

Interim Report, Q2 2020

BioPorto

August 19, 2020





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Highlights from Q2 2020





Highlights from Q2 2020

- Strong sales growth for The NGAL Test - product revenue nearly doubled in Q2 2020 vs. Q2 2019
- Enrollment begins in US pediatric clinical trial of The NGAL Test, submission expected in 2H 2020
- Collaboration with SDU to develop test for COVID-19 active virus based on gRAD technology on plan - currently selecting antibodies prior to optimization
- Successful rights issue completed - cash position strengthened with DKK 38 million. Nordea engaged as advisor in planned share issue in 2H 2020
- CE Mark of NGALds for near-patient testing expected in late 2020
- Guidance for 2020 maintained



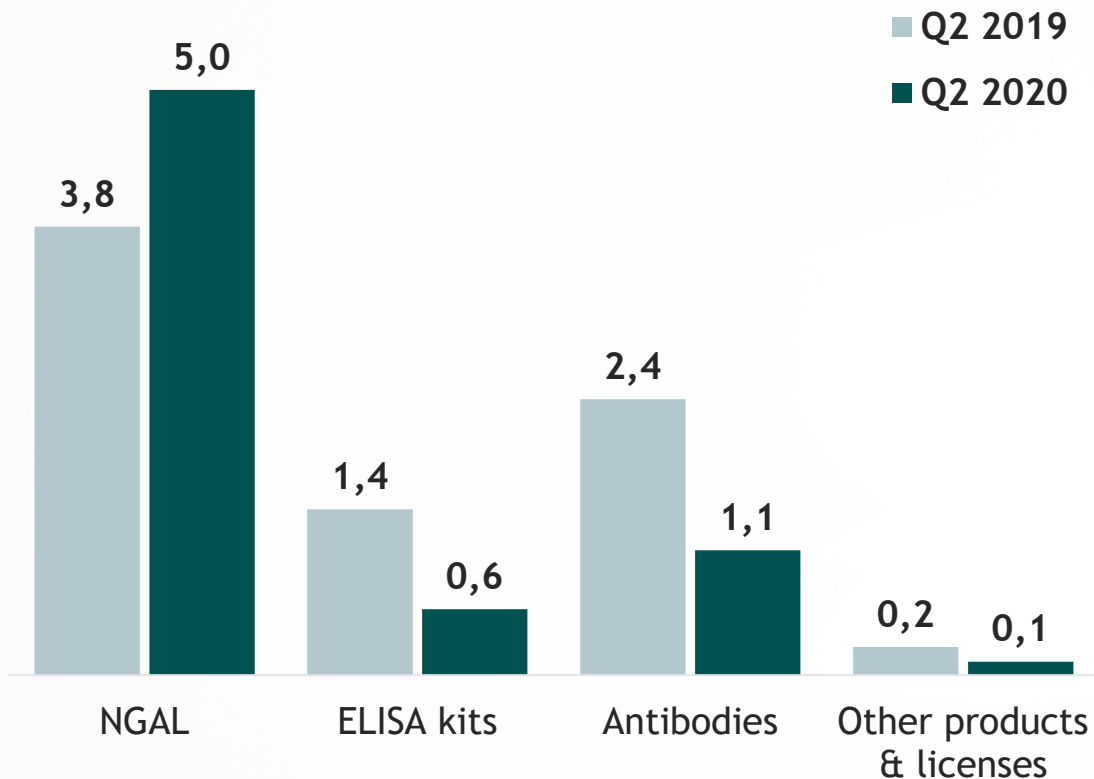
Q2 2020 Financial Results





Strong continued growth in product sales of The NGAL Test in Q2 2020

Revenue by Product Category (DKKm)



NGAL for Q2 2019 includes Other NGAL revenue of DKK 1.2m

US NGAL

+96%

Increase in revenue from RUO use of The NGAL Test in US from Q2 2019 to Q2 2020

ROW NGAL

+85%

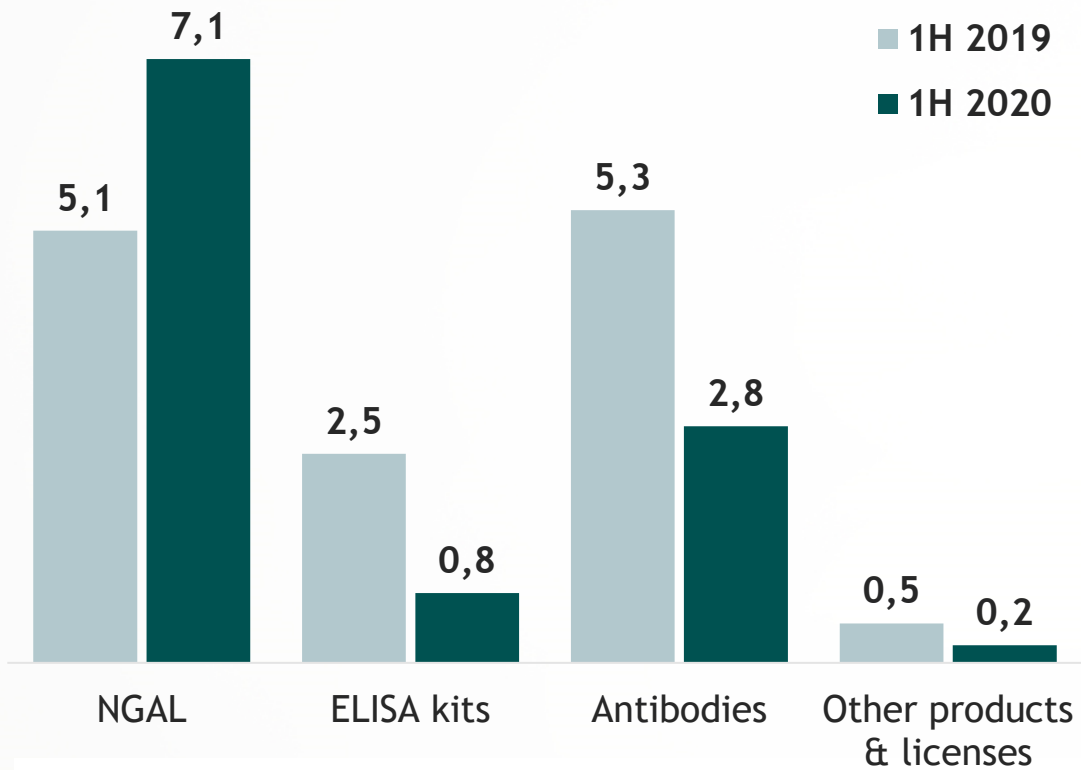
Revenue from ROW product sales of The NGAL Test in Q2 2020 vs. Q2 2019



The NGAL Test sales up 81% YoY in 1H 2020

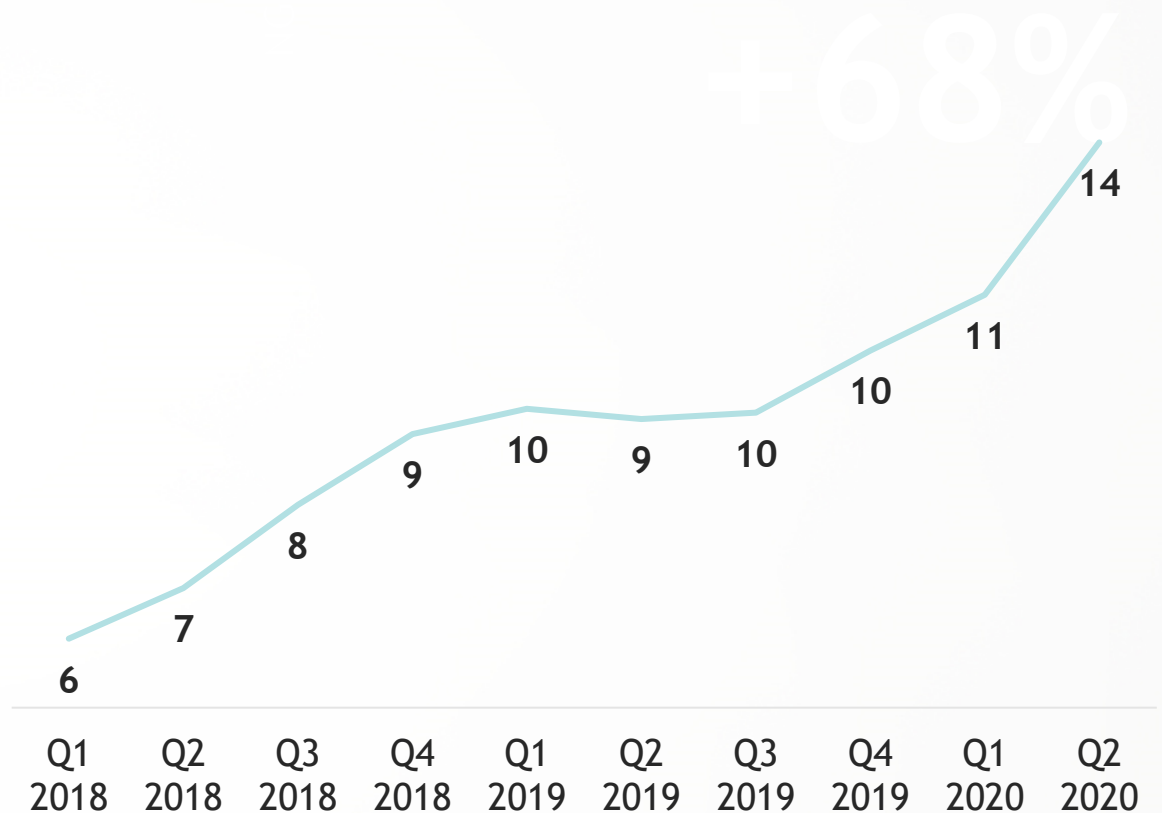
Driven by sales to new and existing customers

Revenue by Product Category (DKKkm)



NGAL for 1H 2019 includes Other NGAL revenue of DKK 1.2m

LTM NGAL Product Sales (DKKkm)





BioPorto Strengthens Financial Position

Fully subscribed share issue in April 2020

- A total of 24,992,053 new shares offered in pre-emptive rights issue in March/April 2020
- Very strong interest in participating - binding commitments and guarantees for >70% of the offering
- Fully subscribed offering yielded net proceeds of DKK 37.9 million

Financing for 2020 in place - plans to further strengthen our financial position

- Cash position at June 30, 2020 was DKK 30.3 million, will fund operations until end 2020
- To further improve the Company's capitalization, BioPorto expects to issue new shares in the second half of 2020. The Company has retained Nordea as financial advisor for this process

NGAL Regulatory Strategy & Status





Regulatory Strategy for NGAL

Pediatrics



1 in 4 affected with AKI³¹
during hospitalization
(ICU)

Predict AKI Risk in
Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

De Novo application being
developed, expected
submission 2H 2020

Adults



1 in 5 adults affected with AKI
during a hospital episode of
intensive care³²

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;



Study overview

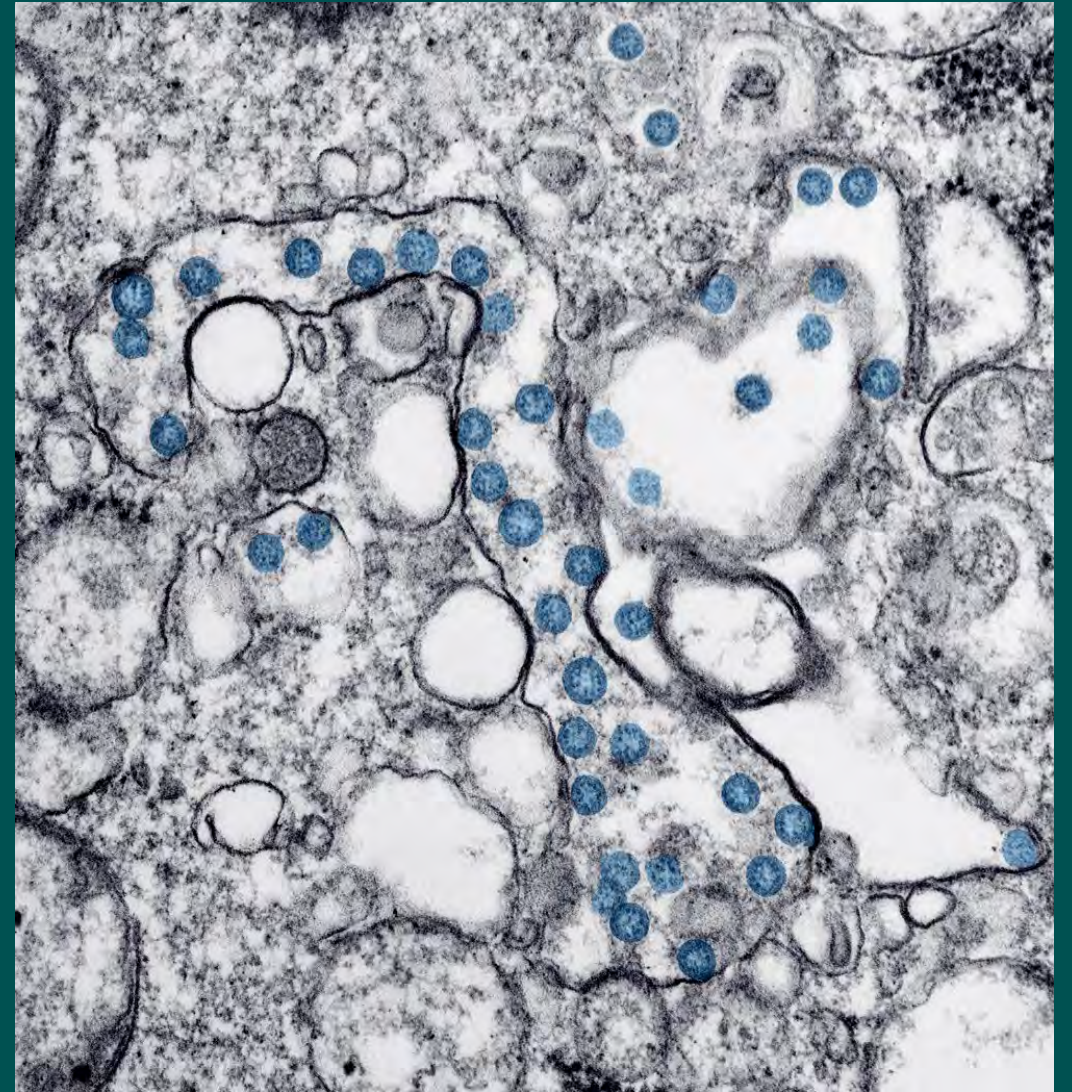
NGAL 2020 Pediatric Study

- Prospective trial to establish and validate the performance of The NGAL Test
- Pediatric population (≥ 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
- De Novo application planned to submit 2H 2020



Recent Developments

NGAL & COVID-19



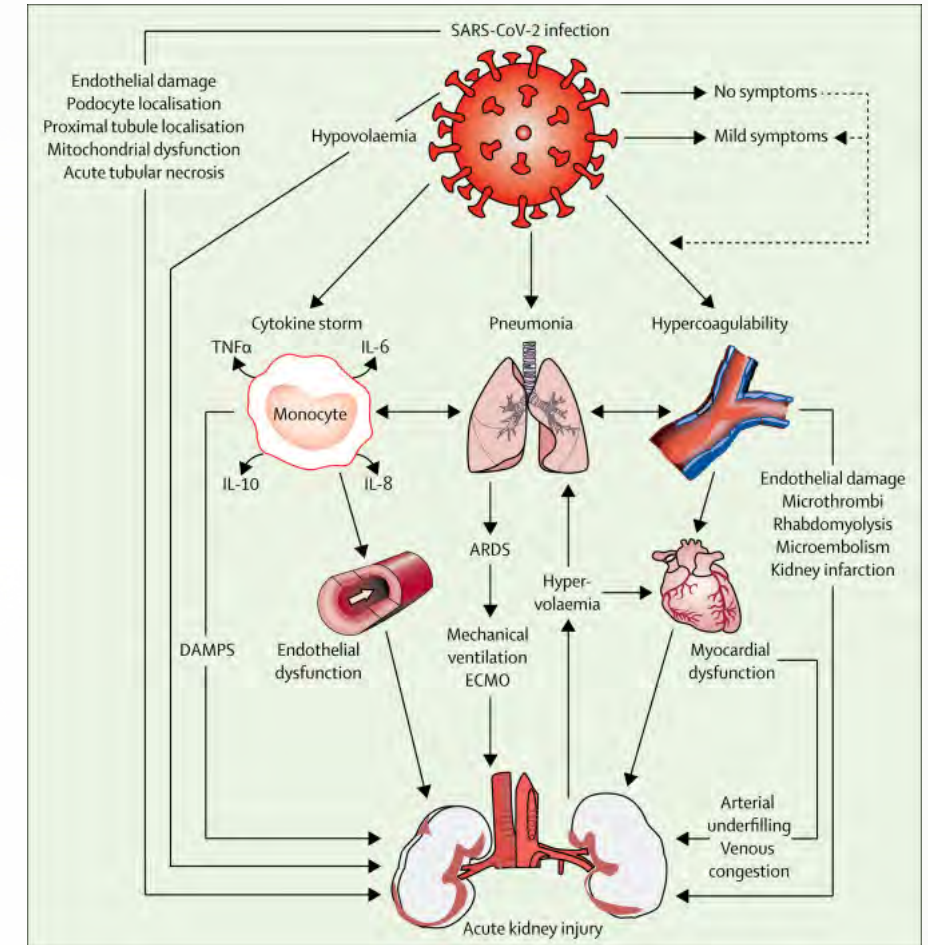


Multifactorial Causes of Kidney Dysfunction

- Kidney involvement in hospitalized patients is frequent, ranging from mild dysfunction to progressive acute kidney injury (AKI)
- Multiple dependent pathways in the setting of COVID-19 increase the risk of acute kidney injury
- Systemic inflammation precedes cytokine storms where NGAL production is also observed and could potentially be used to triage care
- At right: the possible hemodynamic, proinflammatory and proapoptotic consequences of lung inflammation, cytokine release syndrome, and hypercoagulability on renal function, and potential organ support options
- NGAL may also indicate broader distress caused by inflammation:

“The parallel is that serum/urine NGAL is reflective of IL-6 expression and IL-6 is a mediator of significant early inflammation.”

-Dr. Raj Basu, Children's Hospital of Atlanta



Ronco, C. Management of acute kidney injury in patients with COVID-19; May 14, 2020; DOI:[https://doi.org/10.1016/S2213-2600\(20\)30229-0](https://doi.org/10.1016/S2213-2600(20)30229-0)

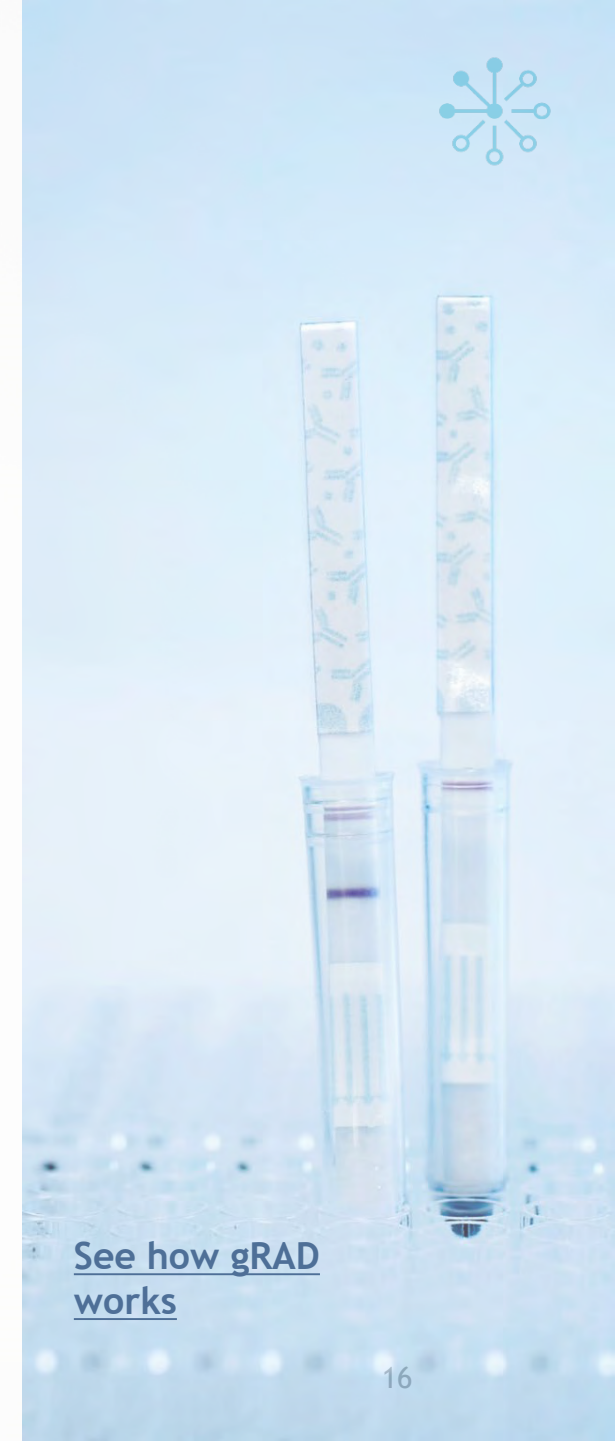
BioPorto's gRAD

A Development Platform



Proprietary Platform: gRAD

- BioPorto's patented Generic Rapid Assay Device (gRAD) was developed in 2016 to enable rapid development of lateral flow tests
- Features of gRAD include:
 - Optimized with two printed lines: a **test line** for biotinylated antibody/protein and a **control line** to capture any mouse, rabbit or goat antibody
 - Biological recognition between the specific capture antibody, the antigen in the sample, and the detection antibody occurs in solution - no specific antibodies are immobilized on the strip
- Dramatically shortens development time compared to standard ELISA development
- Manufacturing process can leverage standard, automated equipment capable of high-volume production



[See how gRAD works](#)



Benefits of BioPorto's gRAD Solution

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

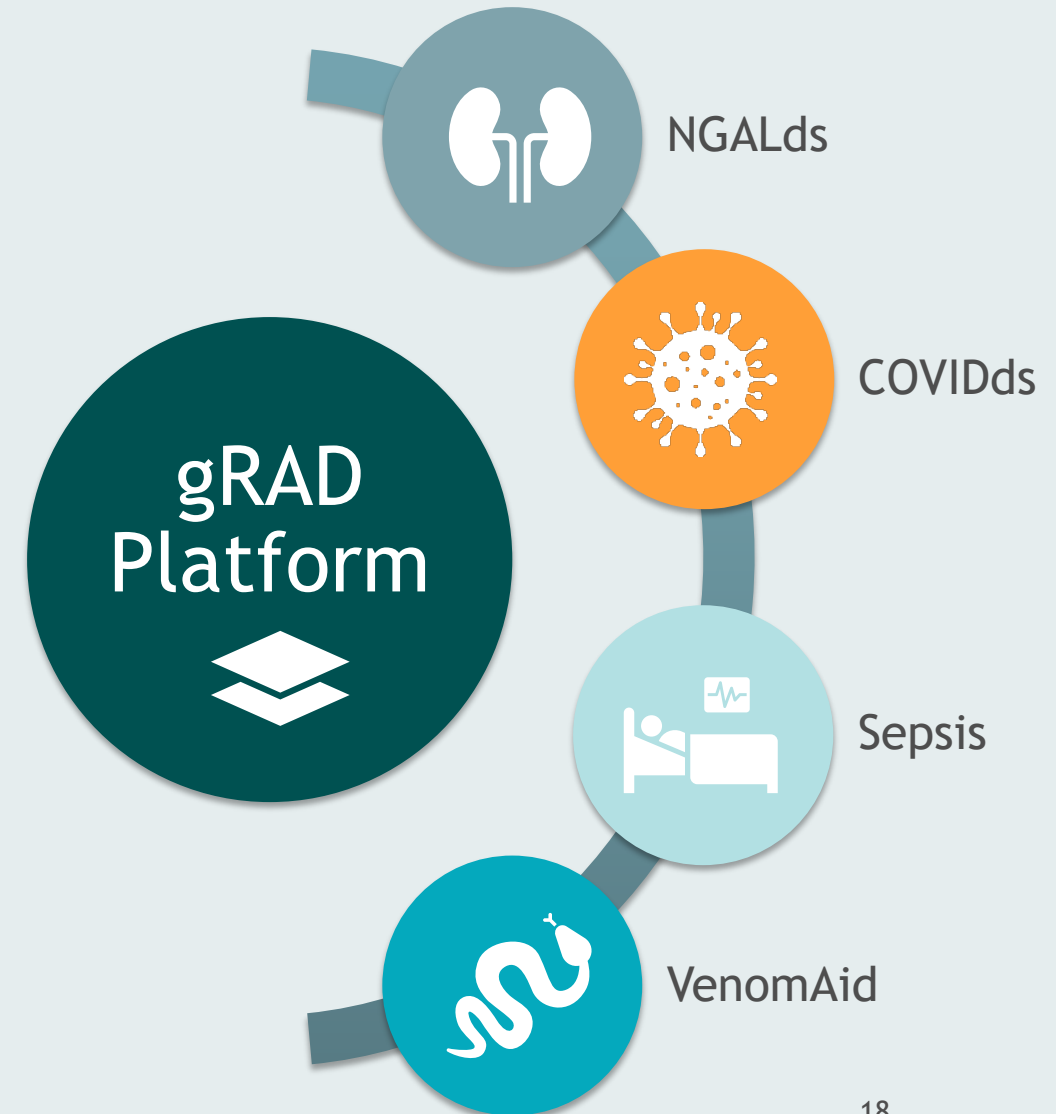


gRAD

Platform for Product Development & Growth

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

1. **NGALds:** for outpatient 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.





NGALds for Near-Patient Testing

- NGALds is the first assay developed on the gRAD platform
- CE Mark expected in November 2020
- A rapid lateral flow test to offer semi-quantitative urine NGAL results without complexity or instrumentation - idea for outpatient or low-resource settings
- A sandwich lateral flow immunoassay specific to NGAL, the kit consists of:
 - Lateral flow strips
 - Vials containing lyophilized NGAL antibody
 - Sample dilution buffer
 - Pipette tips





Unique opportunity to use gRAD technology

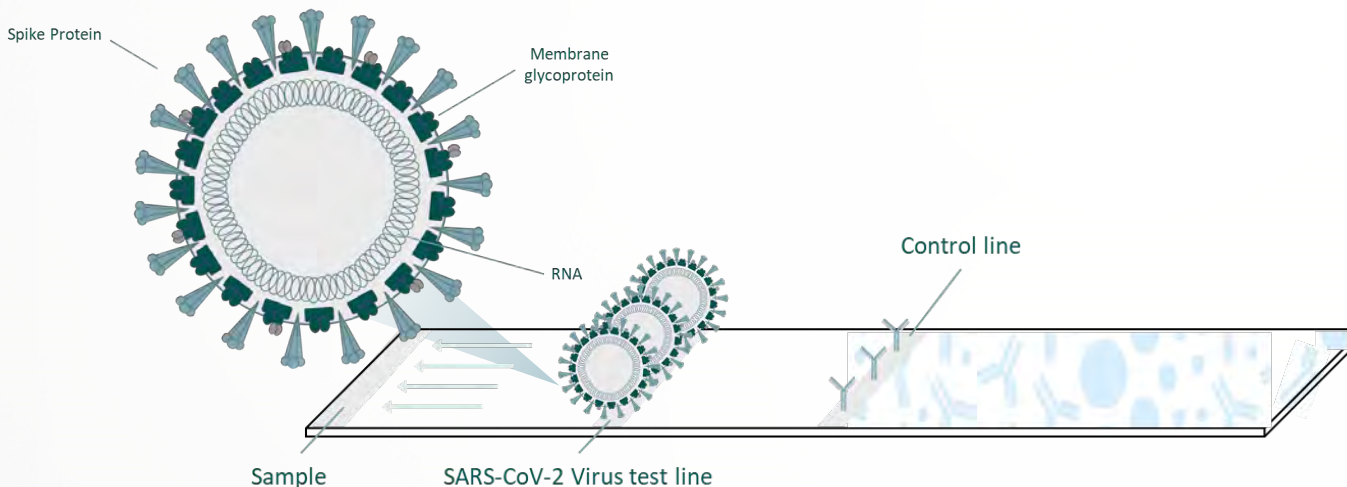
Viral COVIDds

Product Format

- Indication: Screen patients suspected of COVID-19 infection for active virus
- Semi-quantitative, rapid immunoassay detection of SARS-CoV-2 viral particles
- Sample types: buccal swab, nasal swab, oropharyngeal, nasopharyngeal, or sputum

Update & Next Steps

- Antibody development & testing - **ongoing**
- Antibody selection & optimization - **ongoing**
- FDA meeting (pre EUA)
- Develop clinical protocol & validation testing
- Prototype development
- Prototype testing & technical evaluations
- EUA submission



2020 Milestones





Clinical, regulatory and commercial

Targeted 2020 Milestones



- Finalize collection of data for the FDA application of The NGAL Test for pediatrics and submit application in the second half of 2020
- Collect supplementary data to support submission of an application for The NGAL Test in adults
- Co-development of COVID-19 tests for early and rapid detection of SARS-CoV-2 with SDU
- Review new opportunities for NGAL and BioPorto's antibody library
- Grow total revenue by 10%
- Financial Guidance: Revenue of DKK 30 million and an EBIT loss of DKK 73 million

Financial Calendar 2020

November 18, 2020

Q3 2020 Results

Contact:
Ole Larsen (CFO)
ol@bioporto.com



Appendix About BioPorto

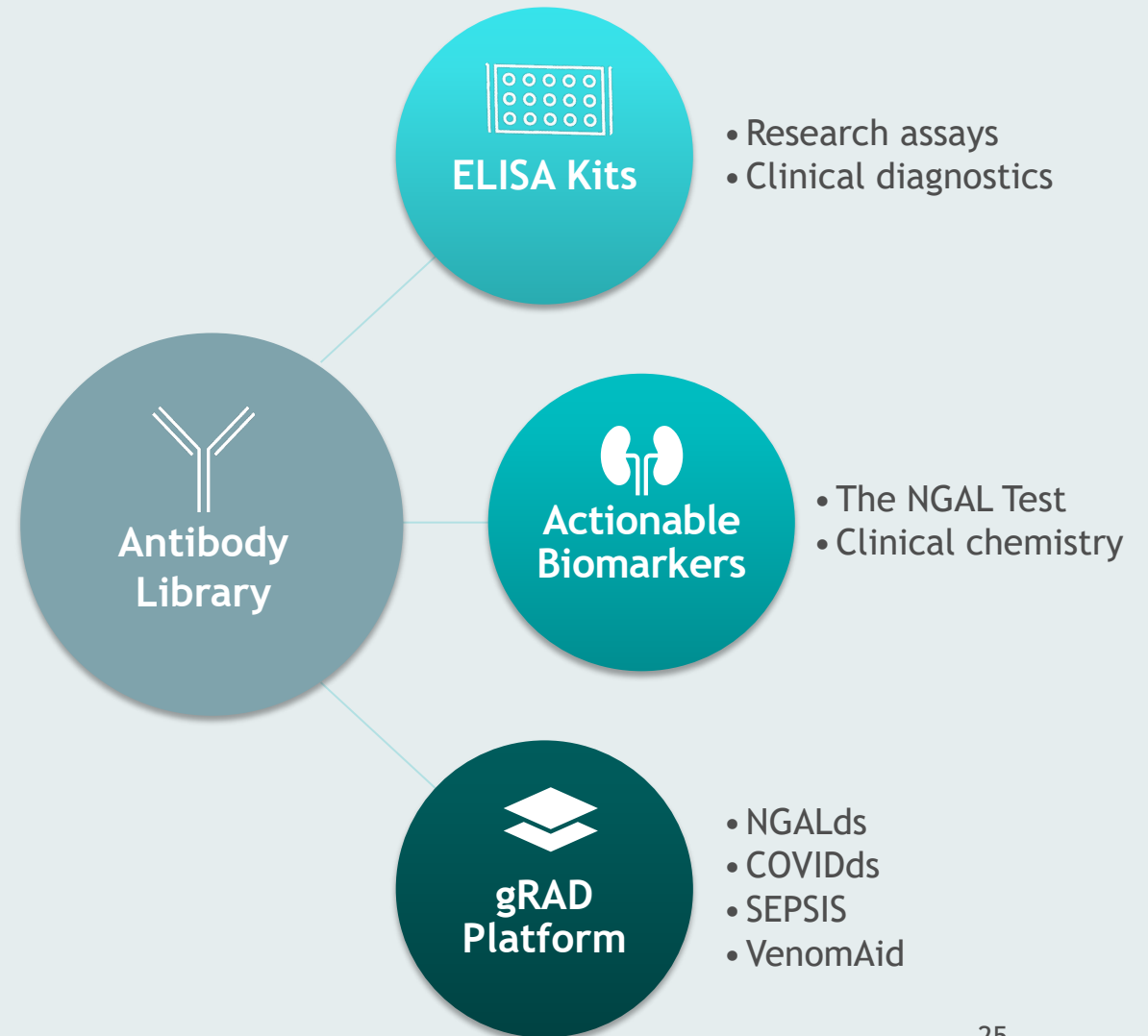




About BioPorto

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 25 employees and 2019 revenue of \$4M.





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



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