

Interim Report, Q3 2021

BioPorto

November 17, 2021





Forward-Looking Statements

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Agenda

- 1 Highlights from Q3 2021
- 2 Q1-Q3 2021 financial results
- 3 Organizational update
- 4 Regulatory update
- 5 2021 guidance



Highlights from Q3 2021

- Revenue growth of 13% in USD on RUO sales of The NGAL Test and new orders on ELISA Kits
- Tony Pare appointed new CEO and Neil Goldman appointed CFO
- Enrollment in US clinical trial of The NGAL Test continues, but at slow pace. Expected to be finalized during 1H 2022.
- Testing of The NGAL Test for EUA initiated
- Interim data for gRAD-based Sepsis and COVID-19 expected in Q4 2021
- EBIT guidance for 2021 improved to loss of DKK 63m and revenue adjusted to DKK 24m



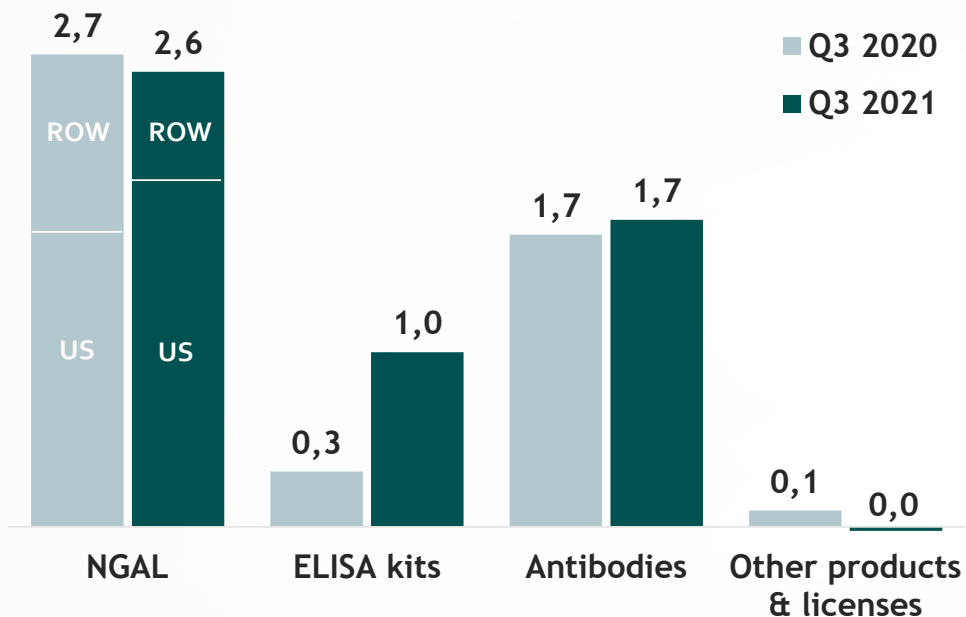
Q1-Q3 2021 financial results





Growth of 13% (USD) driven by increase in RUO sales of The NGAL Test and ELISA kits in Q3 2021

Revenue by Product Category (DKKm)



US NGAL

+17%

Increase in revenue (DKK) from
RUO sales of The NGAL Test in US
from Q3 2020 to Q3 2021

ELISA Kits

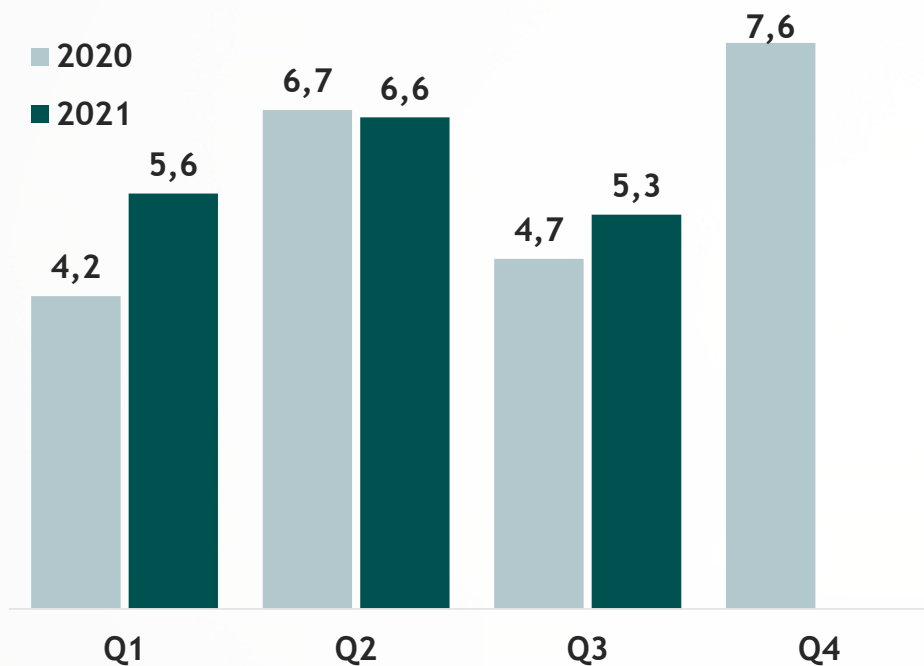
+217%

Increase in revenue (DKK)
from ELISA kits in
Q3 2021 vs. Q3 2020

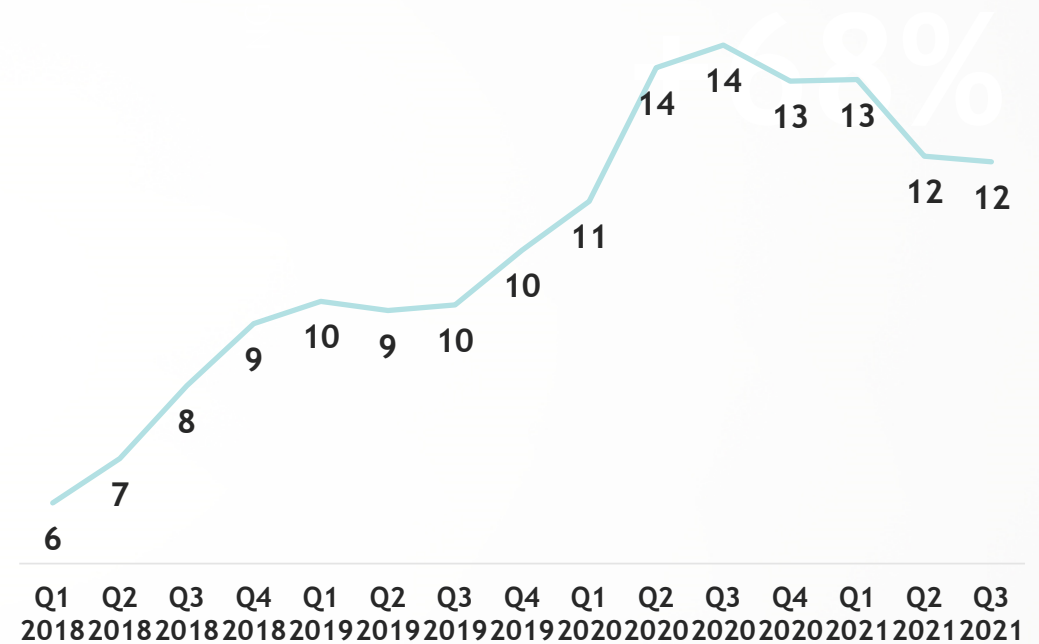


Revenue growth of 19% in USD (11% in DKK) in Q1-Q3 2021

Revenue by Quarter (DKKm)



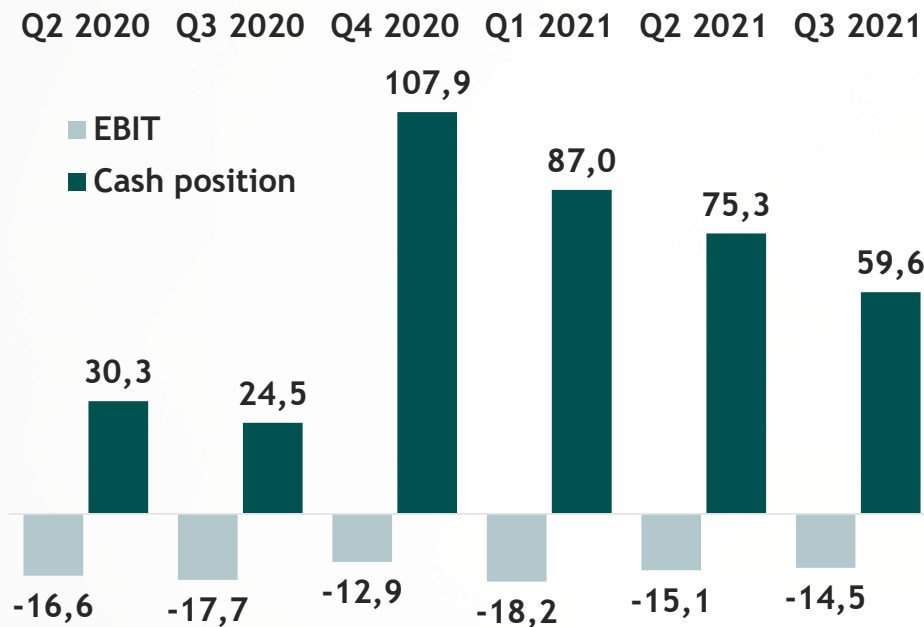
NGAL Product Sales by Quarter (LTM, DKKm)





Enrollment postponements and focus on cost reduce EBIT loss and provide funding to Q3 2022

EBIT and cash position (DKKm)



- EBIT loss reduced DKK 3.2 million in Q3 2021 compared to last year due to top line growth and lower R&D costs
- Slower cash burn and cash position of DKK 59.6 million end-September 2021 provides funding into Q3 2022 (previously Q2 2022)
- BioPorto is exploring further funding opportunities to strengthen the company's long term financial position

Organizational update



New highly experienced international management team in place



Tony Pare

CEO

AS OF NOV. 20, 2021

Has for 24 years been leading product development, commercialization, marketing and operations improvements in leading medtech and diagnostic companies.

Previously CCO at T2 Biosystems, a US Nasdaq-listed in vitro diagnostics company. Before then at Hemanext (US), also as CCO.

Prior to these positions, Tony was in various leadership roles at Haemonetics (US), specializing in blood processing and diagnostic technologies.

He holds a Master's degree in Engineering Administration from George Washington University (US).



Neil Goldman

CFO

AS OF NOV. 15, 2021

Neil brings three decades of valuable experience. He has forged strong relations with investors and global capital markets, raised capital reliably and successfully, optimized business operations, and expanded business through organic growth and strategic partnerships.

Neil joins BioPorto from Chembio Diagnostics, Inc., a global developer and manufacturer of point-of-care tests, where he was CFO. Prior to this Neil was a CFO at J.S. Held LLC and at Unwired Technology LLC.

He is B.S. in Business-Accountancy from Miami University, Oxford, Ohio, US, and began his career at Ernst & Young, where he was an auditor primarily of Fortune 500 companies.

Board of Directors as of November 15, 2021



**Christopher
Lindop**

CHAIRMAN
SINCE 2019

Over 15 years in senior finance leadership roles with public healthcare companies including as CFO of Quotient Limited, Haemonetics, and Inverness Medical Innovations.



**John
McDonough**

VICE CHAIRMAN
SINCE 2021

Diagnostics industry veteran, including leadership of T2 BioSystems and Cytec prior to its acquisition by Hologic Inc.; member of the Board of Directors at Solace Therapeutics and Cytrellis Biosystems.



**Don
Hardison**

BOARD MEMBER
SINCE 2021

Expert in molecular diagnostics, including in oncology, and reproductive health and in global reference labs; Boards have include Stemina Biomarker Discovery Inc., Seventh Sense Biosystems, IQuity, Inc, and Exact Sciences.



**Michael
Singer**

BOARD MEMBER
SINCE 2019

CSO, co-founder Cartesian Therapeutics, developer of cellular immunotherapies for cancer. Co-founder, CSO Topokine Therapeutics and Health Honors.



**Jan
Leth Christensen**

BOARD MEMBER
SINCE 2021

An attorney with expertise in real estate, partner at Lønberg & Leth Christensen Advokataktieselskab; Chairman of Havnens Bygningsudlejnings A/S, Best Ejendomme A/S, Advokaternes Ejendomsadministration A/S.



**Peter
Mørch Eriksen**

BOARD MEMBER
SINCE 2021

BioPorto's CEO from 2013-2021. Has more than 20 years of experience in medtech and life science. Previous CEO of Sense A/S and has held senior positions at Medtronic. Chairs the board of FluoGuide, and a member of Lund University Advisory Board.

Regulatory update



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.

Results from interim analysis as expected, but enrollment delayed by COVID-19



Pediatric study



1 in 4 affected with AKI during hospitalization (ICU)¹

Predict AKI Risk in an Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

Interim analysis

- **EARNEST data evaluated**
- **Sensitivity, specificity and test statistics consistent with expectations**
- **Expansion of enrollment decided to maximize statistical power for upcoming FDA submission**

- Number of participating sites in the US clinical trial for The NGAL Test in pediatrics increased to 14 during Q3 2021
- Enrollment of patients delayed in Q3 and early Q4 by continuation of COVID-19 pandemic which reduce no. of patients and access to ICU's.
- Based on outlook, BioPorto has revised its enrollment forecast and now expects to finalize enrollment in 1H 2022.

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

REGULATORY & MARKET EXPANSION

US Regulatory Strategy for NGAL

Pediatric

Breakthrough Designation
Predict AKI risk (stage 2/3)
in the PICU
Urine samples
Enrollment finalized 1H 2022

Adult

Predict AKI risk (stage 2/3)
in the ICU
Urine or plasma samples
Study planning underway,
submission after pediatric
clearance

Expansion Areas

Nephrotoxicity: Oncology, Cardiology, Diabetes, Transplant, Autoimmune
COVID-19 patient management
Point-of-care applications



Testing of The NGAL Test for EUA in relation to COVID-19 patients initiated

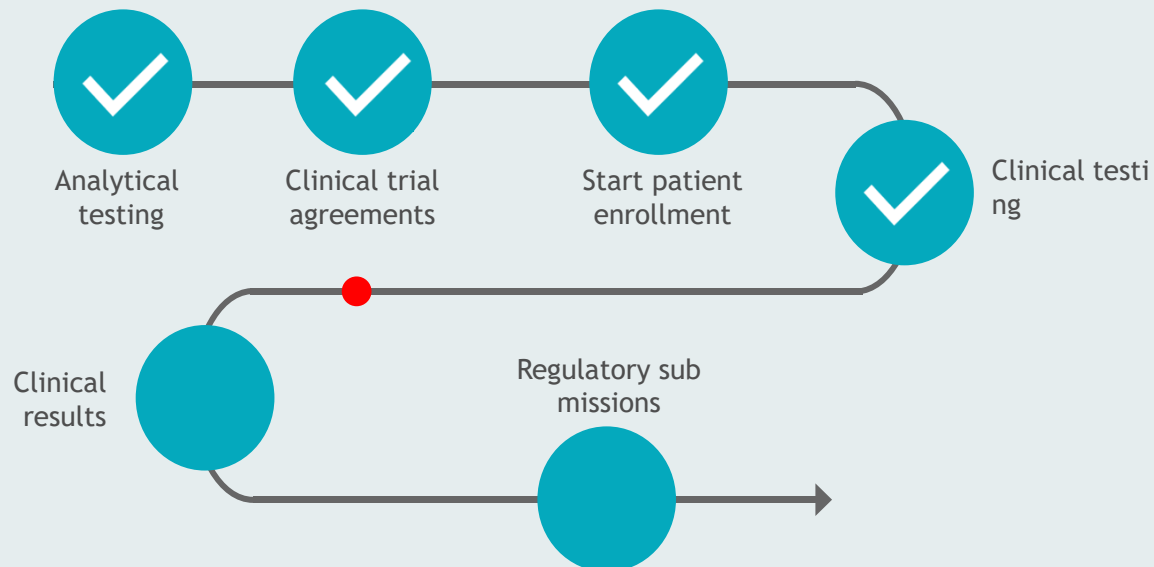
- In Q3 2021, BioPorto has progressed dialogue with FDA on a EUA of The NGAL Test in screening COVID-19 patients for risk of renal failure
- BioPorto has based on positive dialogue, initiated testing of original samples collected by Columbia University using The NGAL Test
- The test targets showing NGAL as an important biomarker to identify COVID-19 patients at low risk of requiring renal replacement therapy, hence providing help to optimize resource allocation
- If so, it could form the basis of the EUA application to the FDA



Rigshospitalet is finalizing interim data report on gRAD-based Sepsis test



Assay Development Timeline

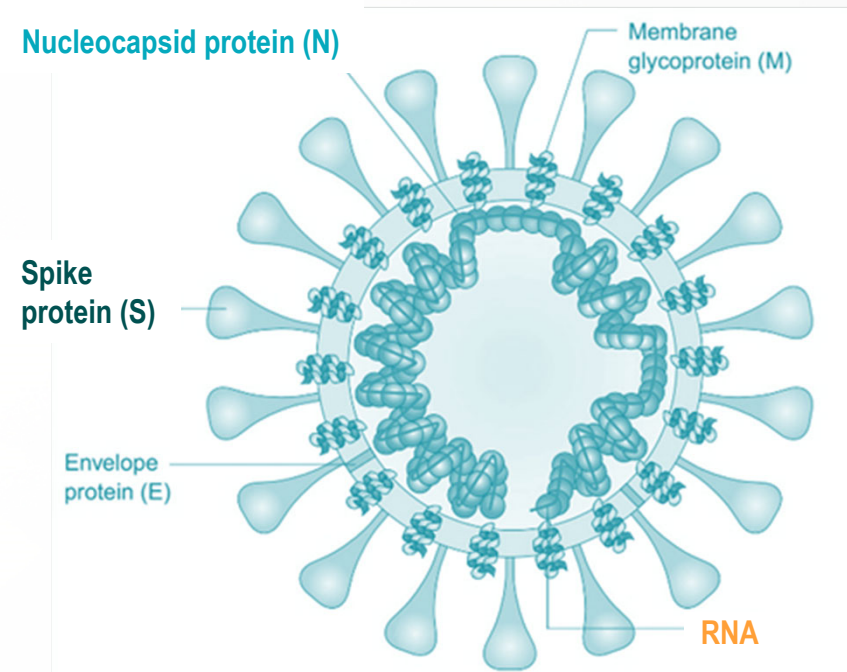


- BioPorto and Rigshospitalet (DK) are co-developing a gRAD test for quantitative determination of thrombomodulin in human plasma
- Test is part of trial evaluating safety and efficacy of thrombomodulin vs. placebo in trauma patients with hemorrhagic shock-induced endotheliopathy
- Rigshospitalet is expected to finalize an interim data report in Q4 2021 leading to a decision on the business perspectives



Data collection for gRAD COVID-19 is being evaluated; conclusion expected at year-end 2021

- Focus is to secure a sensitivity above 80% to strengthen the platform's potential
- Initial results indicate a higher sensitivity compared to other rapid test formats
- Results are currently being evaluated and analysis of clinical potential expected to be concluded year-end 2021



2021 guidance





Clinical, regulatory and commercial

Targeted 2021 Milestones

- Continue enrollment of patients for the US FDA application for The NGAL Test in pediatrics
- Collect supplementary data to support submission of an application for The NGAL Test in adults
- Conclude on interim data for gRAD-based Sepsis test
- Evaluate data supporting regulatory application(s) for gRAD COVID-19 rapid test
- Grow revenues from sales of The NGAL Test and antibodies



Guidance: Reduced cost strengthens cash position end-year and provides cash until Q3 2022

Revenue

**Approx.
DKK 24m**

(previously DKK 30m)

EBIT loss

**Approx.
DKK 63m**

(previously 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

November 17, 2021

Q3 2021 Results

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