

# *Interim Report, Q2 2021*

## BioPorto

August 18, 2021





# Forward-Looking Statements

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# Agenda

- 1 Highlights from Q2 2021
- 2 1H 2021 financial results
- 3 Regulatory update
- 4 2021 milestones



# Highlights from Q2 2021

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- Revenue growth of 84% in USD on RUO sales of The NGAL Test and 118% for antibodies
- Enrollment in US clinical trial of The NGAL Test continues with added sites - interim results expected end-August
- Data collection for gRAD COVID-19 test extended into Q3 2021
- FDA dialogue initiated on EUA for The NGAL Test for COVID-19 patients
- Search for new CEO and CFO progressing
- Guidance for 2021 maintained



# 1H 2021 financial results

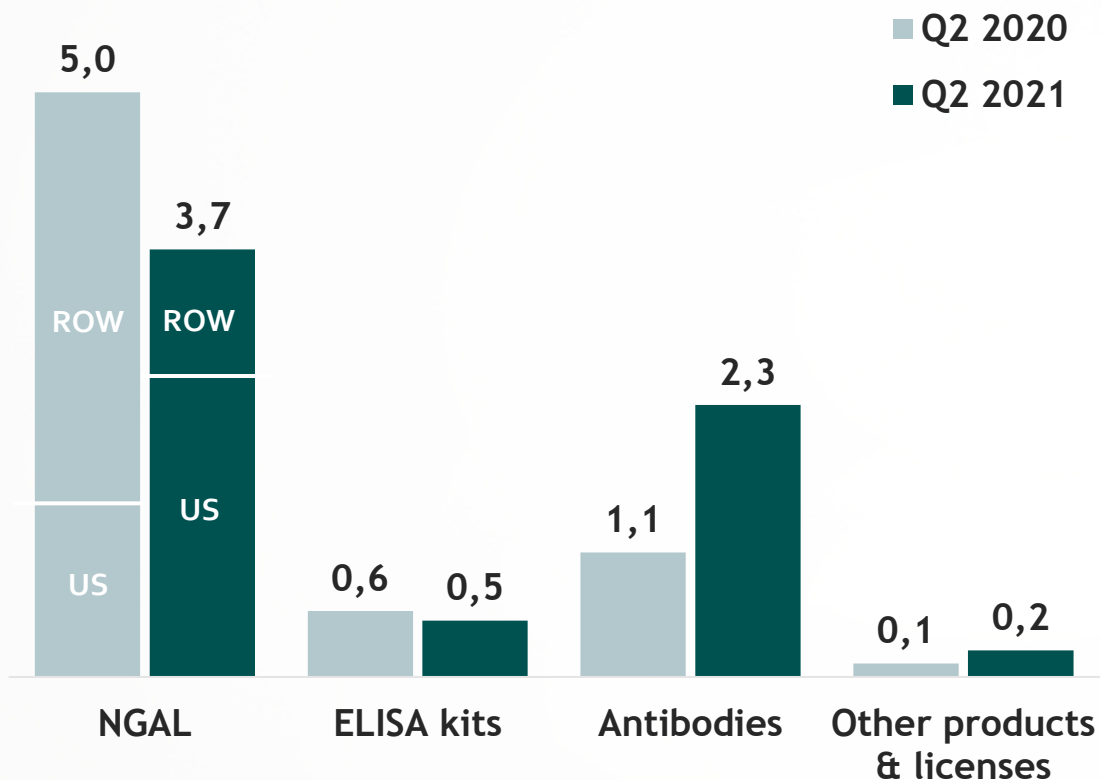
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# Strong increase in antibodies & The NGAL Test in US; ROW impacted by order postponement to H2 2021

## Revenue by Product Category (DKKm)



US NGAL

**+68%**

Increase in revenue (DKK) from  
RUO sales of The NGAL Test in US  
from Q2 2020 to Q2 2021

Antibodies

**+118%**

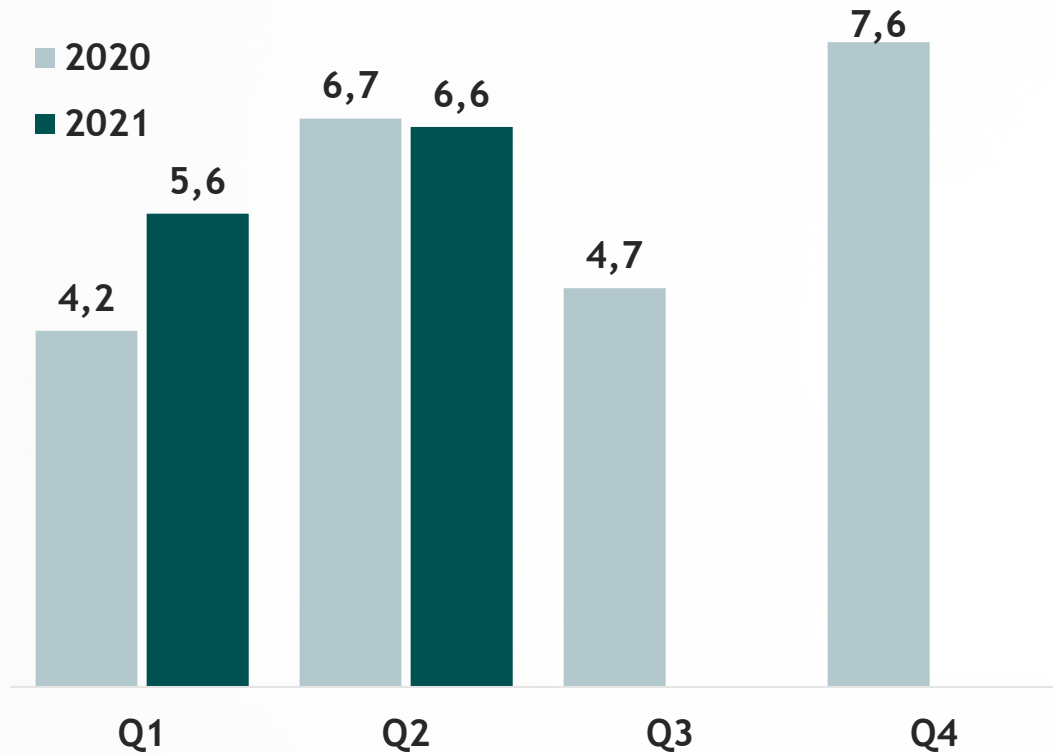
Increase in revenue (DKK)  
from antibodies in  
Q2 2021 vs. Q2 2020



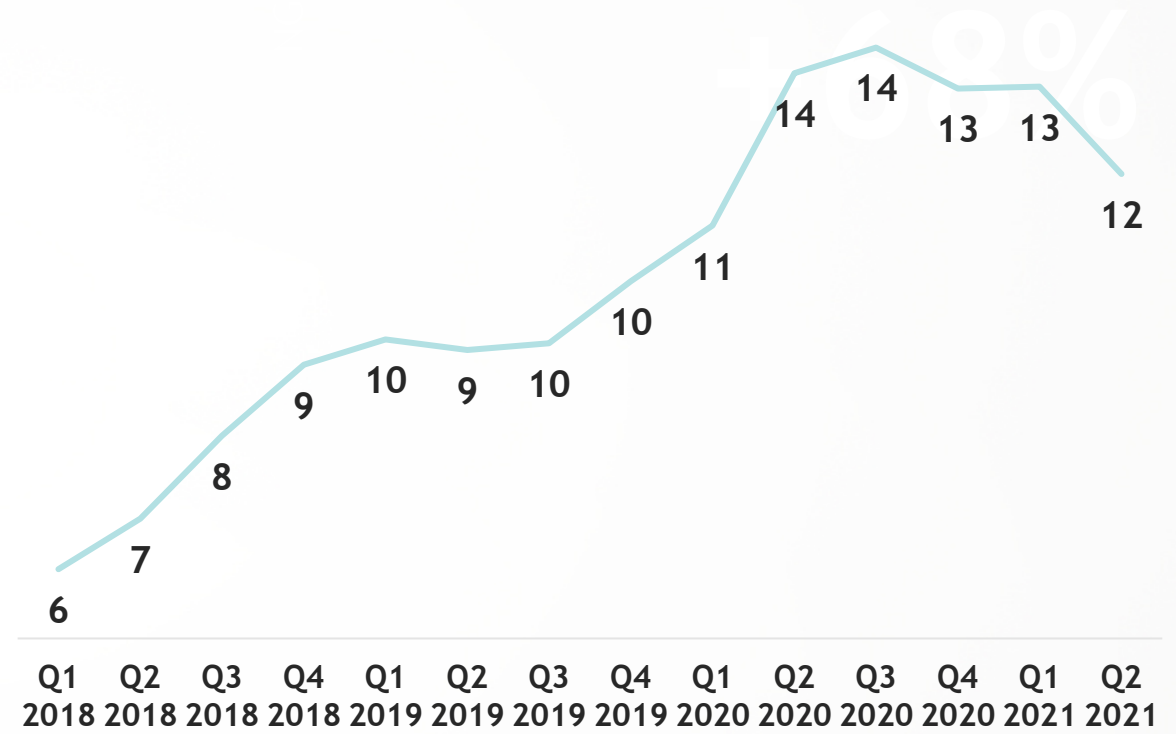


# 1H 2021 revenue growth of 20% in USD; 11% in DKK

## Revenue by Quarter (DKKm)



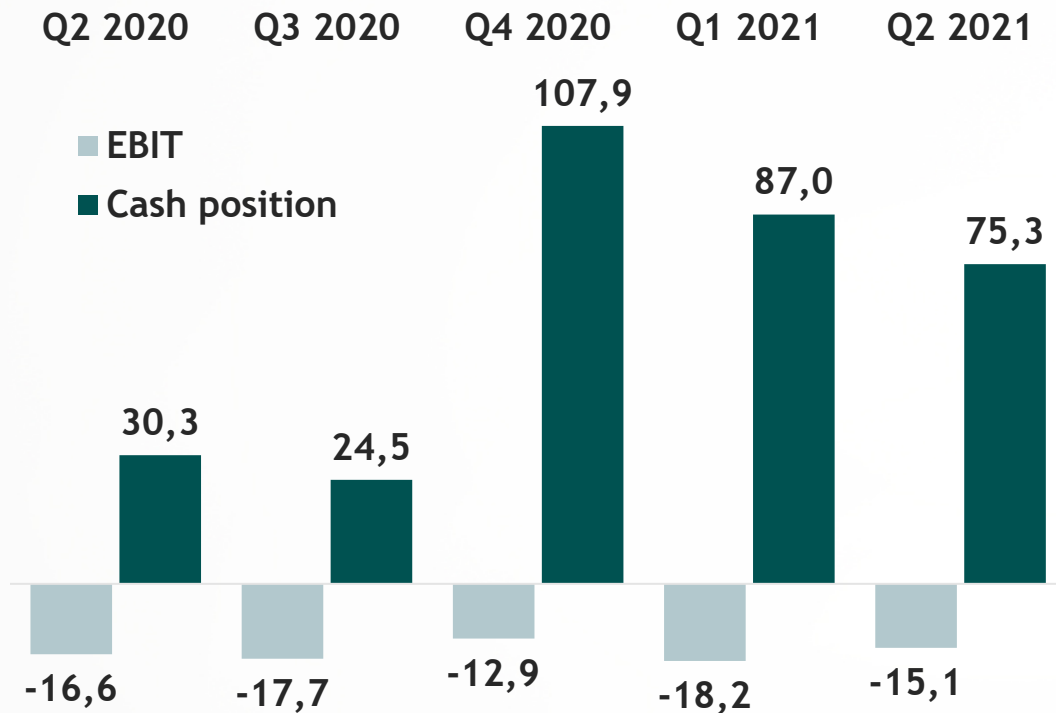
## NGAL Product Sales by Quarter (LTM, DKKm)





# EBIT reflects re-initiation of clinical trial of NGAL; Strong cash position provides funding to Q2 2022

## EBIT and cash position (DKKm)



- EBIT loss on par with last year - lower R&D and sales costs and expected increase in administration costs
- Solid cash position end-June 2021 of DKK 75 million to fund high level of activity on both commercial and development/regulatory into Q2 2022
- Further funding opportunities are being explored to strength BioPorto's long term financial position





# New members elected to the Board of Directors; retained search for CEO and CFO in process

- In April 2021, the Board of Directors was expanded to include Don Hardison, John McDonough and Jan Leth Christensen; Torben Arnth Nielsen and Kirsten Aarup Drejer did not seek re-election
- The Board of Directors is interviewing candidates for the CEO & CFO positions and expects to appoint new members of the executive management team in the fall of 2021



Don Hardison



John McDonough



Jan Leth Christensen

# Regulatory update

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The NGAL Test is CE marked and available for IVD use in the European Union, Canada, S. Korea and Israel. For research use only in all other territories.



# Enrollment in US NGAL study builds; interim results expected in August

## Pediatric study



1 in 4 affected with AKI  
during hospitalization  
(ICU)<sup>1</sup>

Predict AKI Risk in an  
Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

## Interim analysis

- **EARNEST data to be evaluated**
- **Sensitivity, specificity and test statistics**
- **Results of the analysis will guide finalization of study**

- Non-hospital studies have been finalized
- Enrollment of patients in the US clinical trial for The NGAL Test has progressed well in Q2 2021, but is still affected by limitations caused by COVID-19
- 12 sites are now participating, with several new joining in Q2 2021 - pace of enrollment has increased in July; more sites are being added
- In August, BioPorto will conduct an interim analysis of results. Based on expected positive findings, BioPorto will evaluate scope of enrollment to strengthen its submission to FDA

1) Kaddourah A, et al. *N Engl J Med.* 2017; 376(1):11-20.



# The NGAL Test being evaluated for EUA in COVID-19 patients at risk of renal injury

- BioPorto has initiated a dialogue with FDA on potential Emergency Use Authorization (EUA) of The NGAL Test to screen COVID-19 patients for risk of renal failure
- Will base the EUA submission on key findings from an ELISA and dipstick study of NGAL which showed a negative predictive value of 97%. Samples from this study will be tested with The NGAL Test and would form the basis of the EUA
- If granted an EUA, The NGAL Test could be an important biomarker to identify COVID-19 patients at low risk of requiring renal replacement therapy, helping to optimize resource allocation in the emergency department

## Additional Indications for The NGAL Test

- **COVID-19 patient management**
- Therapeutic monitoring
- Diagnosis of AKI
- Point-of-care applications
- **Nephrotoxicity**
  - Oncology
  - Cardiology
  - Diabetes
  - Transplant
  - Autoimmune

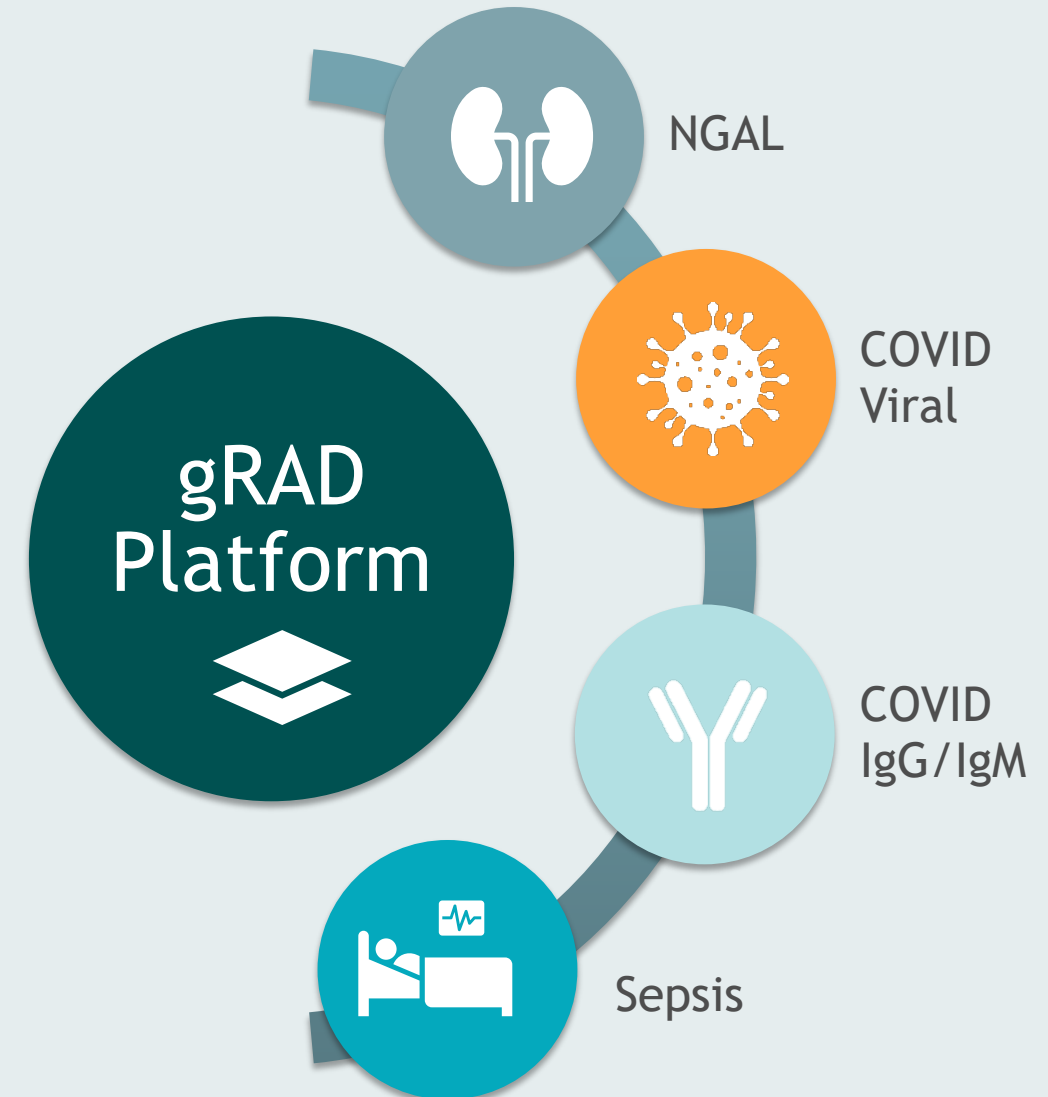


# Generic Rapid Assay Device (gRAD) platform

BioPorto's patented Generic Rapid Assay Device (gRAD) technology is a lateral flow test development platform with no analyte-specific reagents on the strip.

Instead, labelled capture antibodies and gold nanoparticle conjugated detection antibodies form detectable complexes with the analyte in a simple preanalytical mixing step (off-strip).

Complexes are detected by the dipstick and can be evaluated both qualitatively and quantitatively with superior performance characteristics, compared to standard lateral flow assays.



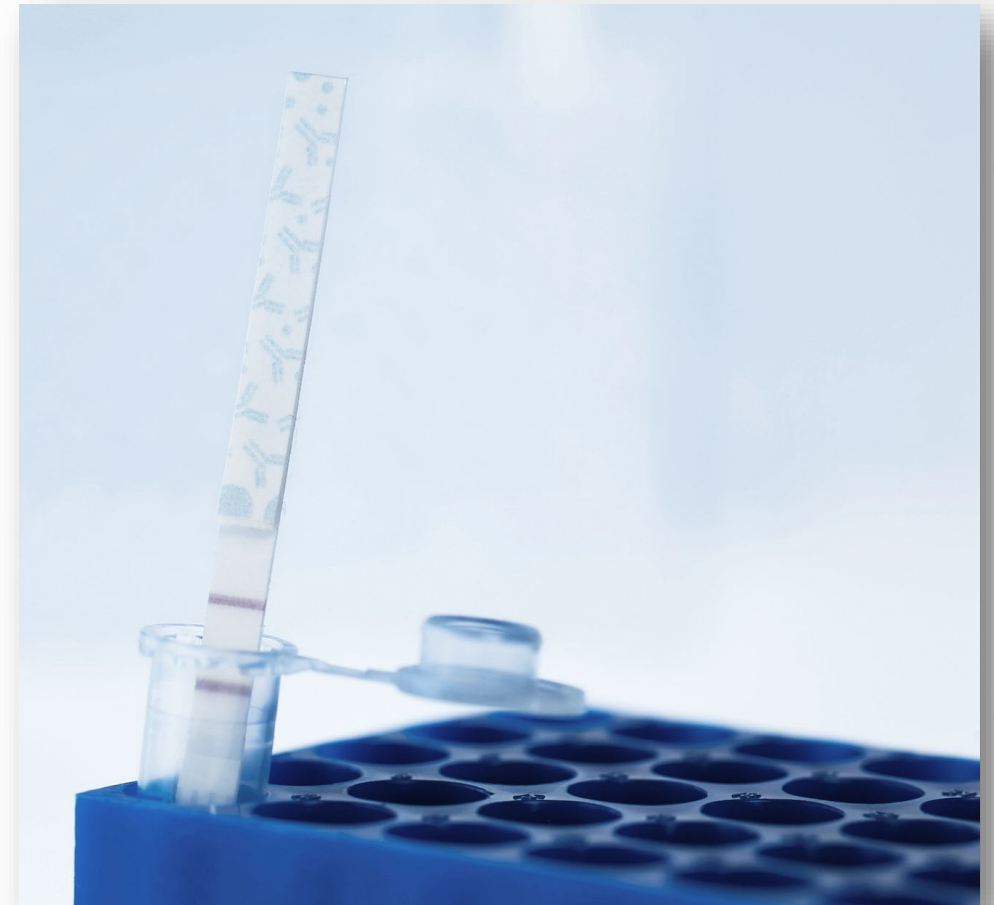




# Data collection for gRAD COVID-19 test continues in Q3 2021

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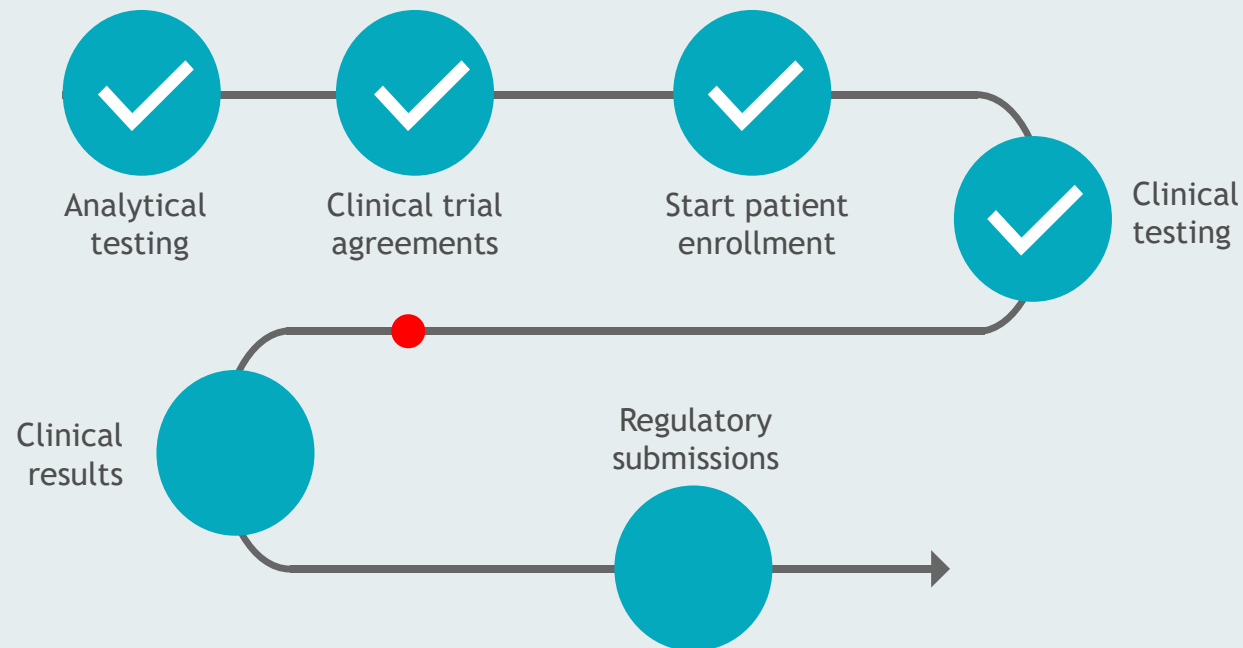
- In Q2, BioPorto increased sensitivity of the gRAD-based SARS-CoV-2 assay, but the number of patients has been low due to a drop in COVID-19 cases
- Focus is to secure a sensitivity above 80% to strengthen the platform's potential
- Target not reached yet, but prospects are promising. Testing resources focused in Denmark in Q3 2021 on the development of the test for new SARS-CoV-2 mutations
- Goal remains to undertake CE filing and potentially submit an EUA to the FDA





# Interim data for gRAD-based Sepsis test pending

## Assay Development Timeline

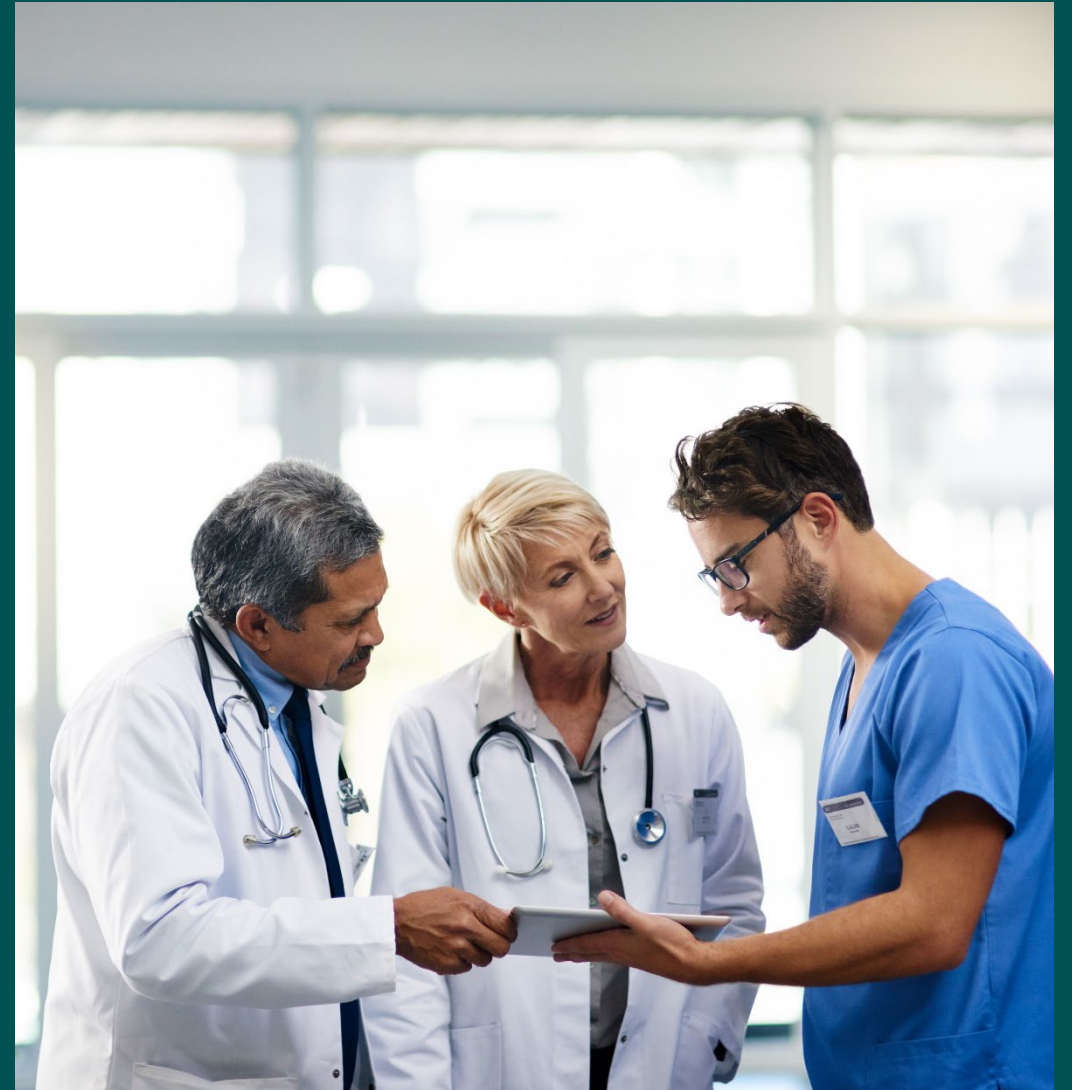


- BioPorto and Rigshospitalet (DK) are co-developing a gRAD test for quantitative determination of thrombomodulin in human plasma
- Test is part of trial evaluating safety and efficacy of thrombomodulin vs. placebo in trauma patients with hemorrhagic shock-induced endotheliopathy
- BioPorto expects interim data to be available in Q3 2021 leading to a decision on the business perspectives



# 2021 milestones

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# Strong news flow expected in Q3 2021

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- Interim analysis of data from The NGAL Test pediatric study
- EUA application for The NGAL Test for risk of renal injury in COVID-19 patients
- Status and update on gRAD COVID-19-test
- Interim data on gRAD Sepsis test





*Clinical, regulatory and commercial*

# Targeted 2021 Milestones

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- Finalize and submit FDA application for The NGAL Test in pediatrics
- Collect supplementary data to support submission of an application for The NGAL Test in adults
- Secure data for study supporting regulatory application(s) for gRAD COVID-19 rapid test
- Progress development of new rapid assays on gRAD platform
- Grow revenues by 25%





# Financial projections for 2021 maintained

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Revenue

Approx.  
DKK 30m

EBIT loss

Approx.  
DKK 73m

Guidance for 2021 is dependent on the global development of COVID-19. Changes to the current outlook for a gradual opening of societies and normalization of access to clinical trials at hospitals and regulatory application processes are prerequisites for the guidance above.

# Financial Calendar 2021

August 18, 2021

Q2 2021 Results

November 17, 2021

Q3 2021 Results

Contact:

Peter Mørch Eriksen (CEO)

[investor@bioporto.com](mailto:investor@bioporto.com)

