

Life Sciences Caucus Meeting

May 1, 2024

7:30am

Co-chairs:

Senators Newton and Woodard

Representatives White and Reives

Meeting will begin shortly



Advocate. Advance.

NC Life Sciences Caucus

Laura Gunter, NCLifeSci President

May 1, 2024

NC Innovation Pipeline



Advocate. Advance.

The NC Life Sciences Organization is the trade association for the life sciences industry in North Carolina.

NCLifeSci represents nearly 300 member companies across the state.

30th anniversary (formerly NCBIO)



Connections

We facilitate networking with peers, colleagues, experts and decision makers to help members find new partners, solutions and ways to grow.



Savings

Our members realize substantial discounts on a variety of products and services thanks to the national buying power of BIO Business Solutions.



Advocacy

We share member stories with decision and policy makers to address challenges and cultivate an environment favorable to the success of our industry and our state.

North Carolina's Innovation Pipeline

North Carolina's Innovation Pipeline



Research &
Development

North Carolina's Innovation Pipeline



Research &
Development

- University R&D*
 - 63.5% Federal
 - 7% Business and Industry
 - 5% State
 - 3.5% Non-profit
 - 20% Other
- Existing Company R&D
- NCInnovation
 - Supports university applied research
 - No funding for private companies

*UNC-Chapel Hill research funding sources (2022)

North Carolina's Innovation Pipeline



Research &
Development



Commercialization

North Carolina's Innovation Pipeline



Research &
Development



Commercialization

- One NC Small Business Program
 - State funded matching program for companies awarded competitive SBIR/STTR grants
- NC Biotechnology Center
 - Translational grants
 - Early/Seed/pre-seed company loans
 - State supported
- SBTDC
 - Part of UNC System/US SBA
 - Business Consulting
 - Grant writing support
- CEDNC
 - Privately funded educational and support resource
 - Venture Connect
 - Connect to Capital

North Carolina's Innovation Pipeline



Research &
Development



Commercialization

- First Flight Venture Center
 - Affordable space
 - Management guidance, shared support services
 - Assistance with federal grants
- Early money
 - Retirement/savings
 - Friends/family
 - Family offices
 - Angel investors
 - Some venture capital

North Carolina's Innovation Pipeline



Research &
Development



Commercialization



Scaling Up

North Carolina's Innovation Pipeline

- Venture capital
- Corporate
 - Venture
 - Partnerships
- Philanthropic/
patient
ventures
- Capital markets



Research &
Development



Commercialization



Scaling Up

North Carolina's Innovation Pipeline



Research &
Development



Commercialization



Scaling Up



Production and
Expansion



North Carolina's Innovation Pipeline

AskBio


The R&D

UNC-Chapel Hill professor Jude Samulski, Ph.D., developed a technology to treat muscular dystrophies using gene editing to correct genetic errors that cause progressive weakness and loss of muscle mass in patients. NCBiotech help recruit Samulski to UNC and supported the work of his lab.

Commercialization

- Samulski, Sheila Mikhail and Xiao Xiao, Ph.D., spun AskBio out of Chapel Hill in 2001.
- NCBiotech provided two early loans, including a company inception loan
- One NC Small Business Program awards of \$75,000 and \$50,00 in 2008 and 2014 matching federal SBIR/STTR grants





“We are very appreciative of the funding and support provided from the matching grants program and staff, and we consider this program as providing North Carolina small businesses with a competitive edge in a difficult current environment.”

-- AskBio

Scaling Up


From 2010 to 2018, the company made tremendous strides by creating Pro10, a way to produce the delivery method for their gene therapy in amounts needed to create a workable treatment.



Production & Expansion

AskBio spun off two companies to focus on Duchenne muscular dystrophy and hemophilia. The subsidiaries were acquired by Pfizer and Baxter.

2019 was a turning point for the company with a \$225 million private-equity investment. In 2020, Bayer AG bought AskBio for \$2 billion.



Today, AskBio continues to operate independently with its headquarters in RTP while maintaining research and production facilities around the nation and the world.

The company has over 350,000 square feet of lab, research and manufacturing facilities and a portfolio of 800+ patents.



North Carolina's
Innovation Pipeline

Humactye



The R&D

Tech to grow blood vessels and similar tissues for use in vascular repairs without triggering an immune response in the patient

Based on work of CEO Laura Niklason, M.D., Ph.D. at Duke University and colleagues at MIT.

Commercialization

- Spun out of Duke in 2004
- Received a \$150,000 NCBiotech loan in 2006
- Received a matching grant of \$50,000 from the One NC Small Business Program in 2010
- In 2014, a Humacyte product was first implanted in a patient





"The One NC Small Business Program helped us to begin working on reducing raw materials costs concurrent with completing the Phase I SBIR study. Initially, we weren't planning to start these efforts until award of a Phase II SBIR. "

--Humacyte

“The SBIR award and the One NC Small Business Program also helped to validate the importance of our efforts in the eyes of our investors. With these awards, we were able to secure additional funds from other investors.”

--Humacyte



Scaling Up

- Humacyte as raised over \$480 million since 2006
- Began construction of Durham manufacturing facility in 2019
- Became a publicly traded company in August 2021 with a valuation of \$1 billion and generating an additional \$245 million in funding




Production & Expansion

Humacyte's most advanced product is its Human Acellular Vessels. HAVs are off-the-shelf vessels that can be used for vascular repair, reconstruction and replacement.

HAV technology is being used to treat the wounded of the war in Ukraine.





Humacyte's HAV technology is now under priority review by the FDA for use in treating vascular trauma.

In the future, Humacyte is looking to create bioengineered tissues and organs for coronary artery bypass grafts, pediatric heart surgery and type 1 diabetes treatment.

BIO Best Practices Report 2023-2024



Peter M. Pellerito

*Senior Policy Adviser, Federal/State Economic
Development*

BIO

Defining The Biosciences



Whether the industry is called “biotech”, “biosciences”, or the “life sciences”, the diversity in scientific discovery and commercialization is singularly defined by the application of biological knowledge

- **Agriculture & Industrial Biotechnology**
- **Biopharmaceuticals**
- **Research & Testing**
- **Distribution**
- **Medical Devices**

BIO Best Practices Report 2023



Report issued every two years

Intended as a resource for state policymakers and other stakeholders to help them understand the bioscience industry

Includes information on building, growing and strengthening the bioscience industry in a state or region

Topics Include:

- Annual growth trends across all aspects of biotechnology industry (health, agriculture, environment)
- The various stages of bioscience company and the economic development programs best suited for each stage in a company's development
- Examples of state initiatives to build and grow the bioscience industry in their state

The U.S. Biosciences Industry in the States:

Best Practices in Innovation, Partnerships, and Job Creation



What Makes the Biosciences an Economic Driver ?

The bioscience industry continues to be a preferred technology sector for company creation and growth by states and regions for several reasons

1. Vital component of U.S. domestic manufacturing by producing high-quality products for a global market
2. Creates highly-skilled and high paying jobs that produce positive down stream benefits to state and local economies
3. Spurs public and private partnerships with colleges and universities around tech transfer and workforce training



Economic Impacts of the Industry

Figure 1: Economic Impacts of the U.S. Bioscience Industry, 2021

DIRECT IMPACT

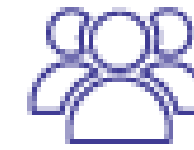


Bioscience Industry
Employment

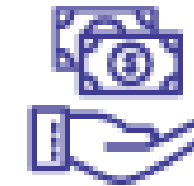
2.14M

TOTAL IMPACT

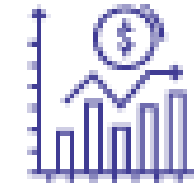
Employment **10.3M**



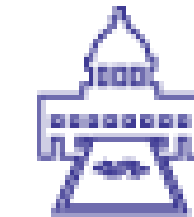
Wages &
Benefits **\$796B**



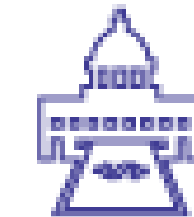
Economic
Output **\$2.9T**



State &
Local Taxes **\$102B**



Federal
Taxes **\$169B**



Source: TEconomy Partners data and analysis using U.S. IMPLAN Input-Output Model.



Bioscience Company Development/Supportive Legislation

Sales & Manufacturing

Clinical Research

Pre-Clinical

Site & Infrastructure Grants
Renewable Energy Tax Credits
Sales & Use Tax Discounts, Exemptions and Refunds
Utility Rebates
Biomanufacturing Workforce Credits

NOL Carryover/ Tax Deductions
R&D Tax Credits
Capital Investment Tax Incentives
Innovation Investment Tax Incentives

SBIR/STTR Matching Grants
Angel Investor Tax Credits
Seed Capital Tax Credit
Incubator/ Accelerator Funding
Refundable/Transferable R&D Credits
Net Operating Loss (Carry-Over)

2024 Update



2024 Economic Development Trends

- **New Science breakthroughs = New therapies for disease
- **Increased geographic distribution----NC and elsewhere
- **Sophisticated partnerships looking for long-term growth
- **Academic research centers are more entrepreneurial
- **Manufacturing and reshoring funding and workforce
- **Pandemic preparedness has raised public awareness and support
- **Growing number of supportive state and regional economic development professionals and incentives....SBIR Matching and R&D Tax Credits for example

BIO Best Practices Report 2023-2024



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