NCLifeSci Advocate. Advance.

# Connections Newsletter

**February 2024 Update**

**Serving the NC Life Sciences Industry**

ncbioscience.net
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## Fix to small-molecule penalty introduced, House votes to restore R&D tax credit

**In August, Rep. Wiley Nickel and staff representatives from the offices of Sen. Ted Budd; Rep. Gregory Murphy, M.D.; and Rep. Deborah Ross were part of a roundtable convened by NCLifeSci and hosted by Alexandria Real Estate Equities to discuss the small molecule penalty that is part of the IRA, as well as the R&D tax amortization issue. Several NCLifeSci members, including G1 Therapeutics, Mycovia Pharmaceuticals, Tavros Pharmaceuticals and Ribometrix, shared their pain points.**

We have a couple of big wins at the federal level to report this month.
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North Carolina Reps. Greg Murphy, M.D., and Don Davis (D-NC), along with Rep. Brett Guthrie (R-KY), are introducing bipartisan legislation in the House to fix the small molecule “pill penalty” contained in the Inflation Reduction Act.
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The Ensuring Pathways to Innovative Cures, or EPIC, Act will provide small-molecule drugs with the same number of years of protection from government price "negotiations" as biologics receive.
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The IRA created an arbitrary distinction between biologics and small-molecule drugs. Biologics were granted 13 years of exemption from price controls, while small-molecule drugs were granted just nine years. The legislation would fix this disparity by bringing small molecules up to 13 years.
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On Jan. 31, the House of Representatives passed a critical piece of legislation legislation that would restore the R&D tax credit.

R&D spending would be 100% tax deductible through 2025, reversing a change (as of 2022) requiring R&D expenses to be amortized over five years. Read more below in National Updates.

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## STATE UPDATES

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### Upcoming key dates for state government

**Primary election - March 5**
March 5 is the primary election for all congressional and state races. This will significantly narrow the field of candidates and establish likely winners in districts that lean heavily Republican or Democrat.Â

**Short session convenes - April 24**
The legislature remains dormant as House and Senate members focus on fundraising for their primary and general election campaigns. The short session will convene on April 24, and leaders tentatively expect it will adjourn in mid-to-late July.
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Speaker Tim Moore is running for Congress (along with a few other state legislators), which means there could be a significant push to get in and get out so that candidates can focus on campaigning.

**General Election - Nov. 5**
Nov. 5 is the general election for all candidates in North Carolina. Those elected to Congress, the Council of State and the General Assembly will begin their terms January 2025.

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## NATIONAL UPDATES

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**If there are any topics or issues that are affecting your business or you want to know more about, please contact Laura Gunter.**

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### Can continues down road as Congress' latest kick funds government through March

The House of Representatives on Jan. 18 passed a stopgap spending bill that will keep the federal government funded through early March.
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The vote, which came just hours after the Senate's passage of the bill, was a necessary step to avoid a partial government shutdown that would have begun Friday at midnight.
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The stopgap measure, known as a continuing resolution, passed with mostly Democratic support in a 314-108 vote. However, the bill faced opposition from some Republicans who were unhappy with the level of spending it authorizes.
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With parts of the government now funded through March 1 and March 8, leading appropriators have a lot of work to do in the coming weeks. They need to finalize a dozen annual spending bills that Congress has so far failed to pass, as House conservatives have been pushing for deeper cuts.
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If lawmakers can't pass the spending bills by the early March deadlines, they may have to

resort to another continuing resolution that would keep the government funded at current levels for the rest of the fiscal year. This would be a blow to many federal agencies, which would face flat budgets or even cuts.
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The most recent stopgap spending bill is the third passed by Congress this fiscal year, which began on Oct. 1. The delay in passing regular spending bills has been caused in part by infighting among House Republicans.

## What we're watching in Congress in 2024

As the 118th Congress begins its second year, these are some of our top federal priorities for industry and patients in 2024.Â

- **R&D amortization**: As of 2022, R&D expenses must be amortized over five years, reducing the full deduction to 20% annually. With remedial legislation moving through Congress, BIO has launched a campaign to urge policymakers to reverse the change. *See more details below.*
- **PBM reform**: Acting as middlemen between drug makers, pharmacies, and insurers, pharmacy benefit managers exploit their market power to profit by driving up drug prices. Congress advanced PBM reform last year, with the House passing the Lower Cost, More Transparency Act by a bipartisan vote in December. (BIO's taking action on PBMs, too.)
- **The Inflation Reduction Act's effect on orphan and small molecule drugs**. The law disincentivizes the development of orphan drugs for rare diseases and small molecule drugs. The newly introduced EPIC Act aims to bring parity and move negotiation timelines for all new drugs out to 13 years.
- **March-in rights**: The Biden administration has taken the position that the cost of some drugs developed with federal funds limits their availability and gives the administration the right to "march in" and assign licenses to manufacture the drugs to third parties. The public comment period for this unorthodox interpretation of the Bayh-Dole Act ends Feb. 6.
- **The ORPHAN Cures Act**, making its way through Congress, would exempt orphan drugs from price controls even if they're approved for multiple indications.
- **The Pandemic and All Hazards Preparedness Act**, which awaits reauthorization, will help us get ready for the next pandemic.
- **The Farm Bill**, which was renewed for one year but awaits the full five-year reauthorization, can support much needed agricultural biotech and biomanufacturing.
- **Antimicrobial resistance**: The PASTEUR Act would address market problems to encourage the development of antimicrobials.
- **The Rare Pediatric Disease Priority Review Voucher Program** needs funding to incentivize the development of novel therapies to treat pediatric diseases and spur investment to help the most vulnerable.Â
- **Transitional Coverage for Emerging Technologies** would create an alternative, expedited pathway to coverage and payment for emerging devices and diagnostics to improve on the average of five years it takes for medical technologies to achieve nationwide coding, coverage and payment.
- **Ethylene oxide** sterilization is one of the most common ways to sterilize medical devices. New EPA regulations proposed for the gas could force the closure of a number of sterilization industries, which the FDA says would be catastrophic for patients.

More at BIO

## House votes to restore R&D tax credit

On Jan. 31, the House of Representatives passed a critical piece of legislation legislation that would restore the R&D tax credit.
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R&D spending would be 100% tax deductible through 2025, reversing a change (as of 2022) requiring R&D expenses to be amortized over five years.
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Ways & Means Chair Jason Smith (R-MO) said restoring R&D deductions will create 850,000 jobs and $58 billion in additional take-home pay and help us compete with China. Reps. Ron Estes (R-KS) and Suzan DelBene (D-WA) noted China's R&D investment grew 400% this decade.
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Finance Committee Chair Ron Wyden (D-OR), is leading the effort in the Senate to restore the tax credit.
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NCLifeSci worked with BIO to blanket Capitol Hill offices to make sure policymakers heard our industry's voice on this matter. Letters were sent to the leadership of both the House of Representatives and the Senate, an online campaign flooded Congressional offices with messages of support and the media were leveraged to make sure lawmakers understood the importance of the full R&D tax deduction to the development of critical cures and innovations.
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NCLifeSci convened a roundtable in August hosted by Alexandria Real Estate and attended by Rep. Wiley Nickel and staff representatives from the offices of Sen. Ted Budd; Rep.

Gregory Murphy, M.D.; and Rep. Deborah Ross. The effects of the R&D tax penalty was one of the topics discussed.
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You can join the BIOAction campaign still underway and ask our lawmakers to support the immediate expensing of R&D.

## FDA unveils plan to loosen regulations on diagnostics

The FDA is proposing to streamline the approval process for certain diagnostic tests, potentially making them available to patients faster. This change would affect tests for infectious diseases and those that help determine if a specific drug is right for a patient.
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Currently, these tests require a more rigorous approval process, but the FDA believes they can be safely regulated with less stringent requirements.
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Instead of the lengthy premarket approval pathway, manufacturers of these tests could use the faster 510(k) pathway, which compares the new test to similar ones already approved. This could significantly reduce the time and cost of bringing new diagnostic tests to market.
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The FDA plans to reclassify most of these tests from high-risk to moderate-risk, reflecting their belief that additional safety and effectiveness checks can be implemented through specific controls alongside existing general regulations.
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This move is expected to benefit patients by speeding up access to new diagnostic tools, potentially accelerating diagnoses and treatment decisions. However, some experts raise concerns about the potential impact on safety if the regulations are loosened too much.

## Biden administration supports U.S. IP protection in WTO treaty negotiations

U.S. negotiators working on a global treaty that aims to guide the world's response whenever a new deadly pathogen emerges have rejected proposals to loosen patent protections, a step that is supposed to enable developing countries to quickly make their own versions ofÂ vaccines and drugs.
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The U.S. has voiced support for a TRIPS waiver of IP protection for COVID-19 vaccines and therapies, but the U.S. position in the current treaty negotiations shows there are limits to the president's willingness to upend the patent system.
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During the worst of the COVID pandemic, under pressure from the progressive wing of his party, the Biden administration reversed longstanding U.S. policy opposing waivers of patent protections.
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In May 2021, U.S. Trade Representative Katherine Tai announced America's support for a proposal from South Africa and India that would waive those protections for Covid vaccines as part of World Trade Organization talks.
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The administration supported the TRIPS waiver because of the gravity of the situation at the time in an effort to end the pandemic, the Department of Health and Human Services has said.
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But when WTO member countries agreed finally in June 2022 to issue the waiver, theoretically permitting developing countries to make their own Covid vaccines using U.S. drugmakers' formulas, it came too late.
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Pharmaceutical companies in Western countries and India were pumping out millions of doses but demand for shots had waned globally, as people saw the risk of severe disease diminishing.
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Talks about extending the TRIPS waiver to include COVID tests and treatments continue at the WTO but face bipartisan opposition in Congress.
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The WTO process revealed a split within the Democratic Party, with progressives supportive of broad waivers of U.S. intellectual property rights and moderate Democrats strongly opposed. Republicans also opposed the waivers.
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More than a dozen senators from both parties, including Sen. Thom Tillis, wrote to Biden and Tai this month asking them to reject the waiver of patent protections for tests and treatments because, they said, it wouldn't improve global access to Covid drugs while negatively impacting "American manufacturers, innovation, and global competitiveness."
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Nineteen House Democrats signed a similar letter in December, including Wiley Nickel and Deborah Ross.
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Pharma representatives have said that forcing them to share their formulas wouldn't lead to

much manufacturing in the developing world because companies seeking to produce vaccines and drugs need knowledge and expertise that don't come with patents.
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And the Biden administration, despite its willingness to loosen patent protections during the worst days of COVID, has taken pharma's side in the treaty negotiations that could guide the world's response to the next pandemic. Some European nations, including Germany, have also sided with their drugmakers.
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The next WTO treaty negotiations are scheduled for Feb. 19.

## FDA dodges shutdown bullet but long-term budget murky

The latest continuing resolution to pass Congress includes a temporary funding extension for the FDA, preventing a shutdown that would have hampered its work. The bipartisan stopgap measure keeps the agency afloat until at least March 1, but the long-term picture remains unclear.
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While the immediate threat of closure is averted, the FDA's ability to launch new initiatives using taxpayer dollars is currently on hold. However, the agency finds some financial stability through user fees paid by drugmakers, which contribute nearly half its revenue.
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Despite a broader agreement on overall nondefense spending, the specific allocation for the FDA remains shrouded in uncertainty. The final figure hinges on a yet-to-be-finalized deal on fiscal 2024 spending, slated for late February.

## Top FDA diagnostics regulator retires

Timothy Stenzel, the United States' head diagnostics regulator, left the FDA at the end of 2023.
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Courtney Lias, director of the FDA's Office of Gastrorenal, ObGyn, General Hospital and Urology Devices, is serving as acting director of the agency's diagnostic office while the agency conducts a national search to fill the role.
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Stenzel helped lead the government's Covid-19 testing response. Stenzel's retirement comes as the FDA braces for the departure of Principal Deputy Commissioner Janet Woodcock.

## Cost-sharing rule appeal dropped after court loss and public pressure

The Biden administration reversed course on Jan. 16, abandoning its appeal of a court ruling that struck down a controversial Trump-era regulation on cost-sharing for prescription drugs. The decision, which followed bipartisan criticism and an outcry from patient advocates, leaves the rule overturned.
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The dropped appeal means insurers cannot disregard copay assistance when calculating patients' out-of-pocket costs. This provides financial relief for medication-dependent individuals and aligns with the Biden administration's broader health care goals of affordability and accessibility.
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The 2021 rule allowed insurers to exclude drug maker copay coupons from counting towards patients' maximum out-of-pocket costs. This meant patients relying on such assistance could face higher bills. Federal Judge Richard Seeborg in September declared the rule unlawful, prompting the administration's initial appeal.
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However, the administration reconsidered after mounting pressure from members of Congress and patient advocate groups who argued the rule created financial burdens for patients struggling to afford medication, particularly those with chronic conditions.

## California court paves way for HIV drug lawsuit against Gilead

A California appeals court has dealt a major blow to Gilead Sciences and the pharmaceutical industry as a whole, allowing a lawsuit claiming injuries from the HIV drug TDF to proceed to trial. This could open the door for similar lawsuits against drugmakers accused of prioritizing profits over patient safety.
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The lawsuit, filed on behalf of 24,000 patients, alleges that Gilead delayed the development of the safer TAF drug to extend profits from its already-marketed TDF, which can cause bone density loss and kidney problems. While not claiming TDF is defective, the plaintiffs argue Gilead had knowledge of TAF's potential by the early 2000s and should have prioritized its development.
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The unanimous decision marks a significant legal precedent, as the court acknowledged a manufacturer's duty to act reasonably and prioritize patient well-being, even if their product isn't technically defective.

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Gilead, unsurprisingly, expressed concern about the ruling's potential consequences, fearing it could stifle innovation and discourage future investments in new drugs. They argue the decision could lead to a flood of lawsuits and hinder progress in the pharmaceutical industry.

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The next step will likely be an appeal from Gilead to the California Supreme Court. If the appeal is unsuccessful, the case will head back to trial, potentially setting a precedent for similar lawsuits against pharmaceutical companies accused of delaying safer alternatives.

## BIO: USDA proposal for genetically engineered plants too complex

USDA's proposed regulatory exemptions for five genetic modifications achievable through conventional breeding are "a positive step," but the rules can be simplified, BIO said.Â

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The USDA Animal and Plant Health Inspection Service has proposed exemptions to its rules for "Organisms Modified or Produced through Genetic Engineering." BIO provided detailed technical input in a joint letter with the American Seed Trade Association and another letter from 60 agricultural organizations.

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Reducing unnecessary regulatory barriers to biotechnology innovation for plants is essential to addressing climate change and ensuring global food security.

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The proposed rules for exemptions are too complex, posing potential barriers to market entry, both letters say.

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APHIS proposes different exemptions for alloploids, which have chromosomes from more than one species, and autoploids, with chromosomes from a single species. This distinction is not supported by science and is not made by other regulatory regimes, the letters say.

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The "increased complexity in the currently proposed exemptions" poses an unneeded obstacle, says the BIO-ASTA letter. APHIS should use "a more streamlined, plain language set of exemption criteria, consistent with the approach taken in several other global jurisdictions."

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# NCLifeSci Updates

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**DEI Committee Co-chairs LaQuinta Jernigan and Neil Jones thank NCLifeSci members who contributed to the committee's book and diaper drive.**

## NCLifeSci DEI committee collects diapers, books for N.C. children

NCLifeSci members collected and delivered almost 500 books and over a thousand diapers and related products for Book Harvest and the Diaper Bank of NC, respectively, on Jan. 25.

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The service project was organized by the NCLifeSci Diversity, Equity and Inclusion Committee, and co-chairs LaQuinta Jernigan and Neil Jones were on hand to thank everyone who participated.

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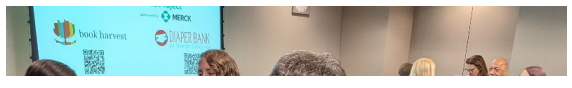
If you would like to support either of these exceptional organizations, you can make a contribution online using the links above.




## NCLifeSci member seal available

New for 2024, NCLifeSci offers a seal our member organizations can display on their websites and wherever they feel it is appropriate and valuable to highlight their relationship with NCLifeSci. Members may use the seal for as long as their NCLifeSci membership is active.
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The image above is adequate for many digital uses, including websites. If you would like receive the NCLifeSci membership seal in all available formats, please email Communications Director David Etchison.Â

## BIO reports on vaccine pipeline

The current pipeline has 249 active novel clinical-stage programs addressing 31 infectious diseases for which there is no approved vaccine, says BIO's report, The State of Innovation in Vaccines and Prophylactic Antibodies for Infectious Diseases.
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"The pipeline is relatively deep for COVID, and it's really shallow for most everything else," says David Thomas, SVP of Industry Research and Analysis at BIO and one of the report's authors. Only 10% of infectious disease threats are addressed by 10 or more programs, and nearly 30% of candidates target COVID-19.Â
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"Vaccines have led to a 100% reduction in the risk of death for a host of devastating diseases," says Phyllis Arthur, BIO SVP, Infectious Diseases & Emerging Science Policy. "Yet many common infections don't have any vaccines in clinical development. That needs to change."
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Only 3.4% of biopharma venture capital ? $6.5 billion ? went to companies with infectious disease programs in the last decade. By comparison, oncology drug development received $72.6 billion, or 38% of the VC.
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BIO recommends:

- Capitalizing on platform technologies, with better use of data and AI.
- Expanding vaccine access.
- Rebuilding vaccine confidence.
- Revising the review process to "adapt to the changing vaccine landscape and create a predictable review environment."

More at BIO

## NCLifeSci Member News

**AES Clean Technology** announced the appointment of John Costalas to its senior leadership team as vice president of construction. More >>
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**Alcami** announced the opening of its new 65,000 sq. ft. state-of-the-art Pharma Storage and Services Operations Facility in Garner, close to Research Triangle Park. More >>
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**Azzur Group** is offering a new whitepaper on the current trends driving an ongoing capacity crunch and market study findings that help explain what is driving decisions to build, broker or blend. More >>

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**Biogen** announced plans to reprioritize its resources in Alzheimer's disease by continuing to advance LEQEMBI and accelerating development of potential new treatment modalities. The company will discontinue the development and commercialization of ADUHELM and will terminate the ENVISION clinical study. More >>

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**CBRE Group** has acquired full ownership of CBRE Raleigh, which was established in 2001 and has operated in recent years as a joint venture between CBRE and an independent entity owned by Raleigh and Triad-based partners. More >>

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**Eisai** announced that the Scientific Advisory Group will convene to discuss the marketing authorization application of lecanemab (generic name, brand name: LEQEMBI), which is currently under review by the European Medicines Agency. More >>

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**Eisai** and **Biogen** announced that humanized antisoluble aggregated amyloid-beta monoclonal antibody LEQEMBI has been approved in China as a treatment of mild cognitive impairment due to Alzheimer's disease and mild AD dementia. More >>

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**Frontier Scientific Solutions** has secured the first Foreign Trade Zone 214 in the state of North Carolina. Pharmaceutical companies importing materials into the FTZ can defer or reduce import duties and streamline customs procedures. More >>

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**Kymanox** rolled out of its Product Design, Development, and Commercialization group Jan. 4. This strategic initiative reflects Kymanox's commitment to fostering seamless collaboration among specialized teams, with a primary goal of supporting the swift and successful commercialization of high-impact combination products for its clients. More >>

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**Locus Biosciences** received $23.9 million from the Biomedical Advanced Research and Development Authority to continue the development of Locus' CRISPR-enhanced bacteriophage therapy, LBP-EC01, for treating urinary tract infections caused by drug-resistant E. coli. More >>

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**Novozymes** and Chr. Hansen have announced that the name of the future combined company will be **Novonesis**. Novonesis means "a new beginning" and derives from the Greek word genesis. More >>

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**Precision BioSciences** completed a strategic transaction with TG Therapeutics, Inc. for an exclusive license to develop Azercabtagene Zapreleucel (azer-cel) for autoimmune diseases and other indications outside of cancer. More >>

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**Ultragenyx Pharmaceutical** announced that the National Institute for Health and Care Excellence has issued a final draft guidance recommending EvkeezaÂ® (evinacumab) to NHS England. More >>


**During a Jan. 25 visit to Wilmington, NCLifeSci Membership Director Natacha Janvier and President Laura Gunter (right) stopped by Alcami for a tour of the CDMO's location there (Alcami's Katie Schlipp and Jackie Martin on the left). They also met with Kimberly Lupo, CEO of CRO Portrett Pharmaceuticals,Â and with Sen. Michael Lee (R-New Hanover). Afterwards, they joined the Network for Entrepreneurs at Ironclad Brewery downtown (below) to talk about the city's growing life sciences sector. Speakers at the event included Gunter and Kymanox CEO Stephen Perry as moderator.**


## Events


Find your next partner at BIO CEO & Investor Conference Feb. 26-27

Don't miss one of the largest investor conferences in our industry where institutional investors, industry analysts, and senior executives are shaping the future investment landscape of biotechnology.
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Join BIO in February to:

- Find and request meetings with potential partners using the BIO One-on-One Partnering? system
- Discover the latest innovations in biotech during Company Presentations
- Hear from thought-leaders during sessions on therapeutic advancements, market outlook, and policy priorities

**LEARN MORE**


Get your MDMA FDA Forum registration discount now

NCLifeSci has partnered with the Medical Device Manufacturers Association to support their upcoming FDA Forum being held in Palo Alto, California, March 13-14. NCLifeSci members are eligible for discounted pricing. Contact Amber Niebauer for a promotional code.Â

MDMA's 2024 FDA Forum will feature senior officials from FDA and industry and focus on the key regulatory issues impacting the medical device industry.
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Designed specifically for medical device regulatory professionals and executive decision makers, MDMA's FDA Forum promises to deliver key regulatory insights and preview trends that will impact your regulatory and business strategies.

- MDMA Members - $695
- Nonmembers - $895

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## Emerging Company & Tech Forum: Access to Capital March 14

Join NCLifeSci on Thursday, March 14, for our Emerging Company and Technology Forum sponsored by TriNET. This panel, which includes a representative of the New York Stock Exchange, will focus on "Access to Capital" and discuss funding mechanisms and provide an overview of expectations for 2024 and into 2025. We will be adding additional details and speakers soon.
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If you are interested in sponsoring the Emerging Forum, contact Membership Director Natacha Janvier for more details.

**REGISTER NOW**

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## Register, reserve accommodations for BIO International

Register and reserve your housing for the 2024 BIO International Convention in San Diego June 3-6. BIO is where business and breakthroughs converge, and we look forward to uniting a global network of business leaders, policymakers, investors and scientists again this June.Â
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Register before March 7. If you requested a discount code from BIO, you should have received that from them on Jan. 16. You can combine your discount with the early bird rate for additional savings. Additionally, we encourage you to book your housing early, too.

**REGISTER** **HOUSING**

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## NCLifeSci calendar

- 18th Annual Ag Development Forum hosted by NCDA & CS (2/1/2024)
- BPD BioGrow: Training and Education Across North Carolina hosted by NCBiotech (2/1/2024)
- Shaping the Future of Food: Putting Plants at the Center of the Plate hosted by NCBiotech (2/1/2024)
- Outlook for Tech hosted by NC TECH (2/2/2024)
- Navigating Global Market Access for U.S. Medical Device & Diagnostic Companies hosted by U.S. Dept. of Commerce (2/7/2024)
- Entrepreneurial Support to Advance Your Small Business Health Innovations hosted by NCATS (2/21/2024)
- CEO & Investor Conference hosted by BIO (2/26/2024 to 2/27/2024)
- FDA Forum hosted by MDMA (3/13/2024 to 3/14/2024)
- NCLifeSci Emerging Company and Technology Forum: Access to Capital (3/14/2024)

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## Business Solutions from NCLifeSci


### Options for lab, waste disposalÂ

From waste disposal and laboratory chemical packing to onsite environmental cleaning and emergency response, Clean Harbors helps life science companies maintain regulatory compliance and manage waste. Trust Clean Harbors to transport and dispose of industrial waste while identifying candidate streams for reuse or reclamation.Â

**LEARN MORE**

## Capitalize on the R&D Tax Credit

Life science companies generate a significant portion of the annual R&D tax credits claimed. Yet, the majority of startups and small-to-midsized businesses do not take advantage of federal, state and local tax credits. High wages, lab supply costs, and other research-based activities frequently yield strong R&D Â tax credits for small and midsized businesses developing these drugs and therapies, says BIO Business Solutions partner ADP.

**LEARN MORE**

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