

# Life Sciences Caucus Meeting

May 24, 2023

7:30am

Co-chairs:

Senators Newton and Woodard

Representatives White and Reives

Meeting will begin shortly



# Agenda

- Welcoming Remarks by Chairs

Senators Paul Newton and Mike Woodard

Representatives Donna White and Robert Reives

- Workforce

Astellas Gene Therapies, Sanford, NC

- Brad Mickey, Executive Director, Manufacturing and Operations Site Head
- Nicole McCaleb, Quality Assurance Associate

Thermo Fisher Scientific, Greenville, NC

- Wayne Edgerton, Sr. Director of Operations
- Frederick Donnelly, Formulation Technician II

- Supply Chain

- Michael Braddock, Chief Revenue Officer, Frontier Scientific Solutions, Wilmington, NC
- James Malone, Director Global Supply Chain, Grifols, Clayton, NC

# ASTELLAS IS A SPECIALTY GLOBAL PHARMACEUTICAL COMPANY

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## CORPORATE VISION:

*On the forefront of healthcare change to turn innovative science into proven VALUE for patients*

## QUICK FACTS:

**Top 25**



global pharmaceutical company



Formed in **2005** from the merger of Yamanouchi and Fujisawa; headquartered in Tokyo, Japan



We take a '**Science First**' mindset, focusing on the **best science**, empowering the **best talent** to pursue it, and developing it at the **best location**



Growing expertise in **emerging areas of discovery research**

Over

**14,500**



employees\*

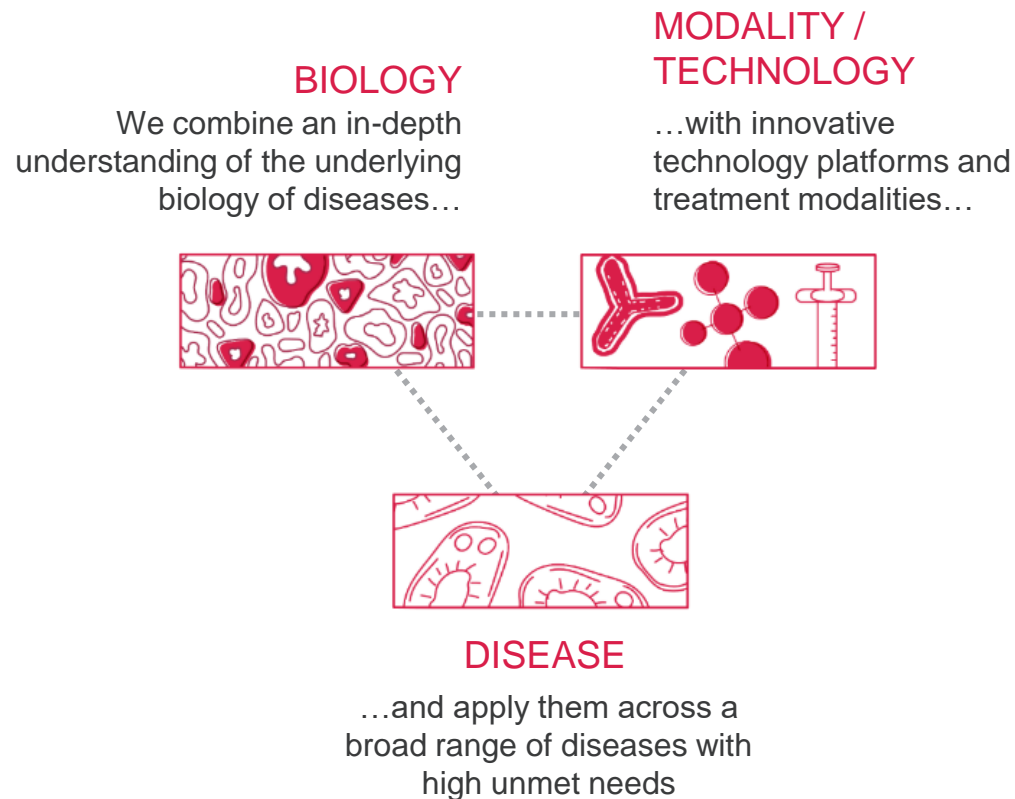


**Broad pipeline** and recognized leadership in oncology, urology, immunology and transplantation






# OUR AMBITIOUS, LONG-TERM APPROACH FOR **MAXIMIZING THE VALUE WE DELIVER** FOR PATIENTS

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We seek to address areas of significant unmet patient need through our **Focus Area approach...**








...centering our research efforts where we can deliver **the greatest value for patients**

	Immuno-oncology	Developing therapies for the majority of cancer patients who do not respond to currently available immune therapies
	Mitochondria	Investigating mitochondrial-based therapies for diseases with high unmet medical needs
	Genetic Regulation	Targeting disease at the genetic level to discover, develop and deliver a broad portfolio of transformative therapies for patients with genetic diseases
	Blindness and Regeneration	Investigating cell and gene therapies for restoring and maintaining vision
	Targeted Protein Degradation	Investigating targeted protein degradation to deliver disruptive clinical benefit for selected cancers and potentially other disease areas




# OUR BROAD AND GROWING PIPELINE

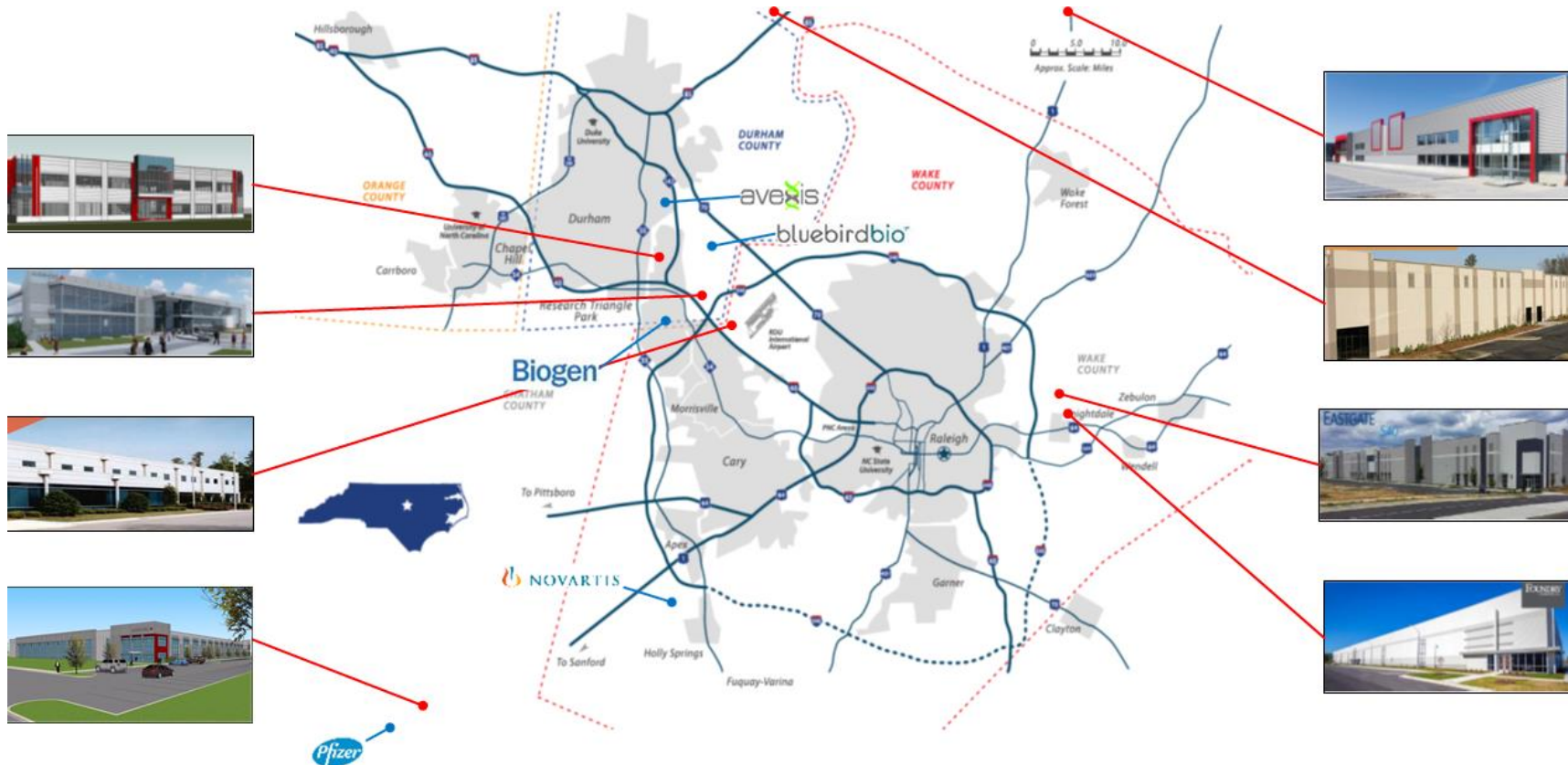
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## Currently disclosed Astellas programs:

Program	Mechanism	Target indication	Current phase	Origin/Partner
<b>AT845</b>	GAA gene replacement	Pompe disease	Phase 1/2	
<b>AT132</b>	MTM1 gene replacement	X-linked myotubular myopathy	Phase 1/2 (on clinical hold)	
AT808	FXN gene replacement	Friedreich's Ataxia	Preclinical	
AT466	Vectorized exon skipping/ vectorized RNA knockdown for DMPK	Myotonic dystrophy	Discovery	
(Not disclosed)	UBE3A restoring	Angelman Syndrome	Discovery	

## Partner programs *(Note: Astellas holds an exclusive option to obtain an exclusive license for TSHA-102 and TSHA-120):*

Program	Mechanism	Target indication	Current phase	Origin/Partner
TSHA-102	AAV9 gene replacement <sup>†</sup>	Rett syndrome	Phase 1/2	
TSHA-120	AAV9 gene replacement <sup>†</sup>	Giant axonal neuropathy	Phase 1/2	
IdeXork	Selective anti-AAV antibody metabolization	Pompe disease	Preclinical	



## NEW FACILITY: Strategic Site Selection

- Where in US?
- Why NC?
- Where in NC?

# NORTH CAROLINA EXPANSION: Staffing Tomorrow's Workforce

The NC facility will be responsible for Astellas's Gene Therapy clinical and commercial supply

The North Carolina facility workforce will double (100 -> 200) over next 5 years with a high demand for the following entry level positions

- Manufacturing
- Warehouse
- Maintenance
- Metrology
- Lab Analysts
- Quality





# NICOLE'S BIO

## About Nicole:

Nicole McCaleb is a United States Army veteran with 11 years of logistical experience. In August 2012, she started her logistic career as an Automated Logistic Specialist in the United States Army. While in service, she acquired a variety of skills. Her ability to remain flexible and display a strong work ethic is one of her strengths. Nicole is a certified logistic technician and master resilience trainer.

Nicole was honorably discharged from the United States Military as a Logistic Advisor with the Special Forces Assistance Brigade in January 2022. She completed the BioWork certification in June 2021 with Central Carolina Community College. This achievement started a new career path after she transitioned from the United States Army in January of 2022.

Since then, Nicole has completed her Associate's in Global Supply Chain and Logistic Management and her bachelor's in business administration. Nicole started her pharmaceutical career with Astellas in January 2022. Nicole is married with three beautiful angels. Three years old Natalie and Nathaniel, and a one-year-old named Nova. She works within the Quality Assurance department with Astellas in Sanford, NC. She also coaches a girls' basketball team to help continue her service to the community. She enjoys spending time with her family and traveling during her free time.





# NICOLE'S CAREER ROAD MAP



Greenville, NC







2,200  
Employees



142 acres;  
73 acres open space  
  
1.7M sq. ft. under roof

## Primary Capabilities

- Pharmaceutical Development
- Oral Solid Dose
  - Continuous Manufacturing
- Sterile Dosage Forms
  - Sterile micro-needle patch manufacturing and packaging

## Functions

- R&D
- Corp. Functions (Finance, IT, HR)
- Commercial/Sales
- Customer Services
- Technical Support
- Premier productivity partner
- Operations (Mfg., Logistics, Supply Chain)
- Quality Assurance
- Regulatory Affairs



FRONTIER  
SCIENTIFIC SOLUTIONS

COLD STORAGE FOR THE LIFE SCIENCES & PHARMACEUTICAL INDUSTRIES

# A NEW FRONTIER FOR COLD STORAGE

Frontier Scientific Solutions (FSS) is a third-party logistics, storage and distribution company strategically headquartered near Research Triangle Park in Wilmington, North Carolina. We have partnered with Wilmington International Airport (ILM) to develop over 1.4 million square feet of cGMP cold and ultra-cold storage for pharmaceutical drug distribution.

FSS is dedicated to enabling Life Sciences Organizations around the world to safely store and deliver drug products with greater speed and precision. Our campus is located in a foreign trade zone with direct runway access and within a 15-minute drive to the Port of Wilmington. We are your global distribution partner in the United States.

Drug development has become much more complex with unprecedented growth for specialty drugs such as biologics, orphan drugs and cell/gene therapies which include large and small molecule drugs. We understand the unique and complicated challenges our customers face to deliver their products to market. FSS is responding with significant investments to expand our expertise, capacity and capabilities to enhance your productivity and scalability.



# Region

LOCATED IN WILMINGTON, NC

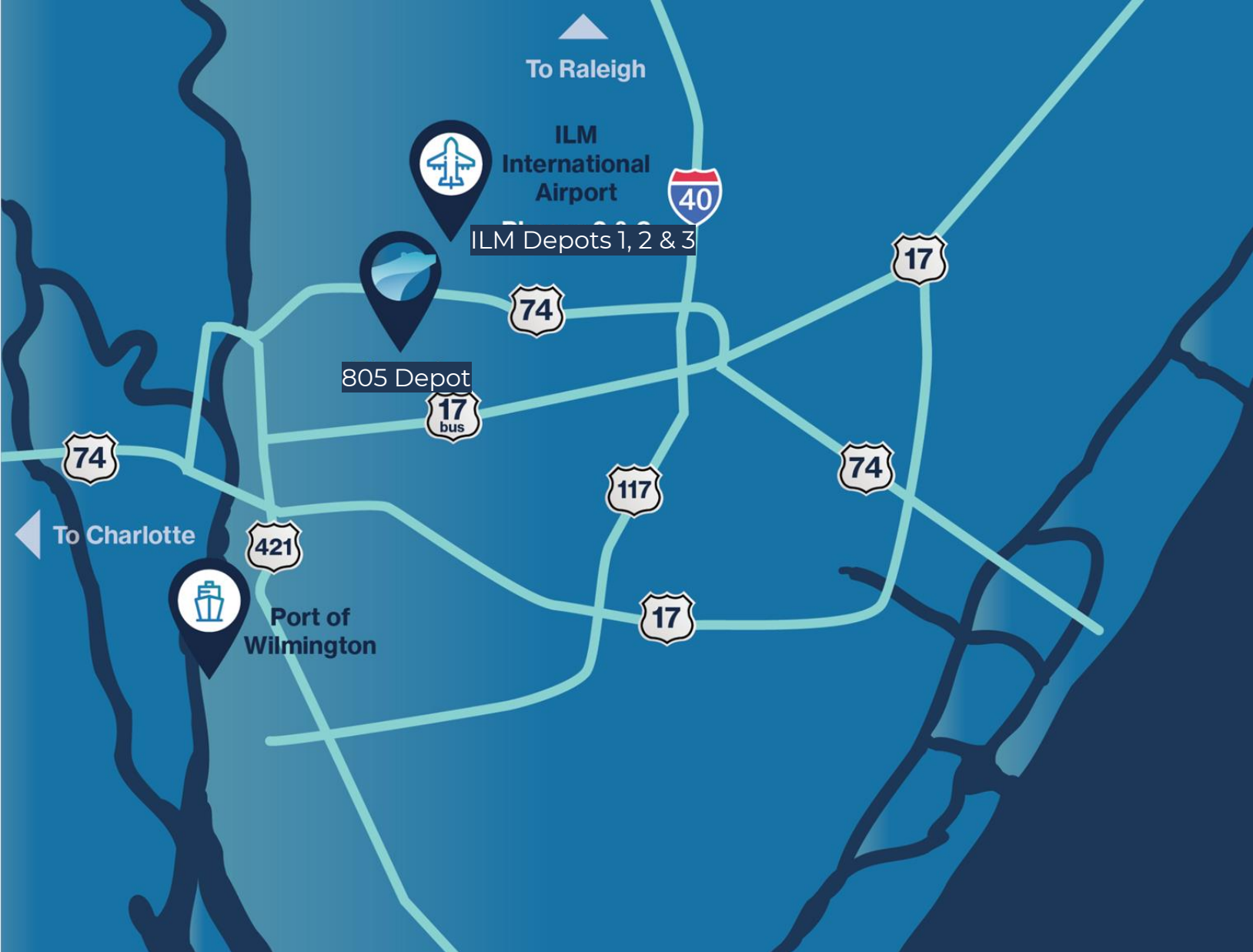
- 2 Hours from RTP (Research Triangle Park) via I-40
  - The Largest Life Sciences Research Park in the United States
- 3.5 hours from Charlotte, NC
- Easy Access to I-95 via I-40



# Local

## FACILITY LOCATION HIGHLIGHTS

- ILM Depots
  - At Wilmington International (ILM) Airport
  - 7 Miles (15 Minutes) Port of Wilmington
- 805 Depot
  - 2 Miles (5 Minutes) from Wilmington International Airport (ILM)
  - 5 Miles (12 Minutes) from Port of Wilmington





# ILM Airport



ILM Depot 2  
250,000+ Sq Ft

ILM Depot 3  
350,000+ Sq Ft

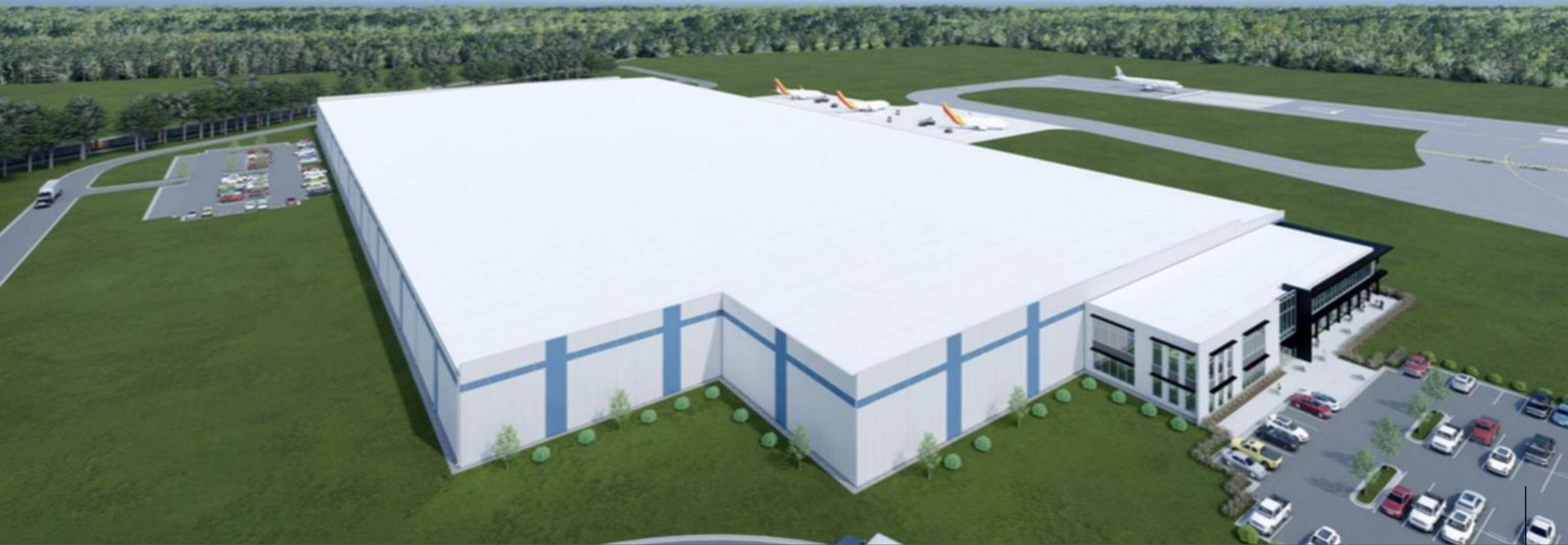
ILM Depot 1  
500,000 Sq Ft



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# ILM Depot 1



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# ILM Depot 2



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# ILM Depot 3



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# 805 Depot



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# Why Frontier?

## SAFEGUARDING YOUR WORK & INVESTMENT

- Uniquely Positioned at the Wilmington NC Airport with direct runway access
- Located in a Foreign Trade Zone with Customs and Border Patrol onsite
- Under 2 Hours from Research Triangle Park
- Less than a 15-minute drive to the Port of Wilmington
- Incredible highway access with rail adjacent to the campus
- Fewer Product Touch Points in the Supply-Chain Mitigating the Risk of Product Loss or Damage
- Industry leading expertise utilizing the latest cutting-edge technologies
- Ability to expand capacity to serve the industry's growth needs





To Learn More Contact:

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Chief Revenue Officer

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Wilmington, NC 28405

[WWW.FRONTIERSCIENTIFICSOLUTIONS.COM](http://WWW.FRONTIERSCIENTIFICSOLUTIONS.COM)



A person wearing a blue lab coat with a "GRIFOLS" patch on the chest is holding a small glass vial. The background shows a laboratory or pharmaceutical manufacturing environment with various equipment and racks of vials.

# Grifols Supply Chain Management

**GRIFOLS**

# Biopharma therapies

A leader in the production of plasma-derived medicines and other innovative solutions for the treatment of chronic and rare diseases, at times life-threatening.

GRIFOLS



# From donors to patients

Our vertically integrated  
process ensures  
excellent quality and  
safety standards.

GRIFOLS

# High quality supply chains

Highly regulated products require supply chains that provide the same sort of quality and safety found in our production.



GRIFOLS



# Life Science Legislation

- **Budget comparison**

- House – adds an additional \$2M in recurring funding for the One NC Small Business Fund
- Senate – adds no additional funds
- **ONCSB** fund provides matching funds for small, high growth, entrepreneurial companies that receive highly competitive federal grant funds. These matches provide critical dollars to help companies further commercialization at a critical junction in proving their technology.

- **H246: Revise Pharmacy Benefits Manager Provisions**

- **Sponsors:** Sasser, Bell, Blackwell, Humphrey (Primary)
- Bill includes provision ensuring enrollees in HSA-eligible high deductible plans may include manufacturer cost-sharing assistance toward their deductibles.
- Passed House unanimously and awaits action in the Senate.

- **S673: Wastewater Regulatory Relief Act**

- Sponsors: P. Newton, Sawrey, Lazzara (Primary)
- **Intended** to provide more realistic design flow rates that match actual use, thereby providing more capacity to local water systems.
- Passed Senate unanimously and awaits action in the House.

# Q&A/Discussion

# Life Science Caucus Meeting

May 24, 2023

7:30am

Co-chairs:

Senators Newton and Woodard

Representatives White and Reives

Meeting adjourned

