faster, more efficient reviews and decisions without sacrificing product safety or effectiveness, the FDA said in the 38-page MDUFA V commitment letter. For example, the agreement sets the goal of making 510(k) clearance decisions within 128 calendar days for applications received in fiscal year 2023 and reducing that time to 112 days within two years.

The deal authorizes the FDA to collect at least $1.78 billion in user fees over five years and

The deal authorizes the FDA to collect at least $1.75 billion in user fees over five years and up to $1.9 billion if it hits performance targets, compared to around $1.1 billion in the last MDUFA reauthorization.

More @ Medical Design >>

WTO nations reach agreement on TRIPS waiver

The U.S., EU, India and South Africa have reportedly reached an agreement (PDF) on "key elements" of an intellectual property waiver for COVID-19 vaccines, per Reuters, though it would still need to be finalized and approved by World Trade Organization members. Here's what we know so far.

The "tentative" agreement would apply only to patents for COVID-19 vaccines, Reuters reports. The agreement does not include COVID-19 treatments or tests, and the limitations would likely exclude China from any waiver.

"We still need to see and review the full text before rendering a final judgment," says BIO's Chief Policy Officer John Murphy. "However, the irrational fixation on weakening IP is simply a distraction from the real challenge of overcoming global vaccine hesitancy, removing actual trade barriers and helping countries to strengthen their health care infrastructure so that we can get more shots in arms."

When the administration announced support for the TRIPS waiver last year, U.S. Trade Representative Katherine Tai said, "The administration's aim is to get as many safe and effective vaccines to as many people as fast as possible."

A year later, many of the nations that were supposed to benefit from a waiver have been turning back supplies of vaccine because they can't administer them as fast as they are being delivered. Recently, the director of the Africa Centres for Disease Control and Prevention, said the primary challenge for vaccinating the continent is no longer supply shortages but logistics challenges and vaccine hesitancy.

With over 12 billion doses of vaccine already manufactured, and a total of 20 billion expected by the end of this year, the underlying rationale for the waiver is contradicted by the facts on the ground. BIO agrees that U.S. leadership is vital to solving the COVID-19 pandemic, but those resources and energies must be focused where they are needed most: on building the vaccine delivery infrastructure and supporting efforts to fight vaccine resistance.

A recently leaked proposed compromise waiver would still allow competitors like India to steal intellectual property and profit from it.

At recent hearings before the House Ways and Means Committee and the Senate Finance Committee members of both parties questioned Ambassador Tai about the wisdom of continued support for the waiver, its threat to U.S. innovation and our ability to respond to future pandemics and the failure of the administration to consult and keep Congress informed about the negotiations at the WTO.

What's next? Many details are to be determined, including the length of the waivers. Then, the agreement must be accepted by all 164 WTO members.

More @ BIO >>

NC legislators get behind cancer early detection law

Rep. Greg Murphy, Rep. G. K. Butterfield, Rep. Alma Adams and Sen. Richard Burr have joined Rep. Richard Hudson in cosponsoring H.R. 1946 and S. 1873, the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021.

New blood-based screening technologies hold tremendous promise. By combining the latest advances in genomic sequencing and computing power, new tests have shown the ability to detect many hidden cancers from a simple blood draw. These new tools could dramatically increase early stage diagnosis beyond what is possible with current screenings, enabling earlier treatment for a wider range of cancers. Without the Medicare Multi-Cancer Early Detection Screening Coverage Act, Medicare beneficiaries and their physicians may not have access to these tools, even after FDA approval, for years.

NCBIO has joined with a diverse coalition of NC advocacy groups, such as the state chapter of the American Cancer Society, the NC State Grange and Meals on Wheels, to encourage the rest of the state's congressional delegation to support this legislation.

100 experts urge HHS to reject march-in petition

There is currently a march-in request before the US Department of Health and Human Services asking that the federal government use its rights in the patents on the prostate cancer drug Xtandi to allow generic competition of the treatment. This is the second time that a march-in case has been pursued for Xtandi on the grounds that it is not reasonable to charge US residents more for Xtandi than the price in other high income countries. A 2016

case was rejected by the NIH and the US Department of Defense.

The bipartisan Patent and Trademark Law Amendments Act, known as **Bayh-Dole**, empowers universities, small businesses and nonprofits to own and license inventions made with federally funded research to turn basic research into tested and approved products. Under Bayh-Dole, the government can "march in" and force additional licenses under limited circumstances, typically when a new technology is not being commercialized and made available. March-in petitions based on price have been rejected by Democratic and Republican administrations.

"The purpose of the Bayh-Dole Act was not to create a mechanism for the federal government to set prices on successfully commercialized products," says a letter to Health and Human Services Secretary Xavier Becerra signed by nearly 100 academic and private-sector innovation experts and organizations, legal scholars, and policy organizations, including BIO. Bayh-Dole created a mechanism for commercializing promising technologies that might otherwise never leave the university nor be developed into useful and lifesaving products.

More @ BIO >>
Background @ Axios >>

PREVENT Pandemics Act is 'a solid first step'

The Senate Health, Education, Labor, & Pensions Committee marked up the PREVENT Pandemics Act (S. 3799), a compilation of more than a year's work to address lessons learned from COVID-19 and build upon investments made during the past two years. The bill passed unanimously out of committee; we wait to hear the next steps for Senate floor consideration.

It's "a solid foundation," wrote BIO's Phyllis Arthur in InsideSources, with provisions to "modernize public health data, improve communication among federal, state, and local health officials, and invest in emergency medical services."

But we must do more to be "adequately prepared for future health crises"—including "leveraging the successes of Operation Warp Speed" and adding The Disease X Act, which would invest in preparing for emerging and unknown health threats, she continued.

Sen. Richard Burr is the co-sponsor on the bill.

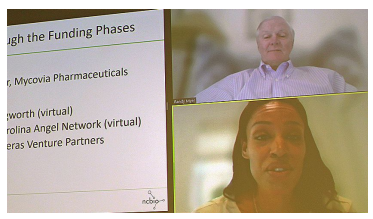
More @ Inside Sources >>

NCBIO Updates

NCBIO forum explores moving technology through funding phases

Moderator Patrick Jordan, CEO, Mycovia Pharmaceuticals

Christy Shaffer, Ph.D., partner, Hatteras Venture Partners



Randy Myer, managing director, Carolina Angel Network; and Jackie Grant, Ph.D., principal, Abingworth

A high quality board of directors and valuable outside partnerships are two advantages that biotech startups would do well to cultivate, according to the expert panelists assembled for the NCBIO Emerging Company and Technology Forum held Wednesday, March 16, at the NC Biotechnology Center.

The panelists were moderator Patrick Jordan, CEO of Mycovia Pharmaceuticals; Jackie Grant, Ph.D., principal at Abingworth; Randy Myer, managing director of the Carolina Angel Network; and Christy Shaffer, Ph.D., partner at Hatteras Venture Partners.

The event was sponsored by the Marsh & McLennan, Nikon Instruments and Wyrick Robbins.

More @ NCBIO >>

Wake Tech opens doors of new Lilly Science and Technology Center

Photo by Wake Tech Community College

The Research Triangle region's new hub for biotech and IT training has officially opened on Wake Tech's RTP Campus in Morrisville.

Elected officials and industry professionals joined college leaders in cutting a symbolic DNA strand of balloons, marking the opening of the new facility on March 17. Wake Tech also announced that the new facility will bear the name Lilly Science and Technology Center in recognition of a $1.1 million contribution from Eli Lilly and Company to support biotech and life sciences programs at the college. It is the largest single corporate contribution in Wake Tech history.

Several companies and organizations stepped up to support Wake Tech's biotechnology and life science programs. Sponsored areas in the new facility include the Amgen Co-Laboratory, the FUJIFILM Diosynth Biotechnologies Early College Suite, the Lighthouse Worldwide Solutions Aseptic Suite, the Research Triangle Foundation Executive Office Suite and the Sam Taylor BioWork Lab (NCBIO).

More >>

NCBIO President Laura Gunter and Sam Taylor's wife Nancy Reed at the opening of Wake Tech's Lilly Science and Technology Center. The building's BioWork Lab was named for Taylor.

NCBIO Member News

To be included in member news, send information about your organization to David Etchison.

NCBIO members presenting at CED Venture Connect April 6-7 in RTP include the following:

- **AgBiome**
- **Alexandria Real Estate Equities**
- **AskBio**
- **BioCryst Pharmaceuticals**
- **BioLabs NC**
- **The Conafay Group**
- **Dean Dorton**
- **Gemelli Biotech**
- **Life Edit Therapeutics**
- **Lindy Biosciences**
- **Lucerno Dynamics**
- **Locus Biosciences**
- **Precision Biosciences**

Amgen broke ground on its newest biomanufacturing facility, located in Holly Springs, on March 7. The facility is expected to be operational by 2025. More >>

Biogen and **Eisai** have amended their existing collaboration agreement on aducanumab, which is commercialized in the United States as Aduhelm. More >>

Bioventus announced that the FDA has awarded 510(k) clearance to the next generation StimRouter Neuromodulation System for the treatment of chronic pain of peripheral nerve origin, excluding craniofacial pain. More >>

Chiesi USA contributed more than $815,000 in 2021 through its Chiesi in the Community corporate social responsibility program. As an employee-led program, Chiesi employees supported 85 unique charitable organizations with 1,124 hours of time or donations in 2021. More >>

The **Lilly** Science and Technology Center opened at Wake Tech March 17. The center was named in recognition of a $1.1 million contribution from Eli Lilly and Company to support biotech and life sciences programs at the college. Spaces in the center were also named for **Amgen** and **FUJIFILM Diosynth** in recognition of their support. More >>

Novan has acquired EPI Health, a specialty pharmaceutical company focused on the U.S. dermatology market. More >>

Novartis announced that the FDA approved Pluvicto (lutetium Lu 177 vipivotide tetraxetan) for the treatment of adult patients with a certain type of advanced prostate cancer that has spread to other parts of the body. More >>

Pairwise launched its Conscious Foods brand and introduced a new produce product, Conscious Greens, nutrient-dense, leafy salad greens slated to hit grocery store shelves in the form of packaged salads in 2023. More >>

Pathalys Pharma, a new private, late-stage biopharma company developing a range of therapies for chronic kidney disease, launched with a novel clinical-stage asset, upacicalcet, acquired through a license granted by EA Pharma. More >>

Thermo Fisher Scientific will invest $97 million to expand its clinical research operations in Richmond, Virginia. The facilities include laboratory operations acquired with the purchase of **PPD**. More >>

Thermo Fisher Scientific's pharma and biopharma customers recognized its contract manufacturing leadership in all six categories of the 11th Annual CMO Leadership awards. More >>

Thermo Fisher Scientific's clinical research business has won a 2021 TOPRA Award for Regulatory Excellence, recognizing the important role of its regulatory affairs team in expediting vaccine approvals during the COVID-19 global pandemic. More >>

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 premiere sponsors **Pfizer** and **We Work for Health NC** and sponsors **Biogen**, **Bristol Myers Squibb** and **Lilly** for supporting this event. If you are interested in sponsoring, please contact Membership Director Natacha Janvier.

REGISTER NOW

NCBIO calendar

- Venture Connect hosted by CED (4/6/2022 to 4/7/2022)
- Prepare for BIO 2022 and One-on-One Partnering (4/6/2022)
- Clinical Supervision Workshop Series hosted by UNC-Wilmington (4/9/2022)
- BPD Cell and Gene Therapy Symposium & Vendor Show hosted by NCBiotech (4/14/2022)
- Life Sciences Economic Development Summit hosted by NCBiotech (4/19/2022)
- NC Ag Tech Professional Forum hosted by NCBiotech (4/21/2022)
- Cell Culture Engineering: A Single-Use Perspective hosted by BTEC (4/26/2022 to 4/28/2022)
- MDMA Annual Meeting (4/27/2022 to 4/29/2022)
- 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

- 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)
- Clinical Supervision Workshop Series hosted by UNC-Wilmington (5/7/2022)
- State of Technology Conference on Future of Cloud hosted by NC TECH (5/12/2022)

BIO Start-Up Stadium Applications Open | Deadline April 15
Participating in BIO's Shark Tank-style competition, Start-up Stadium gets you great exposure to investors, discounted registration fees, and free access to BIO One-on-One Partnering.

MDMA Annual Meeting | Washington, D.C. | April 27-79
The topic of the Medical Device Manufacturers Association 2022 Annual Meeting is "Transforming patient care and supporting the innovation ecosystem." NCBIO members can contact Amber Niebauer for a $100 discount code for registration.

Navigating the Life Sciences Boardroom | NACD RTP | May 4
Join directors and C-suite executives in the life sciences industry as the NACD Research Triangle Chapter provides a full day of educational programming and networking. The agenda will focus on key issues being addressed in the life science boardroom, including an assessment of how the nation's biotech hubs are emerging from the Covid-19 pandemic. NCBIO members receive a discount on registration. Email Membership Director Natacha Janvier for the discount link.

BIO is Partnering with ADP to Provide Full-Service HR Support to Life Sciences

NCBIO is pleased to announce the exciting addition of a new human resources service to BIO Business Solutions. We know that you are working hard to build your business and develop cures and innovations that benefit our society – and we want to help. That's why, after a thorough evaluation process, we are confident that NCBIO members will benefit from a partnership with ADP TotalSource, the nation's largest certified professional employer organization.

Through our partnership with ADP, member companies - both large and small - can take advantage of payroll, benefits, tax administration and many other forms of support at a competitively discounted rate. For those interested in full HR support, ADP TotalSource can handle all administrative tasks in a co-employment arrangement so that you are able to dedicate more time to your business. ADP TotalSource can help you attract and retain the best talent with Fortune 500®-caliber benefits, while also receiving guidance from ADP experts.

NCBIO members that begin an evaluation with ADP Total Source in March, April or May will be eligible for waived administrative fees for the first three months.

GET STARTED WITH ADP

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