October 2021 Update

Serving the NC Life Sciences Industry

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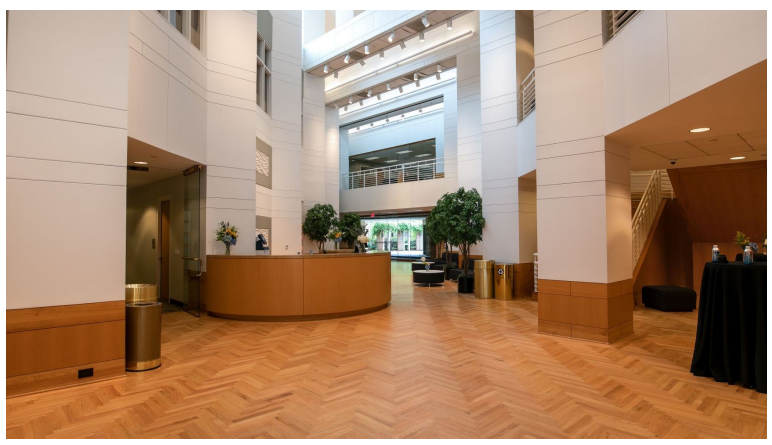
NCBIO This Month

- NCBIO Annual Meeting imminent
- A state budget might be, too
- Life Science Caucus learns about ag tech
- NC passes accumulator ban, drug licensing improvement
- Feds struggle with budget, debt ceiling
- Biden directs OHSA to create vaccine mandate rules

... and more

NCBIO Annual Meeting happening next week



NCBIO's Annual Meeting is being held Tuesday, Oct. 5 at the NC Biotech Center. The meeting is a hybrid event that is being attended virtually or in person by more than 200.

Our keynote speaker is Jude Samulski, Ph.D., president, chief scientific officer and co-founder of AskBio. Samulski will be sharing his 30-year perspective on North Carolina as the cradle for human gene therapy. He will describe his start in North Carolina and discuss where we are now and what will propel us forward to what comes next.

Attendees will hear "Tales from the Trenches" as four homegrown companies from various industry sectors share their stories on navigating the stages of success. They will learn how companies, patient groups and other stakeholders are working together to keep the focus on the patient. Panelists will review the issues currently in play at the federal level, including MDUFA and PDUFA reauthorization, drug pricing, decentralized trials and more.

Follow @ncbio on Twitter for updates from the **#NCBIO21** meeting.

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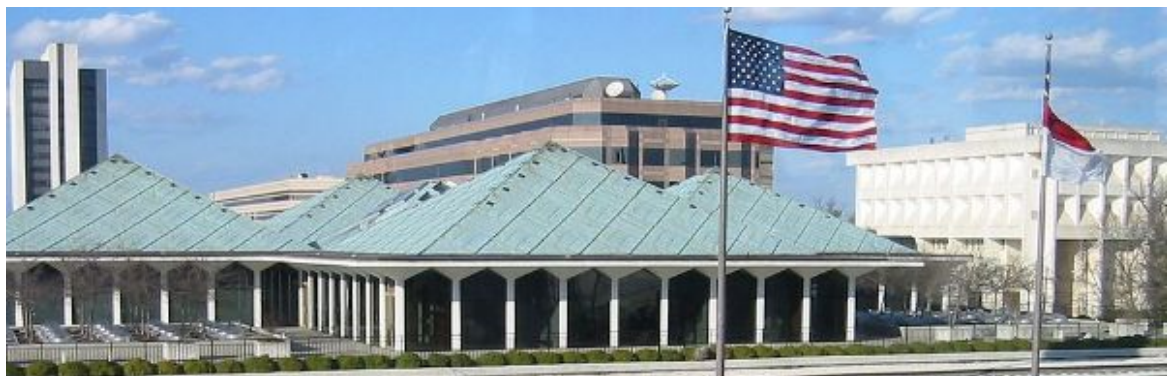

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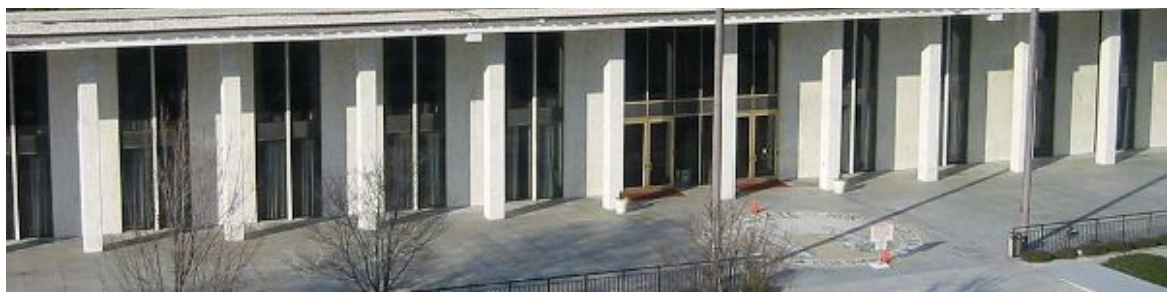

STATE UPDATES

If you have questions or concerns on any of these topics, please contact Laura Gunter.

Legislative leaders to share budget with governor before voting

We're getting closer to a state budget.

According to reports, House and Senate budget negotiators in the General Assembly have come to an agreement on the tax cuts they want to see in the budget. The few remaining disagreements were to have been worked out between Senate leader Phil Berger and House Speaker Tim Moore, and they should now be ready to share the budget proposal with Gov. Roy Cooper but not with the public.

The legislators are trying something new this year by consulting with the governor before voting on the budget. Berger and Moore have said they want to present Cooper with a budget that he is willing to sign and avoid the vetoes that sunk the budget proposals of 2019 and 2020. Because this is a new process, no one will say how long they expect it to take.

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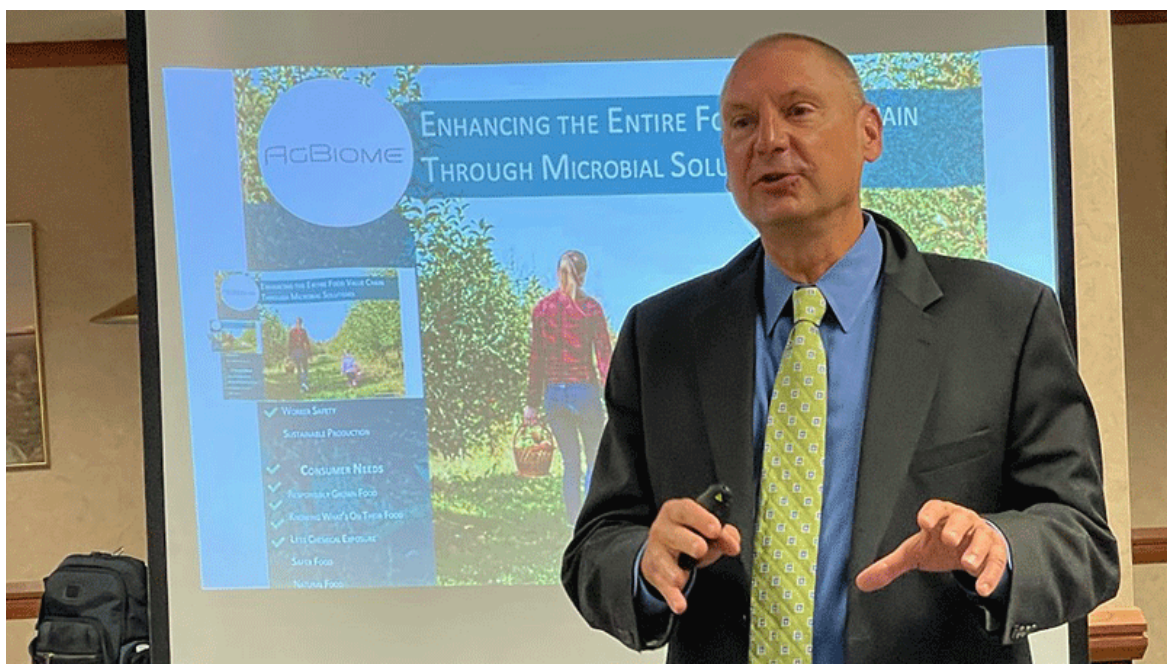
Life Science Caucus focuses on supporting innovative agricultural tech



Scott Uknes, Ph.D., co-founder and co-CEO, of AgBiome

Two of North Carolina's innovative agricultural technology companies, AgBiome and SinnovaTek, along with their farming partners, spoke to members of the Life Science Caucus and the Agricultural/Rural Caucus of the North Carolina General Assembly Sept. 1.

Life Sciences Caucus Co-chairs Sen. Paul Newton, Sen. Mike Woodard, Rep. Robert Reives and Rep. Donna White attended, along with Sen. Brent Jackson, chair of the Agricultural/ Rural Caucus, and about three dozen other legislators and company representatives.

Scott Uknes, Ph.D., co-founder and co-CEO, of AgBiome kicked off the day's presentations by explaining how his company uses microbes to control pests and prevent diseases in crops. He was joined by John Fleming, a farmer and partner with Fleming Brothers Farms, LLC in Halifax.

Up second was SinnovaTek, a North Carolina State University spin-off and a for-profit public benefit company focused on innovation in food processing. The company works to reduce food waste and create better-for-you products, said President and CEO Michael Druga. The company is growing rapidly, from 8 employees last year to 30 this year and an expected 50 to 60 next year, he said. **MORE >>**

Governor signs accumulator ban, will save patients money

An accumulator ban provision was added to S257, the Medication Cost Transparency Act, that passed both houses and was signed into law by Gov. Roy Cooper on Sept. 20. The

legislation prevents health insurers from implementing copay accumulator adjustment programs. These programs prevent patients from benefiting from insurance copay assistance from pharmaceutical manufacturers by not allowing the assistance to count toward annual deductibles or out-of-pocket maximums.

Improvement to drug manufacturing license becomes law

Last month we told you about the NC General Assembly taking action to modernize North Carolina's rules for wholesale drug distribution licensing after the Life Science Caucus heard from G1 Therapeutics, Inc. CEO Jack Bailey.

Caucus co-chairs drafted legislation to allow the NC Department of Agriculture to issue a license to manufacture a drug that is conditional upon that drug's FDA approval. Currently, manufacturers cannot apply for a manufacturing license until the drug receives FDA approval, which leads to months of unnecessary delays.

The legislation became HB95, which passed the Senate and the House unanimously and was signed into law by the governor on Sept. 2. HB95 also ensures that out-of-state companies are treated similarly during the registration process.

NATIONAL UPDATES

In Congress this fall, debt ceiling will dominate, TRIPS waiver and price fixing still in play

The House laid the groundwork (on a party-line vote) for action this fall on a $3.5 trillion budget package called the Build Back Better Act. The Democrats intend to use this package to pass (by a simple majority) many key priorities on health care and climate change. On Sept. 25, the House Budget Committee favorably reported the Build Back Better plan out of committee on 20-16 vote. Rep. Scott Peters (D-CA) joined the Republicans to vote “no” on the package. Next, the Rules Committee would typically schedule a debate and consideration of the final reconciliation package, but most current intelligence suggests that the $3.5 trillion dollar number will not pass and the entire package is on hold. Activity is very fluid right now, and the news is changing constantly.

Appropriations
With the debt ceiling looming over everything, the Treasury Department is already using its "extraordinary measures" to avoid default, and those will be exhausted by Oct. 18, according to Treasury Secretary Janet Yellen. Adding to the drama is the fact that the federal government will shut down at midnight Friday, Oct. 1, unless a continuing resolution is passed to fund the government until a budget — or subsequent resolutions — can be passed.

As this newsletter is being published, Senate Democrats are introducing a stopgap bill after Republican senators blocked a funding measure that also suspended the debt limit. The new bill is known as a "clean" continuing resolution that maintains current funding levels through Dec. 3 plus $6.3 billion to relocate Afghan refugees and $28.6 billion for disaster assistance following recent hurricanes and wildfires. The clean resolution does not address the debt limit.

The debt ceiling deadline is a natural timeline for an omnibus budget bill. But disagreements in the Senate over the appropriations amendments process has frozen the chamber, and the debt ceiling may need to be extended — at least temporarily — on a continuing-resolution vote.

Intellectual Property
Look for continued efforts to weaken IP rights in the misguided belief this will improve access

to treatments without impairing innovation.

The Biden administration has supported efforts to waive the WTO TRIPS agreement — but BIO has pointed out that intellectual property rights have not been, and will not be, a barrier to the development and distribution of COVID vaccines globally. The Biden administration is already pursuing many of the strategies outlined in BIO's proposed SHARE Program — and they are yielding important results.

Drug price fixing
The provisions of H.R.3 that impose government set price controls on prescription drugs tied to the prices paid in foreign countries have insinuated themselves into the Build Back Better Act. NCBIO continues to work against these provisions by writing and calling policy makers and gathering testimonials from our smaller biotechs who stand to lose the most in investment dollars.

Agriculture and Environment
Overall, the budget resolution would give the Agriculture Committee $135 billion over the next 10 years.

The package will include tax credits to incentivize the production of clean electricity, clean transportation fuels, and energy efficiency. Whether these incentives are closer to Senate Finance Committee Chairman Ron Wyden's Clean Energy for America Act (S. 1298) or Chairman of House Ways & Means Subcommittee on Select Revenue Measures Mike Thompson's (D-CA) Growing Renewable Energy and Efficiency Now Act (H.R. 848) will be a major issue that needs to be resolved.

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Biden mandates vaccines or testing for large employers

On Sept. 9, President Joe Biden issued an executive order mandating that federal contractors and large employers require their employees to be vaccinated against COVID-19.

The president directed the U.S. Department of Labor to require all employers with more than 100 employees to either require vaccination or regular weekly testing of employees. The employer does not have to offer employees a choice between the two options, but employers will have to allow exemptions based on medical condition and on sincerely held religious beliefs.

The Occupational Safety and Health Administration is preparing an emergency temporary standard directing covered employers to impose this requirement. This is going to take a while, and it is reasonable to expect legal challenges along the way to delay the process further.

Until the OHSA ETS has been drafted, circulated and adopted, there is no enforceable mandate requiring any employer to take any action.

The mandate will likely not apply to existing government contracts. The vaccine mandate will likely apply to contract extensions and renewals, as well as to totally new contracts, but is unlikely to apply retroactively.

Federal Orphan Drug Tax Credit at risk

The U.S. House of Representatives has several committees marking up the Senate's $3.5 trillion budget reconciliation package. There was an unwelcome surprise: Section 138141 (p.609) would make drug manufacturers ineligible to collect the Orphan Drug Tax Credit "if the drug had previously been approved by the Food and Drug Administration for a separate indication," STAT News wrote.

"The ODTC can help to offset the cost of developing and testing orphan therapies as they move through the clinical trial process," the National Organization for Rare Disorders said. "This longstanding incentive is particularly important for the many smaller companies focused exclusively on rare diseases."

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Small business stock exemption from capital gains threatened, other tax changes proposed

One element of the Build Back Better Act severely curtails the capital gains tax exemption for Qualified Small Business Stock that currently exists in Section 1202 of the tax code. For a qualified small business, investment in their stock currently benefits from 100% exclusion of capital gains tax on gains of up to the greater of $10 million or 10 times your cost basis if the stock is held for at least five years.

The new legislation would reduce the exemption to 50% from 100% and apply the alternative minimum tax that also is currently excluded for tax filers with average gross income over

minimum tax that also is currently excluded for tax filers with average gross income over $400,000. One particularly punitive aspect to the change is that this would apply to all transactions after Sept. 13, 2021, even though the investments could have been made many years ago under the assumption that gains would be excluded.

The Angel Capital Association and a number of other organizations have finalized a joint letter to Nancy Pelosi, speaker of the House, and Kevin McCarthy, minority leader of the House, requesting removal of this proposed change. ACA encourages you to contact legislators in both the House and the Senate abou this tax policy change.

NCBIO would like to hear from members who may be affected by this changes, as well as the following new proposals.

1. Part 3, section 138302 accelerates distributions for IRAs in excess of $10 million for taxpayers earning $400,000 / $450,000.
2. Section 138312 will prohibit IRAs from investing in investments requiring “accredited" status, which is all angel or venture funding.
3. Section 138312 requires IRAs to distribute all existing angel or venture investments within two years.

Biden nominates USTR agricultural negotiator

President Biden nominated Elaine Trevino for Chief Agricultural Negotiator at the Office of the U.S. Trade Representative — a position that’s essential to protecting the interests of American agriculture and biotechnology.

The first woman of color and first Latina who would fill the position, Trevino has a long career promoting agriculture exports. Currently president of the Almond Alliance of California, she previously served as deputy secretary of California’s Department of Food and Agriculture under Gov. Arnold Schwarzenegger, where she focused on the state’s ag exports.

If confirmed, she’ll face tough challenges, including Mexico’s failure to comply with the U.S.-Mexico-Canada Agreement by not issuing ag biotech approvals.

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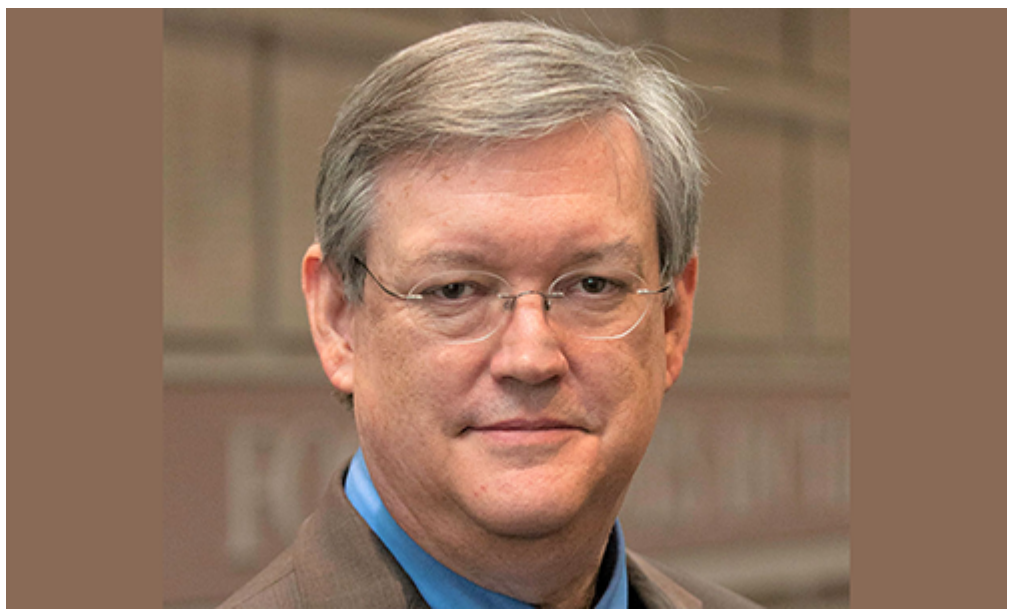
NCBIO Updates



Three students receive first Sam Taylor scholarships

Pledges and gifts to the Samuel M. Taylor Memorial Life Sciences Scholarship in the North Carolina Community Colleges Foundation have topped $155,000. Our goal is to raise $250,000 to endow scholarships for NC Community College students pursuing training and careers in the life sciences.

Three students have been chosen to receive the award this fall.

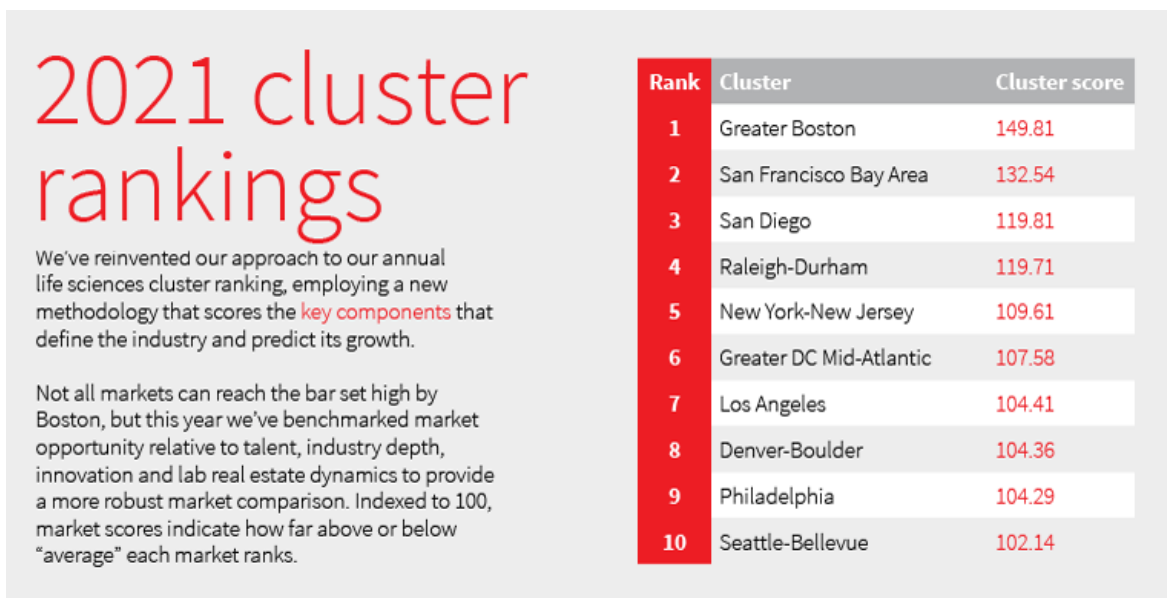
- Stephanie Alston of Wake Forest is studying clinical trials research at Durham Tech.
- Robert Voissem, Jr. of Dudley is studying biotechnology at Wilson Community College.
- Brittany White of Plymouth is studying medical laboratory technology at Beaufort County Community College.

To contribute, contact Casey Nelson for ACH information or make checks payable to the North Carolina Community Colleges Foundation and **write Samuel M. Taylor Memorial Life Sciences Scholarship Fund in the memo field.** Mail them to

North Carolina Community Colleges System
ATTN Bryan W. Jenkins
200 West Jones Street

Raleigh, NC 27603-1379

Raleigh-Durham rises to 4th in life sciences real estate ranking



Rank	Cluster	Cluster score
1	Greater Boston	149.81
2	San Francisco Bay Area	132.54
3	San Diego	119.81
4	Raleigh-Durham	119.71
5	New York-New Jersey	109.61
6	Greater DC Mid-Atlantic	107.58
7	Los Angeles	104.41
8	Denver-Boulder	104.36
9	Philadelphia	104.29
10	Seattle-Bellevue	102.14

Raleigh-Durham moved up to No. 4 in JLL's recently released 2021 Life Sciences Real Estate Outlook, right behind the big three clusters of Boston, the San Francisco Bay Area and San Diego.

A market with a total score over 100 has the right components to cultivate a strong life sciences cluster, the report states. The top three clusters are unchanged from the previous year, but Raleigh-Durham moved up one position. Raleigh-Durham's legacy of strong research institutions, competitive talent pipeline, existing industry depth and viable commercial lab market can support greater industry expansion.

Federal grant boosts biotech programs at Alamance Community College

Alamance Community College got a big boost to its biotechnology programs with a $1.1 million grant from the federal Economic Development Administration.

The money will be used to help buy high-tech equipment to provide training for students and workers in biotechnology-related programs, the college said.

The training equipment will ultimately be housed in the Biotechnology Center of Excellence, a $17.4 million facility scheduled to open in the fall of 2022.

The 34,000-square-foot center, to be located on the college's Graham campus, will house the biotechnology, medical laboratory technology and histotechnology (science centering on the microscopic detection of tissue abnormalities for disease diagnosis and treatment) programs.

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Member news briefs

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

AgBiome has raised $116 million in an oversubscribed series D round of funding, co-led by Blue Horizon and Novalis LifeSciences that included multiple new and existing investors. **More >>**

BioAgilytix Labs was named a 2021 Leaders in Diversity Award recipient by the Triangle Business Journal. **More >>**

Business Journal. More >>

BioDelivery Sciences International, Inc. has completed the acquisition of U.S. and Canadian rights to migraine treatment ELYXYB (celecoxib oral solution). BDSI intends to launch ELYXYB in the first quarter of 2022. More >>

Biogen announced positive topline results from its Phase 2 CONVEY study of vixotrigine, a non-opioid investigational oral pain drug being evaluated for the treatment of small fiber neuropathy. More >>

Biogen issued its first progress report on its Healthy Climate, Healthy Lives initiative, a $250 million, 20-year commitment to address the deeply interrelated issues of climate, health and equity. More >>

Biogen announced that the European Committee for Medicinal Products for Human Use issued a positive opinion and has recommended granting EU marketing authorization for VUMERITY® (diroximel fumarate), a treatment for adults with relapsing-remitting multiple sclerosis. More >>

Bioventus Inc. has elected to make a $50 million escrow payment pursuant to its option and equity purchase agreement with CartiHeal Ltd., signaling its intent to move forward with an acquisition of CartiHeal. More >>

G1 Therapeutics, Inc. will create a 15-person oncology sales force to supplement the Boehringer Ingelheim oncology commercial team to target top tier accounts in order to accelerate sales activities and help maximize the adoption of COSELA (trilaciclib). More >>

Kymanox announced the addition of Brandon Sullivan as director of digital transformation services to enhance digitization initiatives and information technology-based services for organizations seeking to maximize value from their technology investments. More >>

Mayne Pharma received FDA approval for use in adolescents of LEXETTE (halobetasol propionate) foam, 0.05%, a super potent topical corticosteroid, for the treatment of plaque psoriasis. More >>

PPD, Inc. has been recognized as one of the best in the world for its successful employee learning and development programs by the Association for Talent Development. More >>

PPD, Inc. has been recognized with two gold Brandon Hall Group Human Capital Management “Excellence in Learning” Awards for its effective learning programs. More >>

Precision BioSciences, Inc. announced that Michael Amoroso has been named as the company’s president and chief executive officer effective Oct. 15. More >>

Precision BioSciences, Inc. and iECURE announced a license and collaboration agreement under which iECURE plans to advance Precision’s PBGENE-PCSK9 candidate into Phase 1 studies and develop additional gene editing therapies for genetic diseases, initially targeting liver diseases. More >>

SAS and the University of North Carolina at Chapel Hill are teaming up to transform the drug development process to prevent infectious disease threats from turning into pandemics like COVID-19. More >>

BIO International Convention call for sessions is now open

Mark your calendar for the BIO International Convention, June 13-16, 2022, in San Diego! Call for Sessions is now open. **Proposal submission will be accepted through Oct. 12.**

Do you want to showcase your latest findings in front of 17,000+ innovators in biotechnology and life sciences? Does your company have a compelling story to tell about innovative research or projects? This is your chance to submit topics that paint a vision for the global biotechnology industry's future in San Diego, June 13–16.

BIO is seeking speakers who inspire others to dream big, tackle what some might think is impossible and go beyond to create a better future. We are looking for leaders who are forward thinking, diverse, engaging and who drive meaningful discussions about what’s next for the biotechnology industry. Speaking at BIO allows you to establish yourself as an international expert, build critical dialogue, spark creative conversations, profile new technology, and more.

Download the Call For Sessions proposal guide.

LEARN MORE

NCBIO calendar

- NCBIO 27th Annual Meeting (10/5/2021)
- Calculating the Benefits of Biotechnology hosted by BIO (10/5/2021)
- CureDuchenne 2021 FUTURES National Conference (10/8/2021 to 10/10/2021)
- Clinical Supervision Workshop Series hosted by UNC-Wilmington (10/9/2021)
- BTEC Upstream Production Process Development for Biopharmaceuticals (10/11/2021 to 10/22/2021)
- Working in a Cleanroom Environment Training hosted by Azzur Group (10/12/2021)
- Working in a Cleanroom Environment Training hosted by Azzur Group (10/13/2021)
- Regional Economic Summit hosted by Elizabeth City State University (10/14/2021)
- Tax Tips for Grant Compliance hosted by LaunchBio (10/14/2021)
- Science of Socializing™ Oktoberfest hosted by Azzur Group (10/14/2021)
- BTEC Applied Principles and Techniques of Depth Flow Filtration (DFF) and Tangential Flow Filtration (TFF) for BioPharm Downstream Purification Course (10/26/2021 to 10/29/2021)
- Bridging the Gap hosted by NCABR (10/26/2021 to 10/27/2021)
- Triangle Global Health Virtual Annual Conference: Reframing Global Health in a Changing World hosted by Triangle Global Health Consortium (11/4/2021)
- Save the Date: 8th Annual Women in Bio with HBA Joint Networking Event (11/8/2021)

BIO Business Solutions Highlights

Four steps to saving with your NCBIO membership

NCBIO members are eligible for BIO Business Solutions volume-based discounts and favorable contract terms to help you save on products and services you already use. How does it work? Here it is in four simple steps!

- Browse our cost-savings programs – from lab supplies and equipment, research-grade microscopes, office supplies, shipping, insurance, research services and more.
- Contact us – Fill out a short inquiry form to let us know which cost-saving options you're interested in hearing more about.
- Sign up – Depending on the program, you can enroll yourself, talk to the partner for more information, and/or start a free trial.
- Enjoy the benefits – Once your account is set up, your savings will be in place. If you have questions or need support, our team is always here to help!

For all the latest news, promos and event information, follow BIO Business Solutions on LinkedIn.

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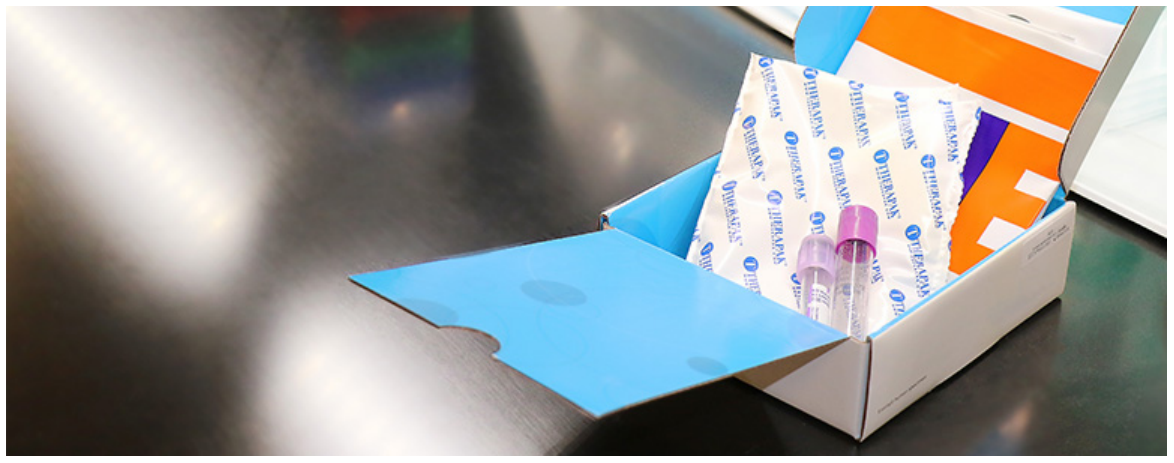

Clinical studies are dynamic and can suddenly require a scale-up in testing. Meeting the needs of a rapidly changing clinical trial requires custom kitting from a trusted vendor.

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VWR's recent acquisition of Therapak makes it possible for you to manage a rapidly changing clinical trial, delivering specimen collection kits on time within local regulations, while ensuring supply chain integrity for traceability and audit compliance.

LEARN MORE

NCBIO Partners

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