

*Interim report, Q1-Q3 2020*

# BioPorto

November 18, 2020





# Forward-Looking Statements

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# Agenda

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- 4 gRAD - COVID rapid test
- 5 2020 Milestones
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# Highlights from Q1-Q3 2020

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# Highlights from Q1-Q3 2020

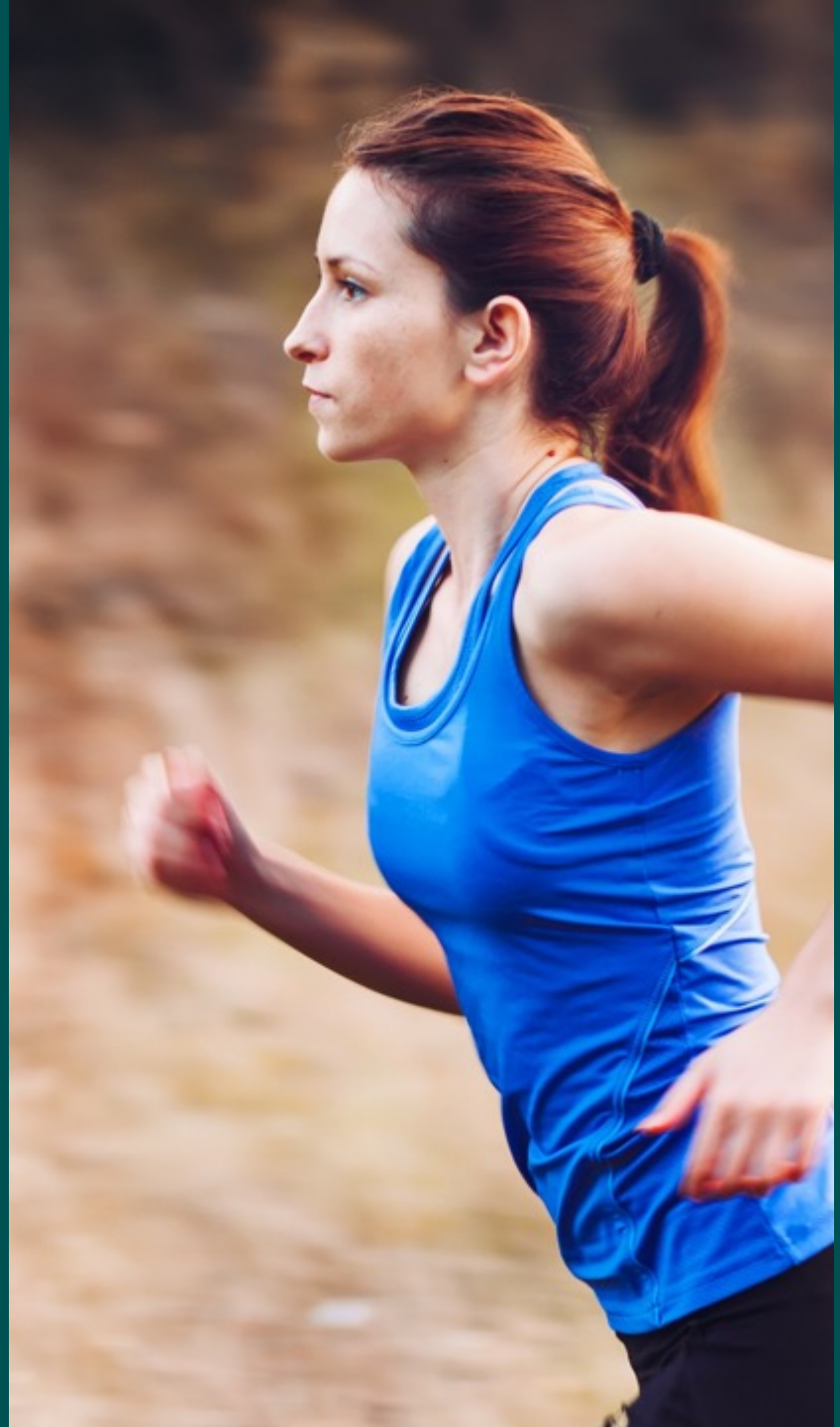
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- Proof-of-concept for BioPorto's Rapid Point-of-Care Test for COVID-19 - patient enrollment will start this week, clinical trials to be concluded by end-2020
- Enrollment continues in US for Pediatric Clinical Trial of The NGAL Test, but second COVID-19 wave restricts hospital access
- Product sales growth in Q1-Q3 2020 of The NGAL Test at +58% YoY - unaffected by COVID-19
- Guaranteed and oversubscribed rights issue completed in October 2020 - cash position strengthened with DKK 94 million
- Guidance for 2020 maintained



# Q1-Q3 2020 Financials Results

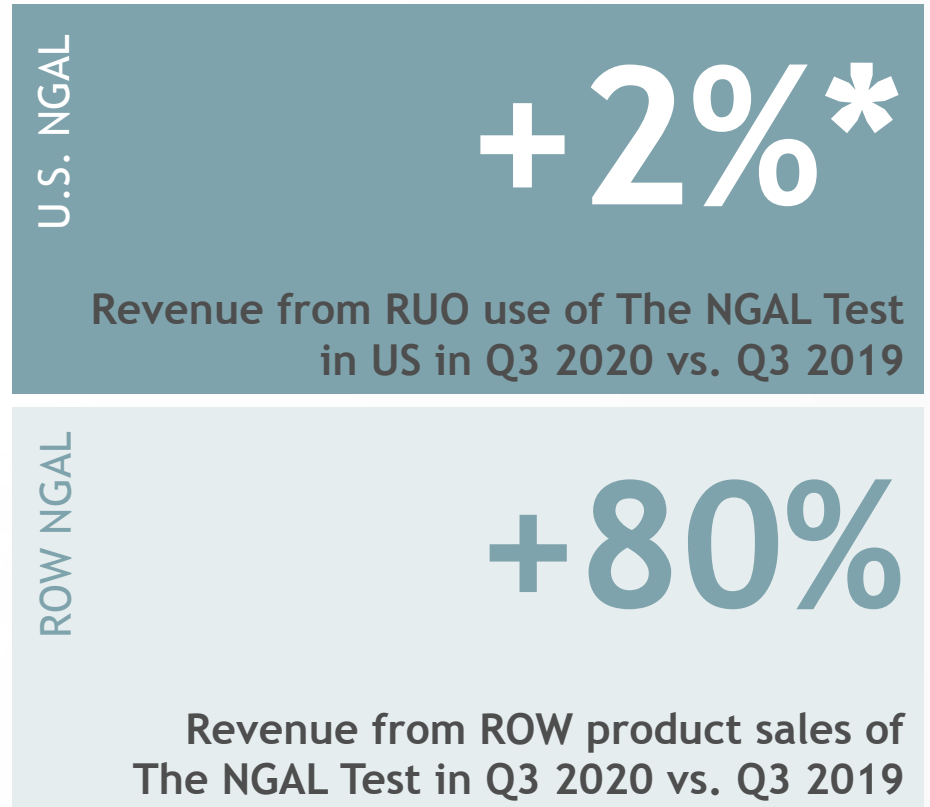
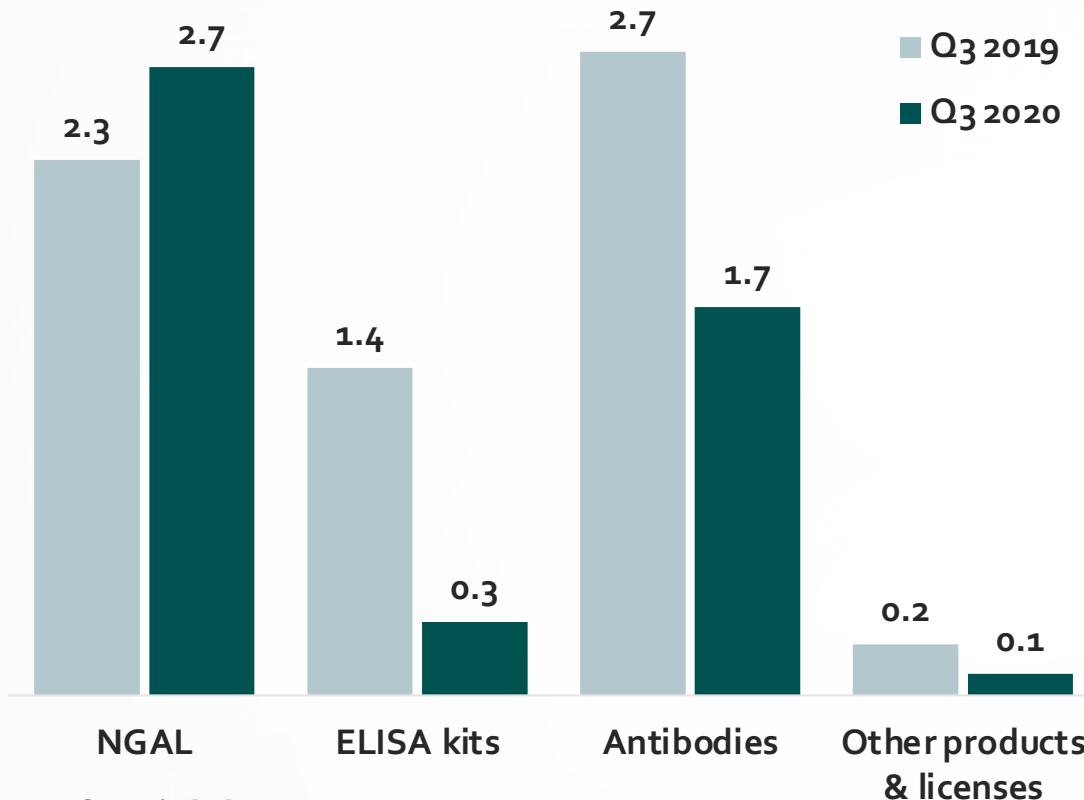
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# Continued growth in product sales of The NGAL Test in Q3 2020 driven by ROW

## Revenue by Product Category (DKKkM)



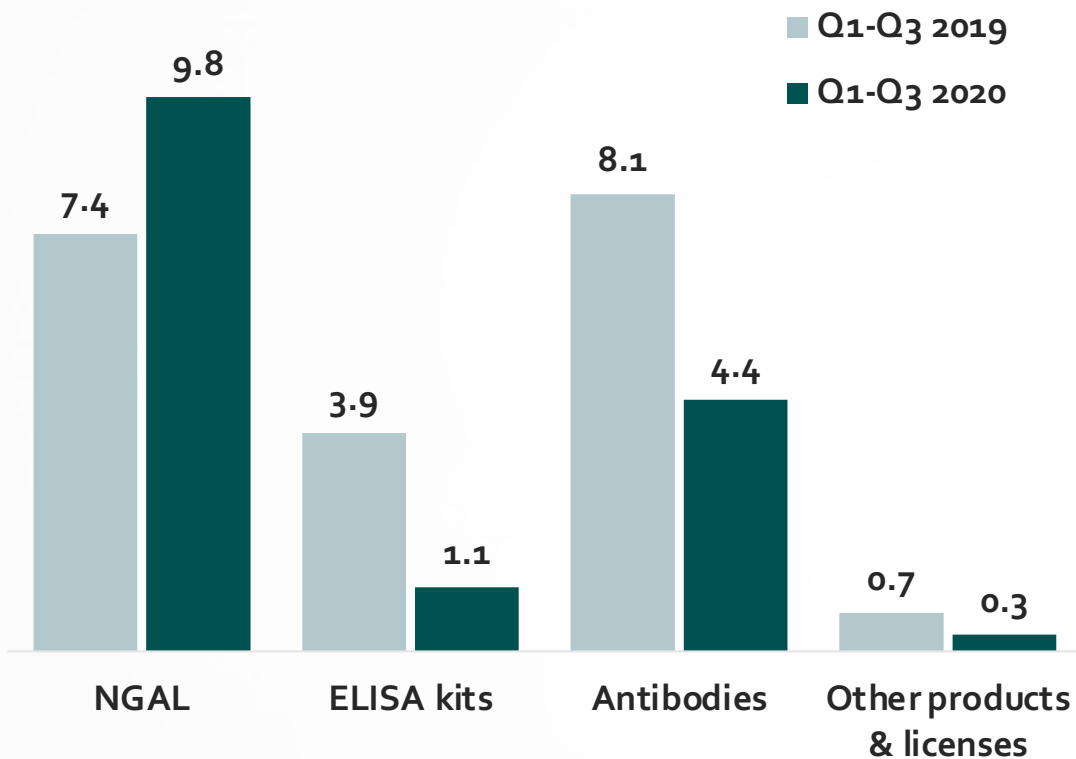
\* +2% in DKK and +6% in local currency (USD)



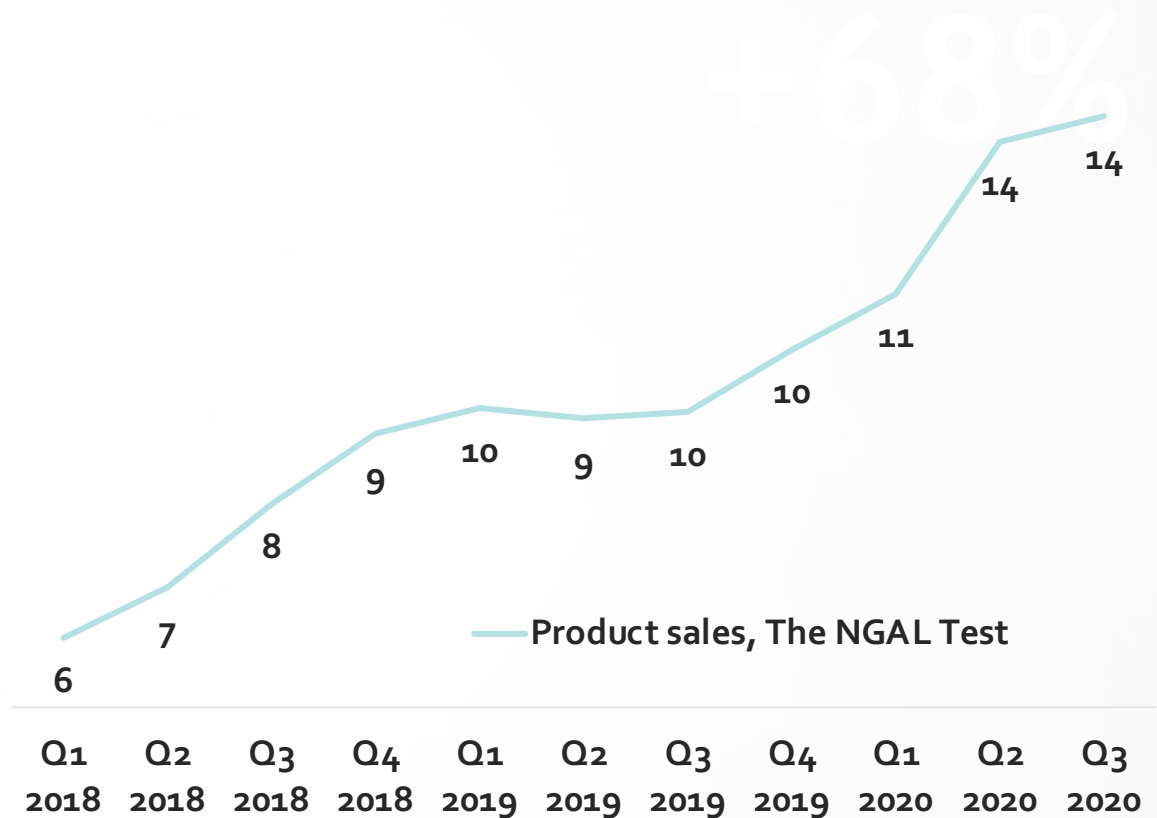


# Product sales of The NGAL Test up 58% YoY as sales remain unaffected by COVID-19

Revenue by Product Category (DKKkM)



NGAL Product sales by Quarter (LTM, DKKkM)





# Fully guaranteed and oversubscribed rights issue with proceeds of DKK 93.6 million

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Fully guaranteed rights issue initiated in September 2020 completed in October 2020 with proceeds of DKK 93.6 million

- A total of 66,645,476 new shares at a subscription price of DKK 1.60 per share offered (1 pre-emptive right per existing share - 3 pre-emptive rights to subscribe 1 new share)
- Very strong interest to participate - binding commitments and guarantees for 100% of the offering
- Oversubscribed by more than 200%

Financing until Q4 2021 in place

- With cash position at September 30<sup>th</sup> 2020 proceeds will fund operations until Q4 2021

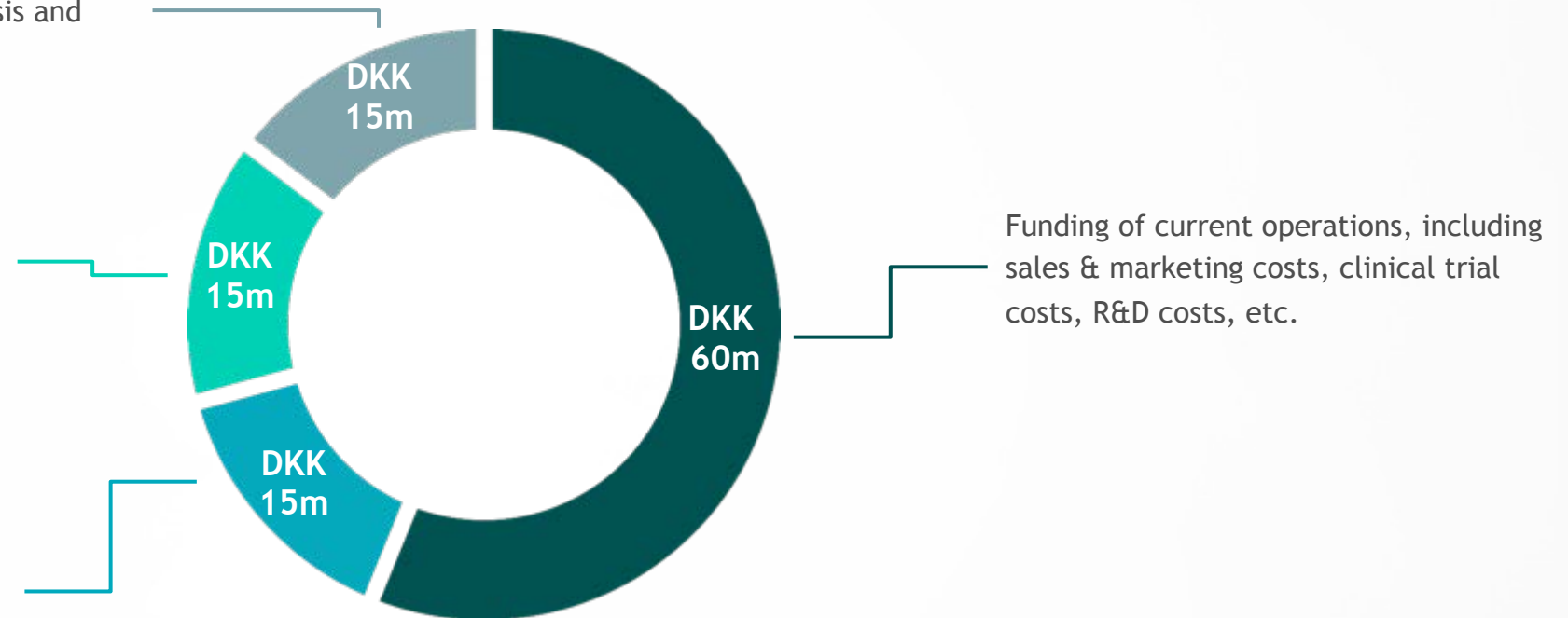


# Total cash position to fund important milestones on NGAL and gRAD

Developing new indications using the gRAD platform, expectedly within the areas of COVID-19, Sepsis and Inflammation

Developing the Company's U.S. organization to prepare for an FDA clearance and commercialization of The NGAL Test for pediatric patients

Supporting the NGAL development, including costs for a clinical trial and the submission to FDA related to NGAL for adults as well as research projects to expand the label or usage of NGAL



# NGAL Regulatory Strategy & Status

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# Regulatory strategy for The NGAL Test

## Pediatrics



1 in 4 affected with AKI during hospitalization (ICU)<sup>31</sup>

Predict AKI Risk in Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

De Novo application being developed, expected submission Q1 2020

## Adults



1 in 5 adults affected with AKI during a hospital episode of care<sup>32</sup>

Predict AKI Risk in Intensive Care Setting

- Urine or plasma samples
- Predict Stage 2/3 AKI

Study planning underway, expected submission to follow pediatric clearance

## Additional Indications

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

Initiate following potential FDA clearance of initial AKI risk assessment indications

31) Kaddourah A, et al. *N Engl J Med.* 2017; 376(1):11-20. 32) Susantitaphong, P et al. *Clin J Am Soc Nephrol.* 2013 Sep;8(9):1482-93;



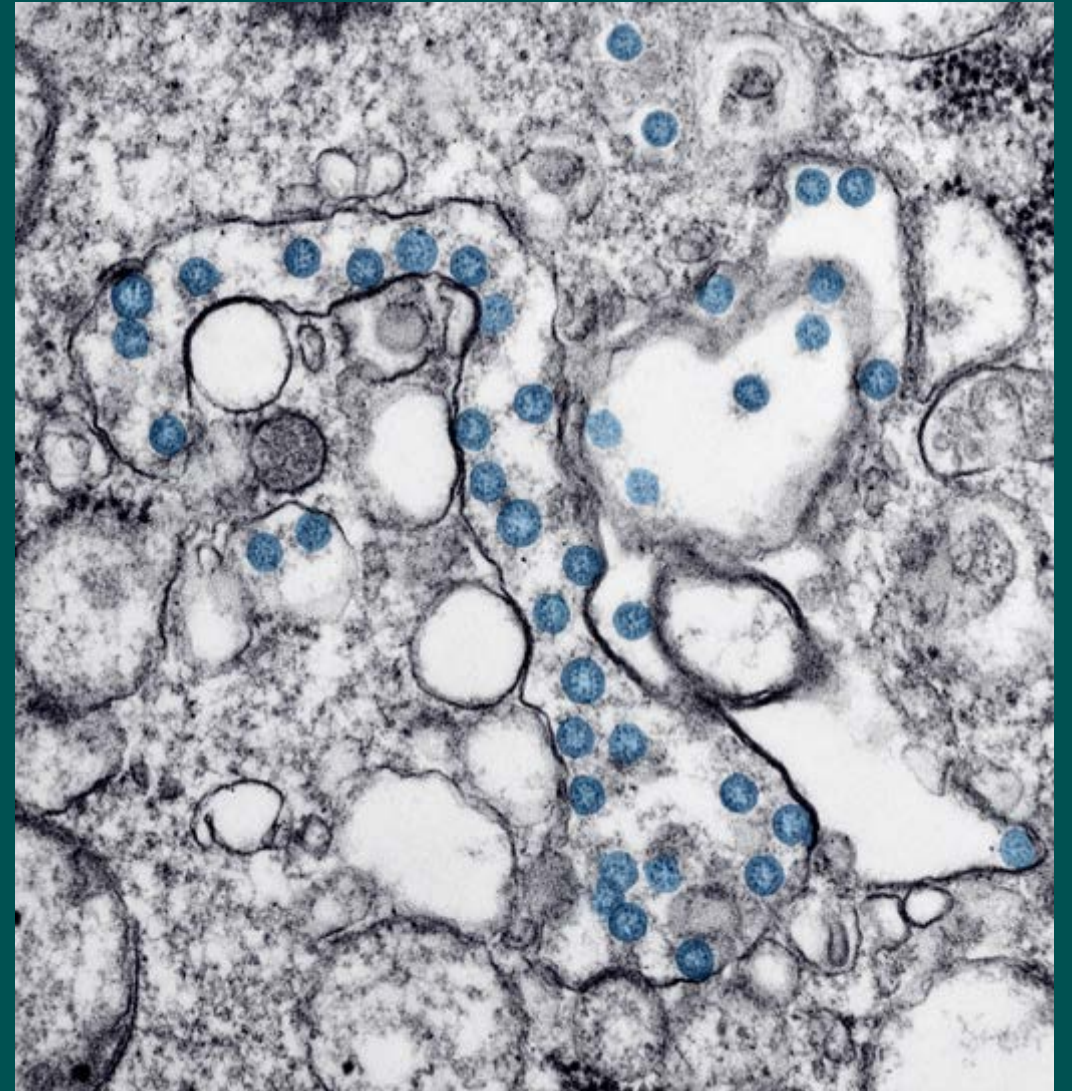
# Pediatric analytical trials on track - Second wave COVID-19 restrictions delays enrollment

- Prospective trial to establish and validate the performance of The NGAL Test
- Pediatric population ( $\geq 3$  months to  $< 22$  years old), urine samples
- Patients admitted to the ICU with cardiovascular or respiratory compromise, or who have had a bone marrow or solid organ transplant
- Predict risk of developing moderate to severe AKI (stages 2/3)
  - Test within the first 12 hours after admission to predict the development of Stage 2/3 AKI in the next 48-72 hours
- Consortium of top US Children's Hospitals participating, led by Cincinnati Children's Hospital
- Second COVID-19 wave has caused restrictions to hospital access - enrollment delayed while analytical trials are on track
- De Novo application now expected to be submitted to FDA in Q1 2021



*gRAD platform*  
**COVID rapid test**

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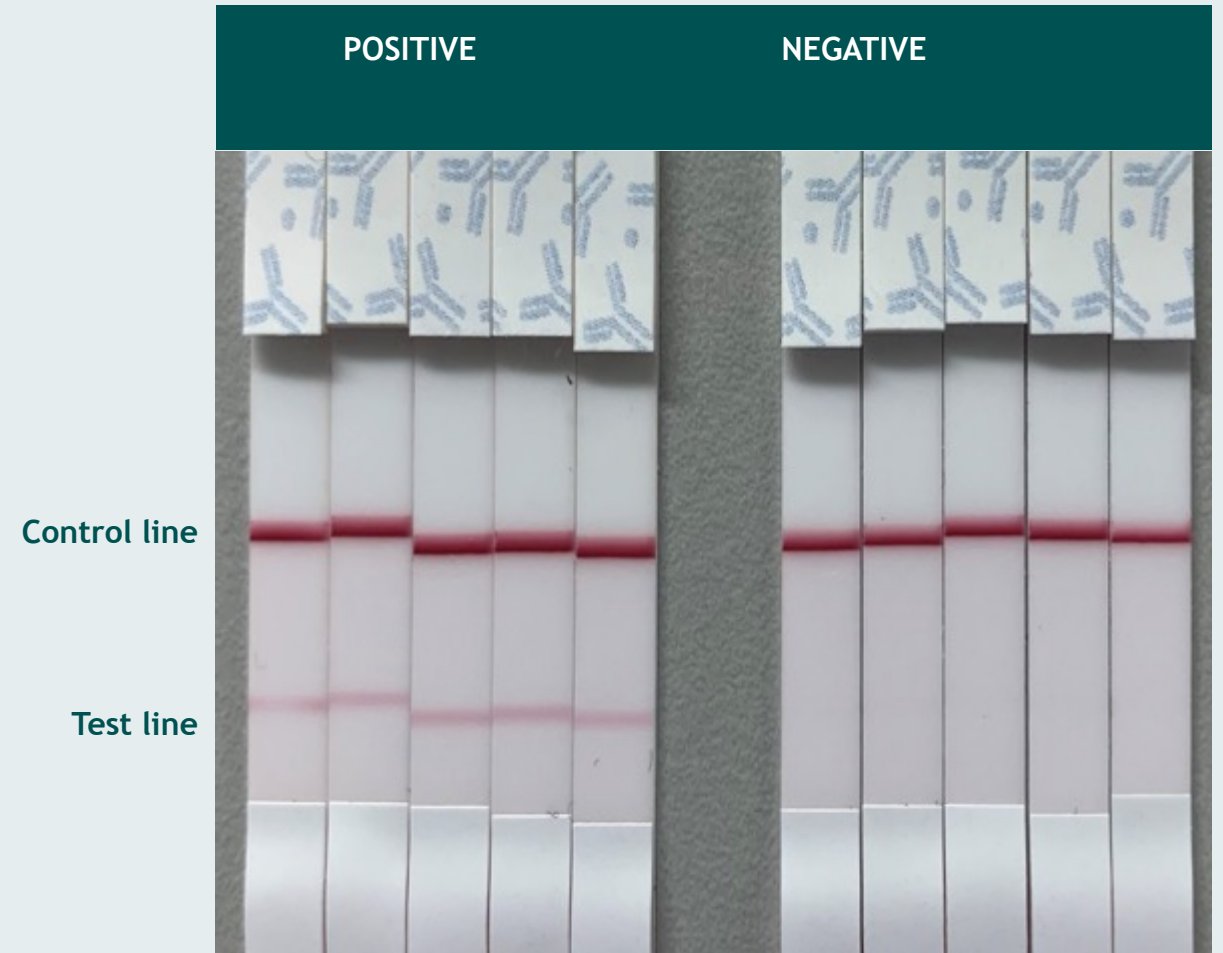




# Generic Rapid Assay Device (gRAD)

*BioPorto has developed a patented technology called the Generic Rapid Assay Device (gRAD). It is a lateral flow 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.*







# Benefits of BioPorto's gRAD Solution

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## Fast



Short  
incubation time  
<15 minutes

## Versatile



Flexible design  
allows different  
sample types

## Easy



No instruments,  
fewer than 5 steps,  
room temp stable

## Low Cost



Simple format  
with few  
components

## Scalable



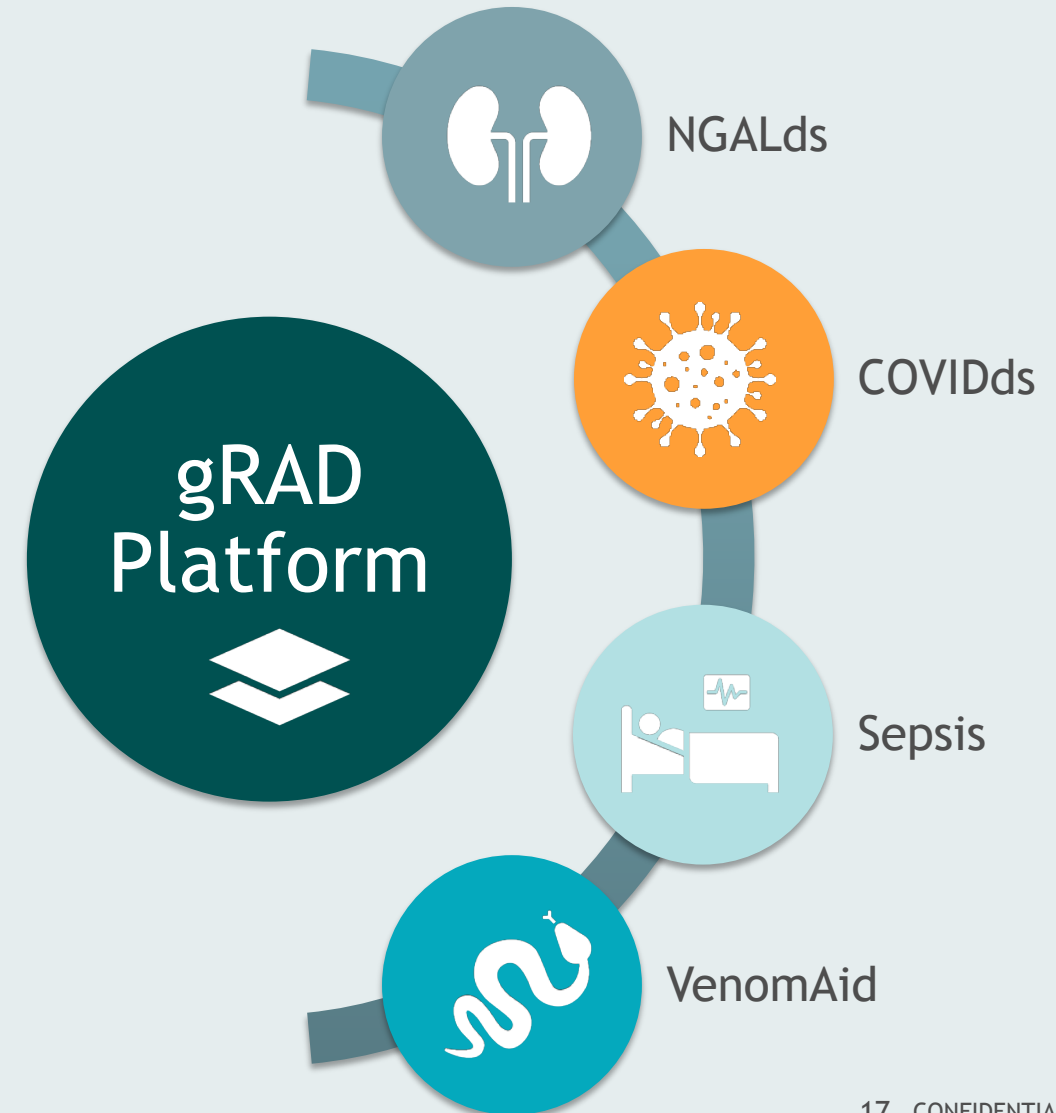
Design allows  
rapid iteration  
(days not  
weeks) and  
scale up



# Platform for Product Development & Growth

Leveraging the gRAD platform, BioPorto is developing tests for NGAL as well as three emerging applications:

1. **NGALds:** for near-patient assessment of kidney injury
2. **Two COVID-19 assays:** a viral diagnostic test and a serology-based test for immunity assessment
3. **Sepsis:** a blood test using antibodies to thrombomodulin, a marker of endothelial injury, for the early identification of septic shock
4. **Stratification of snakebites:** Rapid tests to allow for earlier intervention, with the possibility to treat using specific, rather than broad-spectrum, antivenoms





*Unique opportunity to use gRAD technology*

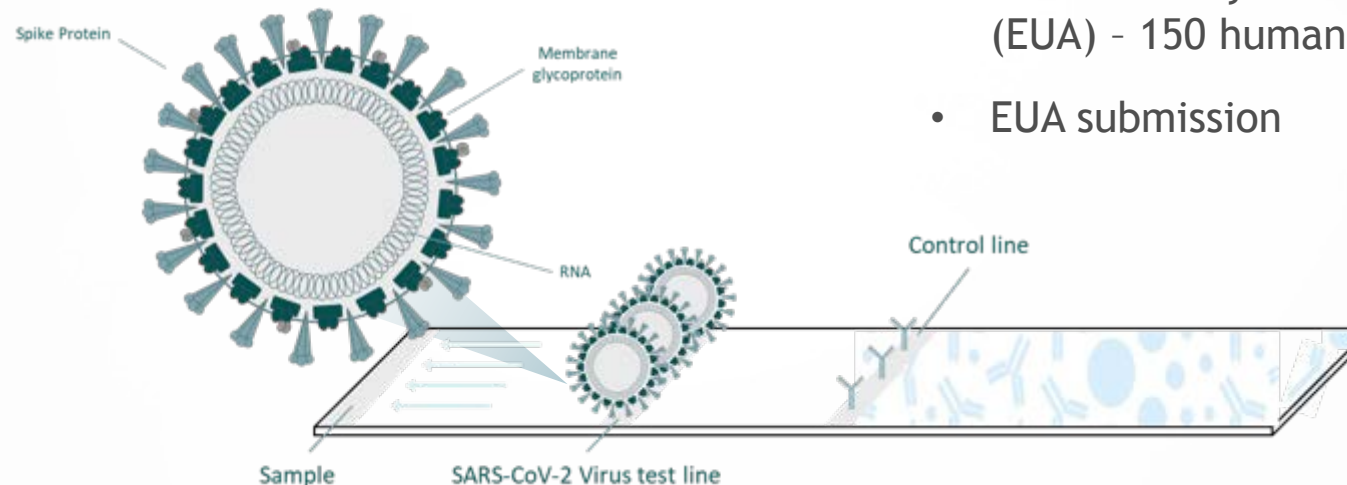
# Viral COVIDds

## Product Format

- Indication: Screen patients suspected of COVID-19 infection for active virus
- Semi-quantitative, rapid immunoassay detection of SARS-CoV-2 viral particles
- Minimally invasive sample types

## Update & Next Steps

- Antibody development & testing - **ongoing**
- Antibody selection & optimization - **ongoing**
- Prototype development - **ongoing**
- Prototype testing & technical evaluations - **ongoing**
- Clinical study for Emergency Use Authorization (EUA) - 150 human samples - **ongoing**
- EUA submission





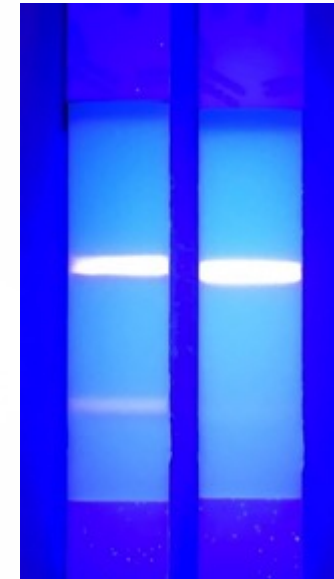
# COVID-19: Laboratory Testing (YTD)

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- Antibodies to the SARS-CoV-2 spike protein developed and characterized
- Antibodies transferred to ELISA and gRAD technologies
- ELISA and gRAD prototypes developed
- On-going design optimization, e.g., using more sensitive laboratory techniques
- Proof-of-concept established with using different forms of inactivated virus

Control line

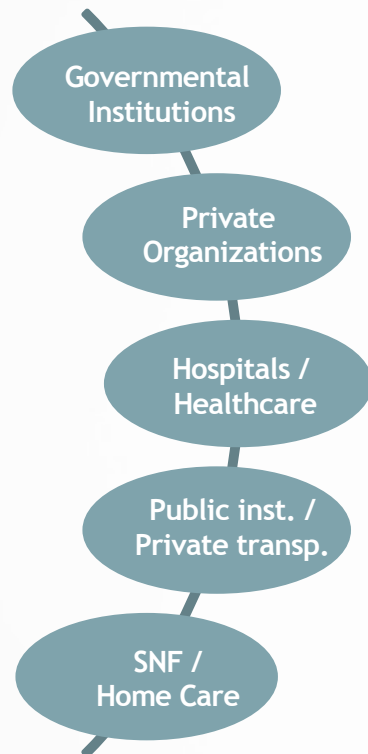
Test line





# Customer Segments, Value Proposition, Key Benefits

## Customer Segments



## Value Proposition

Detection of active SARS-CoV-2 virus in minimally invasive samples (saliva, nasal swabs) using a lateral flow device that leverages high specificity antibodies to the viral spike protein and provides a result within 10-15 minutes.

## Key Benefits

- Reliable and accurate
- Small, portable, easy to use
- Visual, rapid test result
- Highly cost-effective



*Enabling more efficient treatment and infection control decisions*

# 2020 Milestones

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*Clinical, regulatory and commercial*

# Targeted 2020 Milestones

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- Finalize collection of additional patient data for the FDA application of The NGAL Test for pediatrics and submit for clearance in Q1 2021
- Collect supplementary data to support submission of an application for The NGAL Test in adults
- Finalize development and patient enrollment for gRAD based COVID-19 tests for early and rapid detection of coronavirus (SARS-CoV-2) by end-2020 and apply for EUA with the FDA
- Review new opportunities for NGAL, gRAD and BioPorto's anti-body library
- Financial Guidance 2020: Revenue of approx. DKK 30 million and an EBIT loss of approx. DKK 73 million



# Financial calendar 2021

March 17, 2021

Annual Report 2019

April 29, 2021

AGM

May 12, 2021

Q1 2021 Results

August 18, 2021

Q2 2021 Results

November 17, 2021

Q3 2021 Results

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



# Appendix About BioPorto

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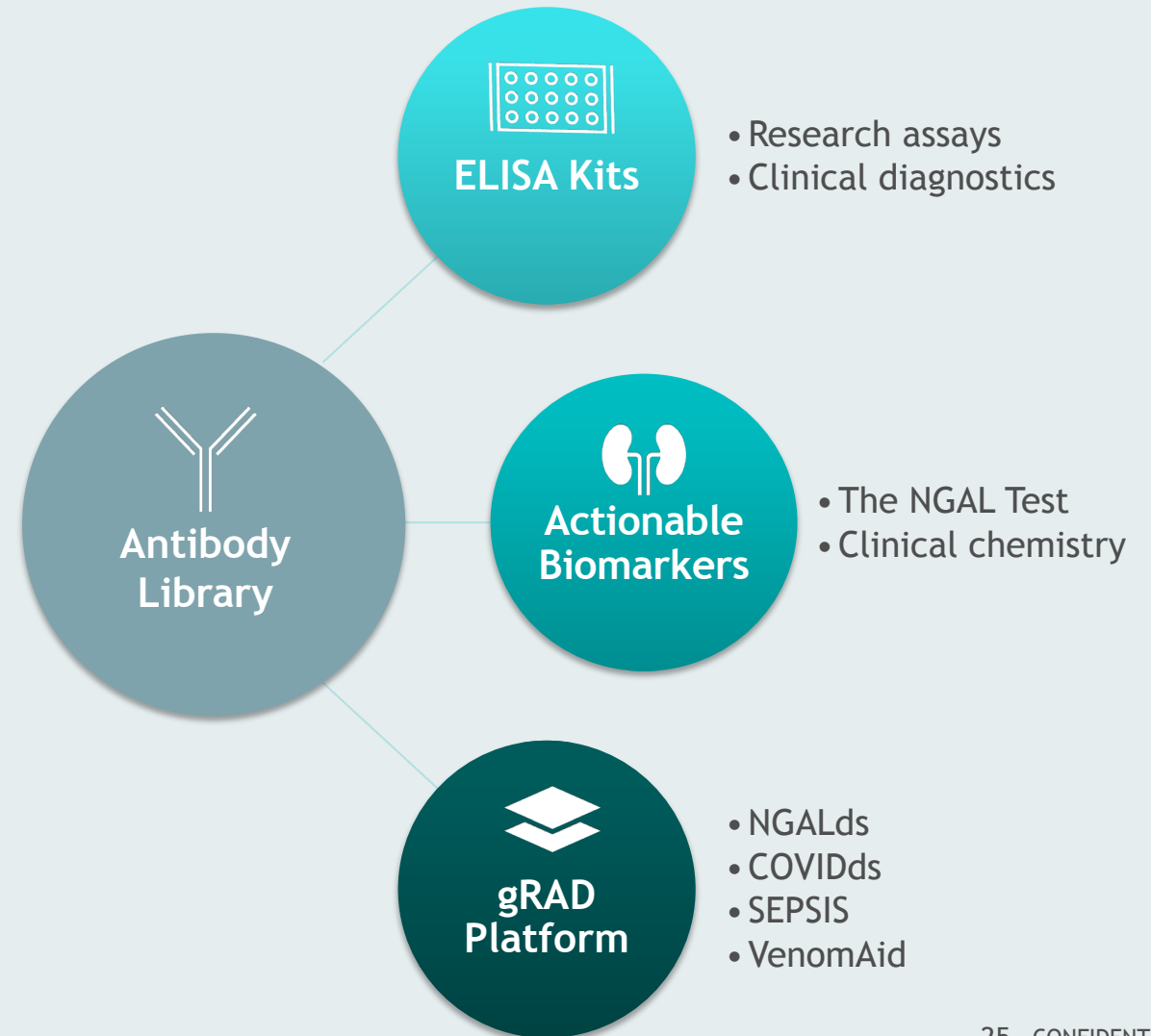




# About BioPorto

*BioPorto is an in vitro diagnostics company that provides tests and antibodies to clinicians and researchers around the world. We use our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives.*

*BioPorto is headquartered in Hellerup, Denmark, with US headquarters outside of Boston, and is listed on the Nasdaq Copenhagen stock exchange [CPH:BIOPOR]. The company has 27 employees and 2019 revenue of DKK 27 million.*





# Mission, Vision and Strategy

BioPorto helps healthcare providers improve patient management and outcomes with products that provide early and specific insights into significant clinical conditions.

By 2025, we aspire to be one of the world's leading companies in diagnostics for kidney health.



## Establish commercial capabilities to drive growth

Through our own commercial team, and through partnerships, we introduce and expand use of novel assays by conveying the clinical and economic value of our products in a clear, relevant and compelling manner.



## Expand product pipeline and clinical knowledge

We expand our pipeline through development of new indications for NGAL and by leveraging the gRAD platform to develop new rapid assays for emerging conditions.



## Strengthen infrastructure to ensure quality and drive profitability

We secure strong suppliers to support our chemistry assays and build in-house expertise in product production, logistics and supply chain in both Denmark and the US.



*BioPorto's leadership*

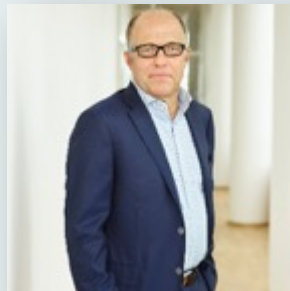
# Experienced International Management Team

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**Ole Larsen**  
CFO

CFO of BioPorto since June 2018. 20+ years CFO experience including 12 years at Bavarian Nordic



**Jan Kuhlmann**  
COO

COO of BioPorto since August 2016. 25+ years in the life sciences with FMC, Cambrex, Fisher Scientific, and Chr. Hansen A/S



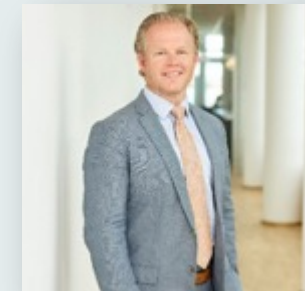
**Peter Mørch Eriksen**  
CEO

CEO of BioPorto since July 2013  
20+ years in medtech/life sciences, including CEO of Sense A/S and VP/GM of Medtronic



**Amy Winslow**  
President,  
BioPorto Diagnostics Inc.

Joined in April 2019.  
25+ years in the medtech industry, most recently as President and CEO of Magellan Diagnostics



**Christopher Bird**  
CMO

CMO of BioPorto since August 2019. 20+ years in the life science industry primarily at Roche Diagnostics