



**May 2023 Update**  
Serving the NC Life Sciences Industry

[ncbioscience.net](http://ncbioscience.net)  
919.281.8960

### NCBIO This Month

- New community college president
- Debt ceiling looms
- Bill to restore R&D deduction introduced
- Proposed ethylene oxide rules revealed
- Members gather for DEI networking
- Register for Medical Device Forum and Luncheon

### NCBIO Sustaining Members



### Proposed Strategic Plan presented to Board of Directors

The NCBIO Board of Directors met Thursday, April 27, at the NC Biotechnology Center to accept new members and to review the organization's proposed strategic plan.

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The board voted unanimously to approve the following new members:

- [Biocair](#)
- [JBK Associates International](#)
- [SpringWorks Therapeutics](#)
- [YourBio Health](#)
- [Mazen Animal Health](#)
- [Tavros Therapeutics, Inc.](#)
- [Akin Gump Strauss Hauer & Feld LLP](#)
- [Eremid Genomic Services](#)
- [Metallix Refining Inc.](#)

Bennett Love and Sinu Bhandaru, members of the board's Strategic Plan Committee and Executive Committee, reviewed the history of the planning process and the Executive Committee's approval. Karen Allbritten of Thinc Strategy walked the board through the proposed plan. NCBIO staff members provided details on the tactics that could be used to implement the plan.Â

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The board was asked to consider the plan and reconvene on May 16 to take further action.

### NCBIO Supporting Members



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## STATE UPDATES

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### Legislature picks up the pace

The General Assembly significantly accelerated its pace last week with dozens of committee meetings and long floor sessions as the legislature enters its most hectic time of the year. The House bill-filing deadline passed on Tuesday, which closed out bill filing for the long session. Nearly 900 bills were filed in the House, and 745 bills were filed in the Senate.

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The House of Representatives passed its version of the biennial budget on April 6, and the Senate intends to unveil its own version and pass it during the week of May 17. The House and Senate will then conference to resolve differences in the budget. This schedule, coupled with the recent party switch by Rep. Tricia Cotham from Democrat to Republican (allowing the House to join the Senate with a veto-proof majority), puts the General Assembly on a path to completing its budget by June 30.

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NCBIO is following a number of budget items, including funding for the One NC Small Business Fund, which received an additional recurring \$2 million in the House budget. The budget also contains \$600 million per year in wastewater grants for municipalities to upgrade public water systems.

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While budget appropriators complete their work, we are also following several dozen bills of interest through the legislative process. Â May 4 is the date for "crossover", by which a bill must pass either the House or the Senate to remain eligible for consideration during the biennium.

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Among the bills under consideration we are following are House Bill 246, which clarifies that manufacturer financial assistance for patients is included in his or her deductible calculation, even for individuals with high-deductible plans. That bill, supported by NCBIO, passed the House unanimously on Thursday. Other legislation we are tracking includes consumer privacy, medical equipment right-to-repair proposals and breast-cancer-screening coverage.Â

### Jeff Cox named president of N.C. Community College System

Jeff Cox, the president of Wilkes Community College and a former superintendent, was named the 11th president of the North Carolina Community College system on April 21.

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Cox assumed the helm at Wilkes in 2014 after serving as superintendent for Alleghany County Schools for nine years. He also serves as the president of the North Carolina Association of Community College Presidents.

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During his tenure at Wilkes, the college weathered COVID-19, the loss of jobs when Lowe's Hardware moved additional roles from Wilkes County to their new headquarters in Mooresville, and other challenges. [More at Education NC](#)

### Wake Tech buys land in Apex, will expand workforce training

Wake Technical Community College recently purchased about 34 acres near U.S. Highway 1 and N.C. Highway 55 in Apex for \$6.8 million. The site will be home to the college's Western Wake Campus, which is currently based in a site the college leases at a shopping plaza on Kildaire Road in Cary.

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This new site, located within the massive Veridea development project by RXR Realty of New York, will be a hub for the college's business and entrepreneurship programs. A separate building will house a workforce development center focused on life sciences and industrial training.

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In 2022, voters approved a \$353.2 million bond measure to fund Wake Tech capital projects aimed at addressing the county's workforce needs. [More at Triangle Business Journal](#)





## NATIONAL UPDATES

If there are any topics or issues that are affecting your business or you want to know more about, please contact [Laura Gunter](#).

### Congress debates debt ceiling as June 1 deadline approaches

Treasury Secretary Janet Yellen warned that the U.S. could default on its \$31.4 trillion in debt in as little as 30 days. Yellen's June 1 forecast piles new pressure on Hill leaders and the White House to strike a bipartisan fiscal deal as cross-party talks remained deadlocked.

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House Republicans passed a debt-limit and spending-cuts plan by a 217-215 vote with four Republicans voting against the plan. Speaker Kevin McCarthy still has to cut a deal with President Joe Biden and Senate Democrats that can also win over the conservative and moderate wings of his conference.

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The House bill is expected to be dead on arrival in the Senate, but Republicans hoped its passage will be enough to bring Biden and Senate Democrats to the negotiating table. Democrats have stressed for months that they want a "clean" debt ceiling increase with no spending cuts attached.

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Biden invited Congress' top four leaders in both parties to a May 9 meeting after the Treasury Department warning. The two chambers only have eight days this month during which they'll both be in session and available to work together on a deal.

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The House Republican bill combines across-the-board spending cuts with other conservative proposals, including stricter rules for social safety net programs and energy production incentives.

### These bills could help early-stage innovators access working capital

The House Financial Services Committee met in a marathon session on April 26, working late into the night to consider a package of 15 bills designed to relieve regulatory burdens and facilitate access to needed capital for biotech startups. BIO has been working with Congress to enact reforms to reduce costly regulatory burdens and help draw new investment to these cutting-edge innovators.

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The bills "represent years of work to strengthen and expand access to our capital markets," said Committee Chairman Patrick McHenry (R-NC). "Over the last three months, Capital Markets Subcommittee Chair Ann Wagner (R-MO) held four hearings and considered more than 30 bills. We've heard from experts across the ideological spectrum. More importantly, we accomplished something that very few committees on the hill have done this year: we agreed on a lot."

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"Many of the bills we'll consider today are bipartisan and I look forward to moving those to the floor immediately," McHenry said.

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#### **The JOBS Act of 2012**

BIO has worked with Congress to improve upon the JOBS Act in order to reflect the realities of running a public biotech company. These improvements include extending the onramp for emerging growth companies and making needed structural changes to market cap thresholds.

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#### **The Equal Opportunity for All Investors Act of 2023**

BIO has worked to expand the definition of accredited investor to increase the number of angel investors available to bridge the so-called "Valley of Death" for biotech entrepreneurs. This bill would enable the creation of a certification exam to qualify as an accredited investor so more qualified investors can participate at these critical early stages.

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This legislation would simultaneously expand access to capital to biomedical innovators and democratize access to wealth-generating opportunities for many more Americans.

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#### **The Small Entity Update Act**

BIO supports H.R. 2792, the Small Entity Update Act, which would compel the U.S. Securities and Exchange Commission to study and update small company definitions and thresholds, which are the leading cause of falling out of key exemptions granted by the JOBS Act.

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#### **The Expanding Access to Capital Act of 2023**

BIO also supports McHenry's H.R. 2799, the Expanding Access to Capital Act of 2023. BIO

especially supports Title II, the Helping Startups to Grow Act, which would extend the emerging growth company exemption period of the JOBS Act by another five years. [More at BIO](#)

## PASTEUR Act reintroduced

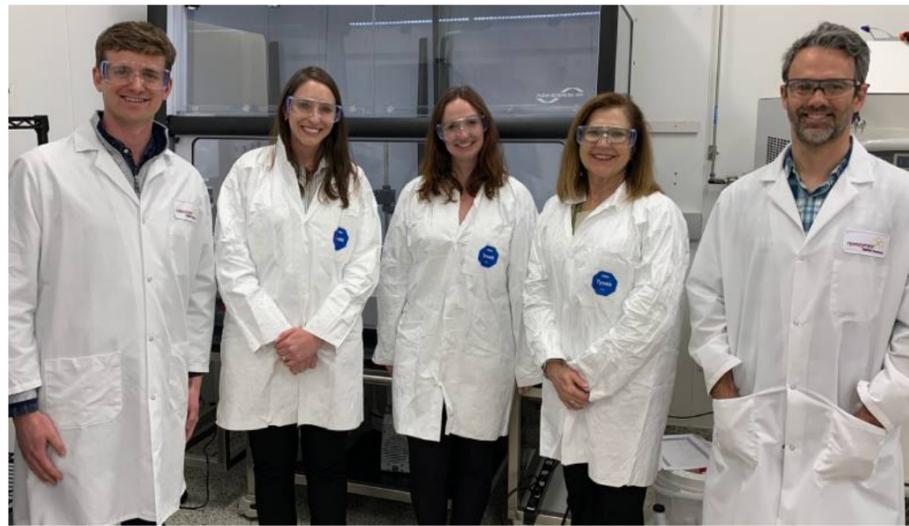
Bipartisan U.S. senators and representatives reintroduced the [Pioneering Antimicrobial Subscriptions to End Upsurging Resistance Act](#), which would commit \$6 billion to reinvigorate innovation in much needed R&D of new antimicrobials.

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“Superbugs were linked to almost 5 million deaths worldwide in 2019, making AMR a leading cause of mortality worldwide,” said BIO’s AMR expert Emily Wheeler. “Unfortunately, the current state of research into antimicrobial treatments is nowhere near where we need it to be to effectively combat the AMR threats we face today, not to mention those that we will inevitably confront in the future.”

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Under the PASTEUR framework, the government would enter into contracts with innovators to pay for consistent access to novel antimicrobials with payments that are decoupled from the volume of antimicrobials used.



**Katie Paulson (center) with Rep. Deborah Ross' office toured Novozymes in Morrisville and Mallinckrodt in Raleigh on April 13. Paulson is pictured here with (left to right) R&D Manager Alan Fast, Senior Regional Strategy Manager Heather O'Keefe (an NCBIO board member), NCBIO President Laura Gunter and Sr. Scientist I Piyum Khatibi.**

## Senate committee to hold hearing on insulin prices

The Senate Health, Education, Labor and Pensions Committee will hold a hearing on May 10 to examine the cost of insulin. The hearing will feature testimony from executives from top insulin makers and pharmacy benefit managers.

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The hearing comes after Eli Lilly, Novo Nordisk, and Sanofi ? which control 90 percent of the insulin market ? announced in March that they would be lowering insulin prices.Â

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Senator Bernie Sanders (I-VT), the chairman of the HELP Committee, has been a vocal critic of the high cost of prescription drugs. He has called for legislation that would allow Medicare to negotiate drug prices and would cap out-of-pocket costs for insulin at \$35 per month.

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PBMs are middlemen that negotiate discounts on drugs with manufacturers and decide which medicines insurance plans will cover. They have come under fire for their role in the high cost of prescription drugs. Critics argue that PBMs raise drug prices and then pocket the difference in rebates.

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The HELP Committee plans to work on a number of bills this week.Â

- The Increasing Transparency in Generic Drug Applications Act, which passed the House and Senate HELP committees last year with bipartisan support, would require the FDA to make it easier for generic manufacturers to match a name-brand drug’s ingredient formulation when seeking approval. NCBIO opposes this legislation without reasonably tailored language to protect trade secrets or proprietary information could be at risk of disclosure by the FDA.
- NCBIO Supports S. 652, the Safe Step Act, which amends the Employee Retirement Income Security Act of 1974 to require a group health plan or health insurance coverage offered in connection with such a plan to provide an exceptions process for any medication step therapy protocol and for other purposes.Â
- The HELP Co-Pays Act is similar to the accumulator ban that was passed in North Carolina but on a national scale. The accumulator ban assures that manufacturer rebates on medications are counted toward patients’ insurance deductible. NCBIO supports this legislation.

The Safe Step Act and the HELP Co-Pays Act could be folded into a larger piece of legislation targeting pharmacy benefit managers.

## RFI open to solicit ideas for ARPA-H, FDA collaboration

Advanced Research Projects Agency for Health announced a new RFI to solicit ideas for collaboration between ARPA-H and the FDA that incentivize public-private partnerships in the health ecosystem.

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ARPA-H will work with patients, health care providers, federal and nonfederal stakeholders and performers to conduct research and to develop programs and transition the successes from those programs to commercial markets. As such, ARPA-H is establishing a collaborative relationship with the FDA to help facilitate the development and transition of these health innovations into safe and effective solutions.

## Bipartisan legislation would repeal R&D amortization rule

A bipartisan group of 66 representatives in the House reintroduced the American Innovation and R&D Competitiveness Act ([H.R. 2673](#)) that allows for immediate research and development expensing looking back to 2022 when the provision expired and has received broad bipartisan support. Rep. Deborah Ross is one of the cosponsors of the bill.

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Ron Estes (R-KS), the lead Republican sponsor of the act, said, "We need a tax code that supports science R&D with immediate tax credits."

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In the Senate, Sen. Todd Young (R-Ind.) and Sen. Maggie Hassan (D-N.H.) reintroduced their bipartisan American Innovation and Jobs Act (S. 866) to support research and development investments by innovative companies across Indiana and the United States. Sen. Thom Tillis (R-NC) is a co-sponsor of the Senate bill.

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The Senate bill would restore incentives for long-term R&D investment by ensuring that companies can fully deduct R&D expenses each year, raise the cap over time for the refundable R&D tax credit for small businesses and startups and expand eligibility for the refundable R&D tax credit so that more startups and new businesses can use it.

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The House Small Business Committee held a hearing on [Paying Their Fair Share: How Tax Hikes Crush the Competitiveness of Small Businesses](#) focused on the impact of a change to capitalization of R&D expenditures. Witnesses said the change will hurt small, R&D intensive companies like those in the biotech community and will also have the unintended effect of undermining the Small Business Innovation Research program, which the committee reauthorized just last year.

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The Tax Cuts and Jobs Act of 2017 made a change to the way that companies can deduct research and development expenses, and the change went into effect in 2022. Previously, companies could deduct these expenses immediately from their taxable income. However, the new law required companies to amortize R&D expenses over five years (or 15 years for R&D activities abroad).

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This change was made to help offset the cost of other tax cuts in the bill, such as the reduction in the corporate rate to 21 percent and the enactment of the 20 percent deduction for certain unincorporated businesses.

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BIO and CSBA have each sent letters signed by all state bioscience associations supporting this legislation to Congressional leaders. If you'd like to call your senator or representative, you can find out who they are at [www.ncleg.gov/findyourlegislators](http://www.ncleg.gov/findyourlegislators) and contact their office to ask for their support of H.R. 2673 or S. 866.



On April 11, after a roundtable at Alexandria Real Estate Equities, Garrett Daniel (second from left), legislative assistant for Sen. Thom Tillis, toured Biogen's biologics facility with NC BIO President Laura Gunter. They are pictured here with Biogen's Director of State and Local Government Affairs (South) Mike McBrierty (also an NC BIO board member); Biologics Site Leader Marc Benz and Chief

**Medical Officer Maha Radhakrishnan, M.D.**

## EPA ethylene oxide proposal calls for substantial upfitting, paperwork

The Environmental Protection Agency estimates that its proposed rules for ethylene oxide emissions would cost medical-device sterilizers \$220 million in capital expenditures to implement pollution controls and \$74 million annually to maintain.Â

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In addition, the EPA estimates that per device it will cost \$30,000 and take six months of work to revalidate existing FDA approvals if EtO is used at lower concentrations. The EPA has proposed an 18-month period to implement the proposed rules. It is unlikely that the FDA has the capacity to process the approvals in time, and some believe the tight deadline could be a negotiation tactic by the EPA.

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EPA believes that implementing its proposed rules will cut EtO emissions in the U.S. by 80 percent, but it also estimates that 10 sterilizing plants will close as a result. The FDA has stated that just two additional closings would be catastrophic for patients.

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According to the FDA, 20 billion medical devices are sterilized via EtO annually with no validated alternatives.Â

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"Reducing an already stretched supply chain would be catastrophic for patient care, and our sincere hope is that the EPA and the Administration will listen to hospitals, FDA and others to ensure that nothing is done that would compromise patient access to safe and effective medical technologies," said Mark Leahy, president and CEO of the Medical Device Manufacturers Association.

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The EPA says that the proposed standards would reduce the increased lifetime cancer risk associated with EtO in all of the communities in proximity to commercial sterilizers to below EPA's Clean Air Act benchmark for elevated cancer risk.

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The comment period on the proposed rules ends June 12.

## Senate Judiciary Subcommittee IP hearing critical of TRIPS waiver

The Senate Judiciary Committee's Subcommittee on Intellectual Property held a hearing on [Foreign Competitive Threats to American Innovation and Economic Leadership](#) April 18.

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Chair Chris Coons (D-DE) and Ranking Member Thom Tillis (R-NC) both called for stronger U.S. IP protection. Lawmakers agreed with witnesses that a WTO waiver for COVID diagnostics and therapeutics would further damage the global IP system and weaken U.S. leadership in biotechnology.Â

## Biden picks cancer surgeon to run NIH

The White House is planning to nominate Monica Bertagnolli, a Boston cancer surgeon, to run the National Institutes of Health. If confirmed by the Senate, Bertagnolli would take control of a sprawling agency charged with investigating a range of diseases and finding new treatments.

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The NIH has not had a permanent director since December 2021. President Joe BidenÂ also pushed hard for the NIH nominee to be an oncologist.

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## NCBIO Updates

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### Mikhail advocates for parity in breast cancer screening

NCBIO board member Sheila Mikhail has asked for the support of NCBIO members in gaining passage of HB 560, [Diagnostic Parity for Breast Cancer Diagnostic Imaging](#), in the NC General Assembly.Â

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A traditional mammogram becomes less effective at detecting breast cancer the more dense a woman's breast tissue is. Insurers typically do not cover supplemental screening via ultrasound, MRI and other advanced imaging techniques. These supplemental screening techniques can cost hundreds to thousands of dollar.

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The legislation requires every health benefit plan offered by an insurer in the state that provides benefits for a diagnostic or supplemental examination for breast cancer to ensure that the cost-sharing requirements applicable to a diagnostic or supplemental examination for breast cancer are no less favorable than the cost-sharing requirements applicable to low-

breast cancer are no less favorable than the cost-sharing requirements applicable to low-dose screening mammography for breast cancer.

## NCPIO members talk DEI at TDM hosted gathering

NCPIO members enjoyed an afternoon of networking and conversation around diversity, equity and inclusion on Tuesday, April 25, hosted by The Diversity Movement in Raleigh. Members had time to mingle and talk before splitting up into small groups to discuss mentoring, leadership, employee resource groups, DEI training and more.



## NCPIO Member News

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

**Biocair** recently completed a qualitative research study of supply chain complexities for CROs that can be downloaded [here](#).

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**BioCryst Pharmaceuticals, Inc.** has secured \$450 million in committed financing from funds managed by Pharmakon Advisors, LP. BioCryst has elected to draw \$300 million of the \$450 million available to the company on the closing date.

[More >>](#)

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**Biogen Inc.** announced that the FDA has approved QALSODY (tofersen) 100 mg/15mL injection for the treatment of amyotrophic lateral sclerosis in adults who have a mutation in the superoxide dismutase 1 gene. [More >>](#)

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**FUJIFILM Diosynth Biotechnologies** has acquired 41 acres of land adjacent to its existing state-of-the-art campus in Research Triangle Park. The additional 41 acres brings the total campus size to just under 119 acres. [More >>](#)

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**IQVIA** has been recognized as a Leader in Customer Experience Platforms by Everest Group for its Orchestrated Customer Engagement platform with its well-rounded portfolio of industry-leading products. [More >>](#)

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**Kriya Therapeutics'** Co-founder, Chairman, and CEO Shankar Ramaswamy, M.D., is the recipient of a 2023 Health Care Leadership Award from the Triangle Business Journal in the category of health care innovator/researcher. [More >>](#)

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**Kymanox Corporation** has acquired of Agilis Consulting Group, a human factors partner for the global medical market specializing in helping new and established companies achieve successful HF submissions while navigating the complex global regulatory landscape. [More >>](#)

## Events

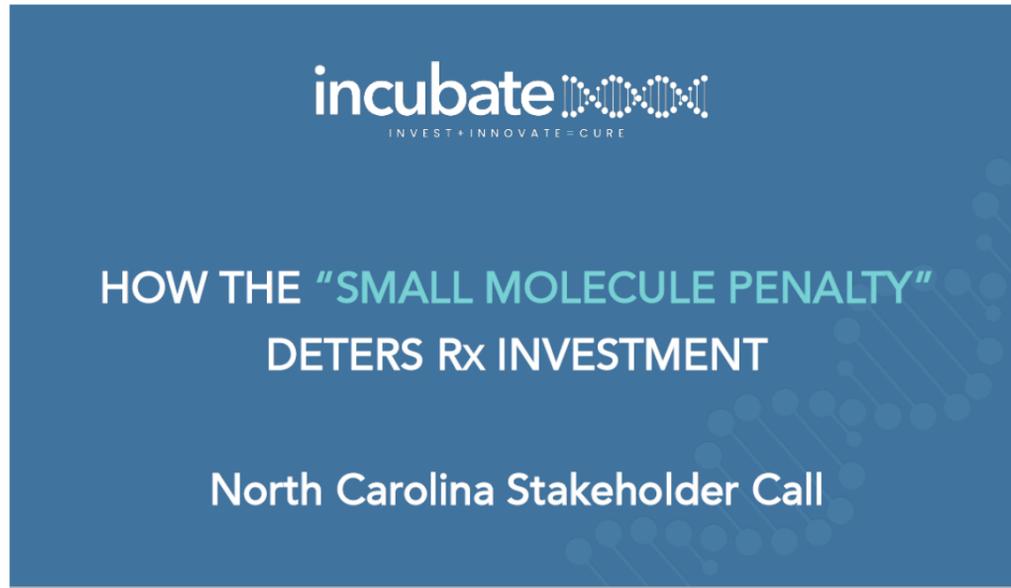
### Medical Device Forum and Luncheon May 16

Join us for the NC BIO Medical Device Luncheon and Forum Tuesday, May 16, at NC Biotech. The discussion will focus on navigating regulatory and supply chain challenges today and tomorrow and include

- **Eric Hill** (moderator), senior director, scientific and technical services, Boston Analytical;
- **Stefanie Johns**, director of regulatory affairs, Kymanox;
- **Sean McCarthy**, senior director of regulatory affairs, YourBio Health;
- **Edgard Ngaboyamahina**, Ph.D., sustainability subject matter expert, RTI International; and
- **Adam Zerda**, senior director, international affairs, BD.

This event is sponsored by [Clancy & Theys Construction Company](#), [Hughes Pittman & Gupton](#), [Mercury Business Services](#), [UniFirst](#) and [YourBio Health](#).

**LEARN MORE**



### How the "Small Molecule Penalty" Deters Rx Investment

Join Incubate for an online briefing May 9 at 10:45 a.m. on the impact of the small-molecule penalty on early stage drug development as outlined in the Inflation Reduction Act. In its current form, the IRA alters the existing system of patents and exclusivities that has long ensured that successful medicines receive 12 to 16 years of profitability after the medicines are approved. The IRA implements price controls at 9 years for small-molecule drugs while biologics are given 13 years.

**REGISTER NOW**



## Polsinelli invites NC BIO members to May 11 networking event

[Polsinelli's Intellectual Property Department](#) invites you to join them for an evening among friends and colleagues. Enjoy crafted cocktails, food and great conversation at Watts & Ward.

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Thursday, May 11, 4 - 7 p.m.  
Watts & Ward  
200 S. Blount St., Raleigh

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If you have questions or would like more information regarding this event, please contact [Ashlee Ryan](#).

**REGISTER NOW**



## North Carolina Reception June 6 at BIO 2023

Join us for the [North Carolina reception](#) at BIO and network with NC Biotech and other life sciences leaders while enjoying delicious food and beverages. NC Secretary of Commerce Mabelle Sanders will be a special guest.

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Tuesday, June 6, 6 - 8 p.m.  
Omni Boston Hotel at the Seaport

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Please register by **May 31**.

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And be sure to attend the panel discussion "Tackling the Global Challenge of Antimicrobial Resistance - What Will It Take?" June 5 at 1 p.m. The panel features **Joe Larsen**, Ph.D., vice president of clinical development at Locus Biosciences.

**REGISTER NOW**



## The biotech event of the year is almost here

BIO2023 in Boston is just a few weeks away. Register now for

### **Innovative programming**

Engaging programming around the current and future state of biotech. BIO plans to showcase over [130+ educational sessions](#) across seventeen focus areas featuring 300+ speakers, including areas like therapeutic frontiers, the business of biotech, regulatory and policy outlooks, and human capital.

**Promising partnerships**

Collaboration is the lifeblood of biotechnology. Last year BIO facilitated over 44,000 partnering meetings in the BIO One-on-One Partnering System. Efficiently find and meet potential partners, investors, and investees from around the world. [View the participating companies.](#)

**High-powered networking**

You can expect to find senior biotech executives and business development leaders from thousands of companies from around the globe. Celebrate the year's industry accomplishments at 20+ BIO hosted receptions and networking. [See what's lined up.](#)

**REGISTER NOW**



**Innovations in Ag: A Regional Perspective July 19, Danville Va.**

NCBIO is excited to announce that we are partnering with Virginia Bio and the Institute for Advanced Learning and Research for an ag biotech event on July 19 in Virginia. This program will look at innovations in ag from a regional perspective. We hope you will join NCBIO members and others in Virginia for this event.

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If you are interested in sponsoring the joint event, please contact NCBIO Events Director [Amber Niebauer](#) for more information.

**REGISTER NOW**



**Discount available for BIO Raleigh ag, environment event**

The [BIO Impact Ag & Environment Conference](#) will be held, Sept. 19-20, in Raleigh This premier event brings together biotech innovators, investors, and policy makers focused on strengthening the bioeconomy to meet societal challenges.

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As a member of NCBIO, you are eligible for a \$200 discount on nonmember premier access and nonmember emerging innovators registration rates. Each code is valid for one registration. [Request your discount code](#) by May 12. Codes will be distributed by June 2. By requesting a code, you are not obligated to

register.

**APPLY NOW**

## NCBIO calendar

- BIO 2023 Advanced Partnering Webinar (5/3/2023)
- Lunch and Learn Technical Seminar hosted by Cygnus Technologies (5/4/2023)
- Larger than Life Sciences - Onward NC hosted by LaunchBio (5/4/2023)
- SAS Innovate (5/8/2023 to 5/10/2023)
- Polsinelli Reception (5/11/2023)
- RTP AgBio and AgTech Meetup hosted by Innovate Carolina (5/11/2023)
- Upstream Production Process Development for Biopharmaceuticals hosted by BTEC (5/12/2023 to 5/26/2023)
- Biomanufacturing Automation Fundamentals hosted by BTEC (5/16/2023 to 5/17/2023)
- NCBIO Medical Device Luncheon and Forum (5/16/2023)
- The Ups and Downs of the DEI Journey (5/31/2023)
- BIO 2023 International Convention (6/5/2023 to 6/8/2023)
- North Carolina Reception at BIO hosted by NCBiotech (6/6/2023)
- Analytical Methods for Gene Therapy Vector Characterization and Testing hosted by BTEC (6/13/2023 to 6/15/2023)
- Population Health Summer Institute hosted by Duke University (6/15/2023 to 6/30/2023)
- Hands-On Essentials of Automation for Biomanufacturing hosted by BTEC (6/27/2023 to 6/28/2023)
- Downstream Biopharmaceutical Processes: Fundamentals and Design hosted by BTEC (6/27/2023 to 6/29/2023)



## PSC offers grant-writing assistance

One of the many services that PSC Biotech offers is grant-writing assistance and planning for life science companies. We partnered with them to create an overview video on the grant proposal process from conceptualization to submission. Click below for PSC's Grant Writing White Paper (PDF).

**GET WHITE PAPER**

## BIO Business Solutions





## Take every opportunity to save

Creating life-changing breakthroughs isn't easy ? or cheap. That's why we offer BIO Business Solutions to NC BIO members. Through BIO Business Solutions, you'll receive access to deep discounts on industry-tailored products and services so you can spend less and grow more.

### LEARN MORE



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### Quicklinks



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