

Life Science Caucus Meeting  
May 19, 2020  
7:30am

Co-chairs:  
Senators Newton and Woodard  
Representatives White and Reives

Meeting will begin shortly

# Agenda

- Welcoming Remarks by Chairs
- Presentation – Pfizer, Rocky Mount (Ramone Frontanes)
- Presentation – Grifols, Clayton (Doug Burns)
- COVID-19 Update
  - Impacts
  - Opportunities
- Legislation of Interest
- Discussion
- Adjourn

# Pfizer – Rocky Mount

**Ramon Frontanes** is Vice President of Operations for Global Sterile Injectables at Pfizer with direct responsibility for Rocky Mount, NC and McPherson, KS operations. Ramon has over 35 years' experience in the pharmaceutical industry. Since joining Pfizer in 2002 in Brooklyn, New York, Ramon has been the Senior Director of Strategic Projects and Initiatives for GSI as well as the Site Leader at Barceloneta and Caguas, Puerto Rico, for more than ten years in total.

Prior to joining Pfizer, Ramon had over 17 years of experience, with multiple roles of increased responsibility at Smith Kline & French, MOVA Pharmaceutical Corporation and Bristol Myers Squibb.



**Breakthroughs that  
change patients' lives**

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# **Pfizer Rocky Mount COVID-19 Response**



# Pfizer's Global Response

*Pfizer is driving for a vaccine and treatment through industry collaboration*

## Pfizer's Five-point Plan to Battle COVID-19

1. Sharing tools and insights.
2. Marshalling our people.
3. Applying our drug development expertise.
4. Offering our manufacturing capabilities.
5. Improving future rapid response.



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### Vaccine



- Tuesday, May 5, Pfizer announced that the first U.S. participants have been dosed in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19 infection (in partnership with BioNTech).
- Pfizer has begun to invest at risk to actively scale up our manufacturing capacity and distribution infrastructure.

### Anti-viral



- Pfizer continues to make progress with our protease inhibitor and studies demonstrate cellular anti-viral activity.

# Delivering breakthroughs for our patients

*Pfizer Rocky Mount provides 20% of the U.S. hospital system's sterile injectables*



"Because of your help we are much more stable with supply, and you have made a significant difference in our ability to manage COVID patients."

– **Beaumont Health**



"Your support has helped ensure mission success for the USNS Comfort and USNS Mercy."

– **Department of Defense**



"The global pandemic is causing an unprecedented strain on the healthcare systems of every country in the world. We extend our gratitude to Pfizer for providing much needed Fentanyl for our critically ill patients battling COVID-19."

– **Memorial Health**

## Criticality for U.S. healthcare systems

- Pfizer has one of the most sophisticated supply chain systems in the industry – over 40 Pfizer-owned sites and 200 suppliers globally
- Rocky Mount provides sterile injectables (such as IV bags, vials, and filled syringes) to numerous global markets
- Pfizer's Rocky Mount site provides about 20% of the U.S. hospital system's sterile injectables
- Maintaining strong operations and continue to operate at >90% capacity on average since mid-March

## Products needed for COVID-19

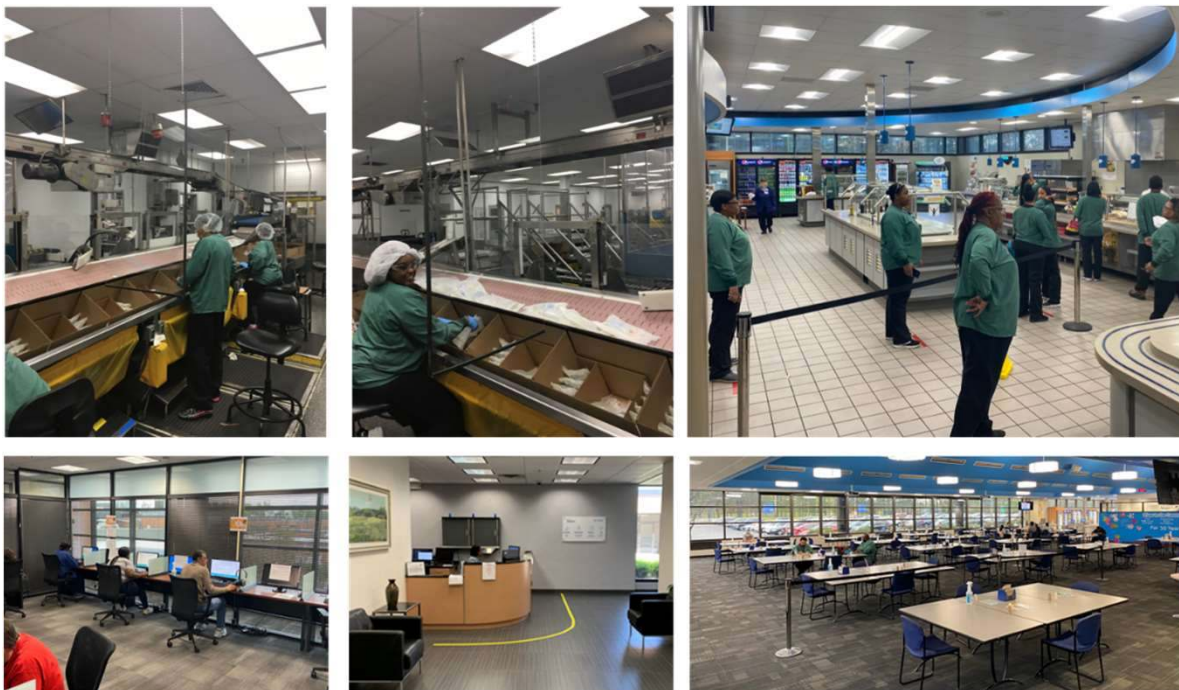
- As the coronavirus hospitalizations increased globally, demand for certain supportive and critical care products has increased significantly.
- Rocky Mount makes over a dozen products used by hospitals in COVID-19 related treatment protocols
- This includes products used for pain management and muscle relaxation for patients who are intubated or placed on ventilators



Breakthroughs that  
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# Protecting our colleagues

*The safety and well-being of our colleagues remains our top priority*



## Social distancing

- Implementing creative ways of working and physical barriers to ensure social distancing
- Leveraging contact tracing to be able to quickly address any concerns

## Enhanced cleaning and disinfection

- Hired additional staff that is providing regular cleaning of high traffic areas.
- Implemented full proactive disinfection at the beginning and end of every shift.
- Added hand sanitizer and hand washing stations around the facility

## Employee benefits

- Enhanced benefits, ensuring that no colleague who is ill is penalized financially or from an attendance policy standpoint.
- Proactively provided accommodations for those in the CDC's high-risk categories.
- Increased our communication and signage, including daily meetings with all 300+ leaders



Breakthroughs that  
change patients' lives



# Serving our community

*Taking social responsibility seriously when our community needs us more than ever*



Providing STEM eTutoring and “virtual field trips” for local students learning remotely

Collected over 160 lbs. of goods for the Food Bank of Central and Eastern North Carolina



Pfizer provided “double match” for colleague donations to select organizations on #GivingTuesdayNow

Funded 18 one-week childcare scholarships at the Rocky Mount YMCA for essential workers



Breakthroughs that change patients' lives



# Questions & Answers

# Grifols, Clayton

**Doug Burns** is President, Grifols Therapeutics. He has been with Grifols (formerly Talecris, formerly Bayer) in Clayton, NC since 2000. He started as a process development engineer in Research and Development, later leading the Development group before assuming responsibility for site manufacturing as Vice President of Manufacturing and ultimately responsibility for the Clayton site as President of Grifols Therapeutics. Prior to working at the Clayton site, he received his Ph.D. in Chemical Engineering at the University of Delaware, and a B.S. in the same field from Purdue University.

# Grifols Response to COVID-19

## Prepared for North Carolina Life Science Caucus

Doug Burns, President, Grifols Therapeutics, Inc.

May 19, 2020

# Grifols Response to COVID-19 Pandemic

**March 25:** Grifols announces formal collaboration with Food and Drug Administration (FDA) and the Biomedical Advanced Research Development Authority (BARDA) to collect convalescent plasma and produce hyperimmune globulin for COVID-19

**April 13:** Grifols begins work to expand multi-purpose facility (MPF) in Clayton, where hyperimmune will be produced. The expansion will specifically deploy viral inactivation technology (methylene blue) to inactivate convalescent plasma.

**April 19:** Grifols announces its plasma donation centers to begin collecting convalescent plasma from recovered COVID-19 patients.

**May 5:** Grifols completes development of high sensitivity molecular test to detect SARS-CoV-2 virus in plasma, blood, and respiratory samples.

## The News & Observer

CORONAVIRUS

### A facility in Clayton will play key role in a potential therapy for COVID-19

BY ZACHERY EANES

MARCH 26, 2020 01:51 PM, UPDATED APRIL 01, 2020 02:44 PM



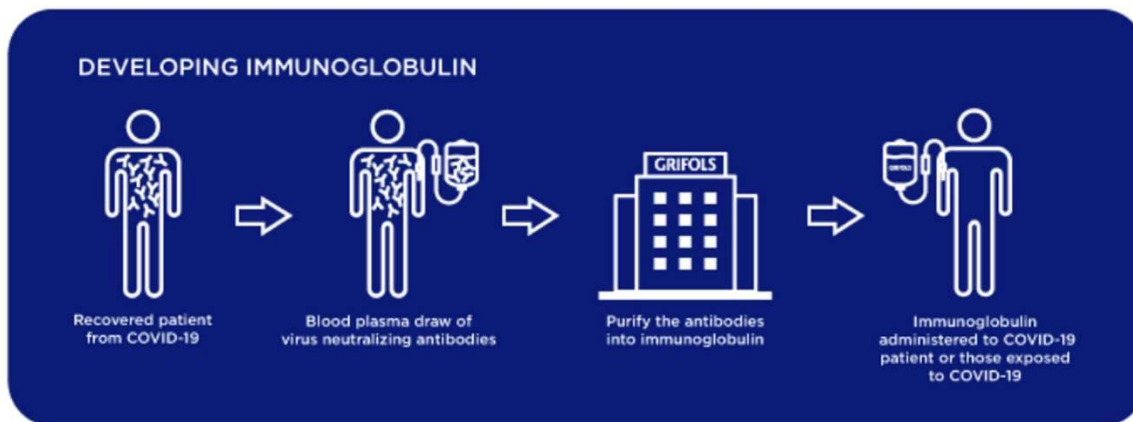
## WRAL TechWire

NEWS ▾ 5

### NEWS

-  **Grifols begins accepting plasma from recovered COVID-19 patients**
- 
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# Developing Anti-SARS-CoV-2 Hyperimmune Globulin



- Plasma is the liquid portion of your blood, comprised primarily of water.
- Plasma contains a number of proteins essential to human health, including immunoglobulins (antibodies)
- Using a process called fractionation, we isolate individual proteins for therapeutic use.
- Recovered COVID-19 patients have SARS-CoV-2 antibodies, which may have therapeutic value for current COVID-19 patients who have no immunity.

## Grifols in North Carolina

Grifols remains open as an essential business in North Carolina, but we have taken a number of steps to address employee safety of our 2,700 employees in state:

- Employees in corporate positions who do not need to be on-site have been directed to work from home.
- Extra social distancing measures in both manufacturing and donor center facilities.



Multi-purpose facility in Clayton will manufacture two potential COVID-19 treatments: 1) virally inactivated convalescent plasma and 2) concentrated anti-SARS-coV-2 hyperimmune globulin

- Separate facilities from Grifols' main fractionation facilities which will continue to focus on production of current products patients rely on.
- All convalescent plasma collected in the United States by Grifols will be received in Clayton.



## What Comes Next

- Multi-purpose facility is ready to begin production of the hyperimmune globulin and is awaiting shipments of convalescent plasma.
- New production facility for methylene blue virally inactivated convalescent plasma has been constructed and is being qualified.
- By end of month Grifols will have approximately 220 donor centers in the United States capable of accepting convalescent plasma donations.
- Plan to have investigational hyperimmune globulin available for clinical trial this summer.



*One of the first donors of convalescent plasma at Grifols donor center in Chicago, IL.*

**Our limiting factor is the ability to obtain convalescent plasma. We currently have 13 centers in North Carolina able to collect convalescent plasma. Please consider helping us spread the word about the importance of donating plasma. For more information, interested donors can visit**

**[www.grifolsplasma.com/en/endcv19](http://www.grifolsplasma.com/en/endcv19).**

# Questions & Answers

# Life Science Update

**Sam Taylor**, President, North Carolina Biosciences Organization

- Impacts of COVID 19 on Life Science Industry
- COVID-19 opportunities & recommendations
- Pending Life Science Legislation

# COVID-19 Impacts

- Pharmaceutical, Medical Device, Agricultural Biotechnology, Industrial Biotechnology and Clinical Research Organizations are **essential businesses** under Governor Cooper's stay-at-home order
- Life science workforce is working from home wherever possible. Regular manufacturing operations are continuing. Research and development have been moderately impacted, but are finding ways to operate, including new enrollments in clinical trials.

# COVID-19 Impacts

- Life science companies are:
- Developing COVID-19 treatments, vaccines and diagnostics
- Producing materials to support COVID-19 products
- Shifting to contract manufacture of traditional products to make room for COVID-19 products
- Repatriating manufacturing of products and supply chain
- Seeing increased demand for traditional products as patients react to perceived potential for supply disruptions

# COVID-19 Life Science Opportunities

- New products, existing products, and repatriated products will be manufactured where there is an existing workforce
- North Carolina has one of largest life science workforces in the nation; with concentration in area from Research Triangle to Greenville
- North Carolina has established workforce training with capacity to meet new demand
- North Carolina has an opportunity to play an important role in the nation's life science response to COVID-19



# COVID-19 Legislative Recommendations

- COVID-19 Select Committees –
- Provide funding to the NC Biotechnology Center for
  - Loans to companies with COVID-19 related technologies
  - Marketing to US companies seeking to relocate production and supply chain to the United States
- Provide funding for universities and community colleges to
  - Bring manufacturing workforce training on-line
  - Provide hands-on training while observing appropriate COVID-19 mitigation practices

# Other Life Science Legislation

- Pharmacy Benefits Manager Licensure (Senate Bill 432)
  - Requires pharmacy benefit managers operating in North Carolina to be licensed by the Commissioner of Insurance
  - Gives doctors, pharmacists and patients more control over how prescriptions are filled
  - Require Pharmacy Benefit Managers to give consumers credit for discount coupons on brand name medicines without a generic equivalent

# Other Life Science Legislation

- Step Therapy (House Bill 450, Senate Bill 361)
  - Establish a consistent and transparent process for patients and their doctors to request exceptions from step therapy.
  - More than 20 states, including Georgia and Virginia, have passed similar legislation.
  - Both bills have passed each chamber but in different forms
  - Please help with consensus step therapy reform that can be enacted this year

# For more information

Laura Gunter or Sam Taylor

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# Discussion

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Co-chairs:  
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Representatives White and Reives

Meeting adjourned