

Annual Report 2020 **BioPorto**

March 17, 2021





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Agenda

- 1 Highlights from 2020
- 2 Financial highlights of 2020
- 3 The NGAL Test
- 4 gRAD - a development platform
- 5 2021 milestones
- 6 About BioPorto



Highlights from 2020

- A year heavily affected by the global COVID-19 pandemic
- High volatility and difficulty in near term planning and execution reinforced focus on maximizing ability, diligence, and agility
- Initiation of multiple clinical studies both in The NGAL Test (expected finalized by summer 2021) and COVID-19 test. If results support BioPorto's laboratory findings, COVID-19 test is expected finalized in second quarter 2021
- Very important verification of gRAD which delivered first CE marked test for near-patient AKI
- Product sales growth of The NGAL Test at 28% in 2020 YoY - both in US and ROW (despite postponement of Q4 orders)
- Two successful and oversubscribed rights issues secures strong financial position with DKK 108 million in cash to support activities in 2021

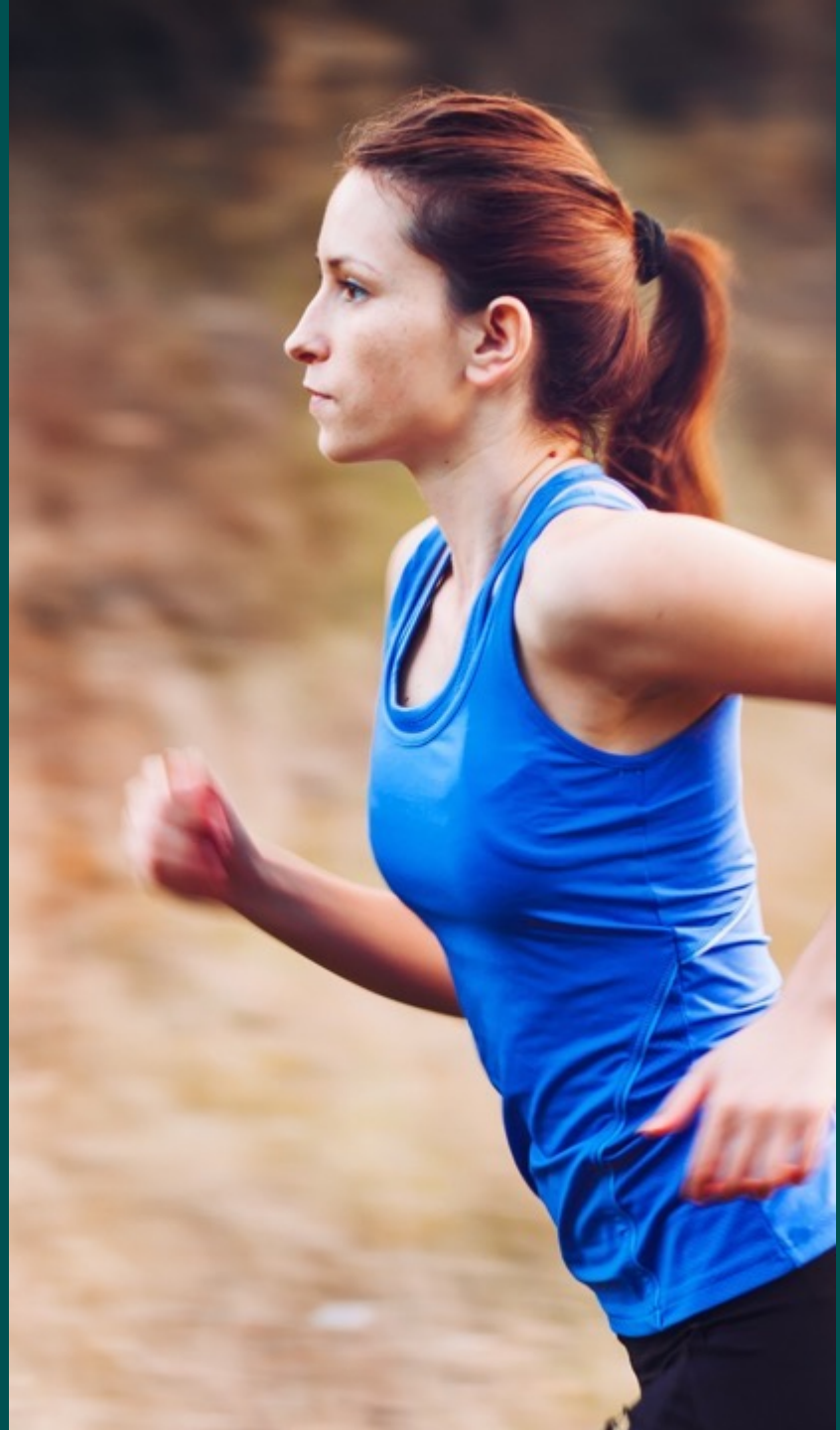




Main events of 2020



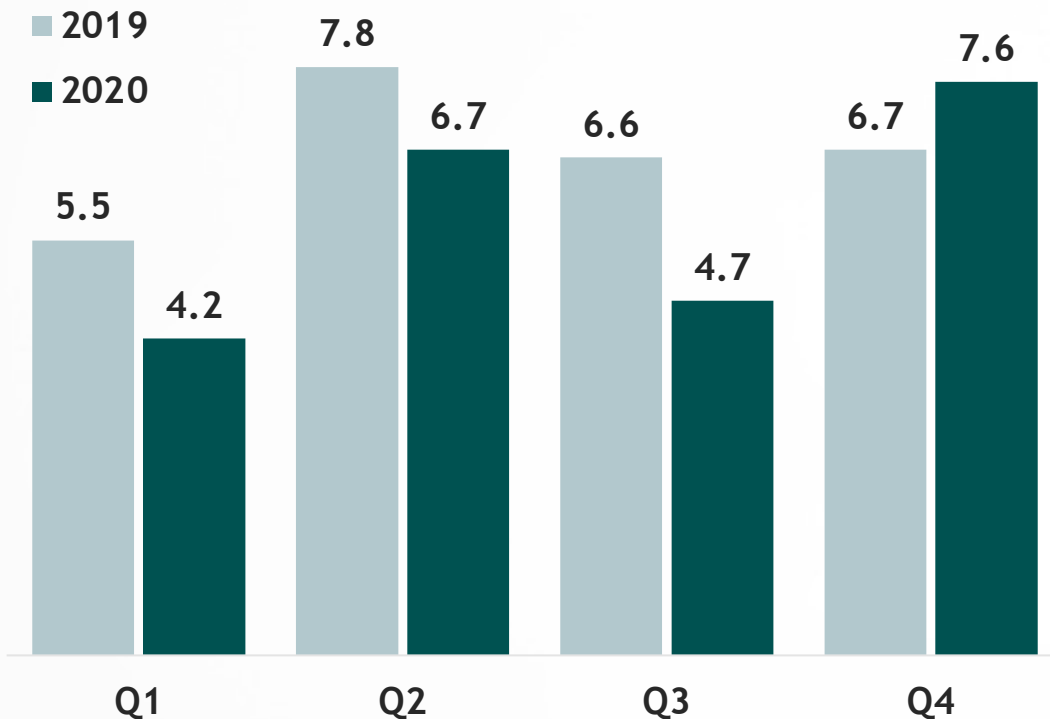
Financial highlights of 2020



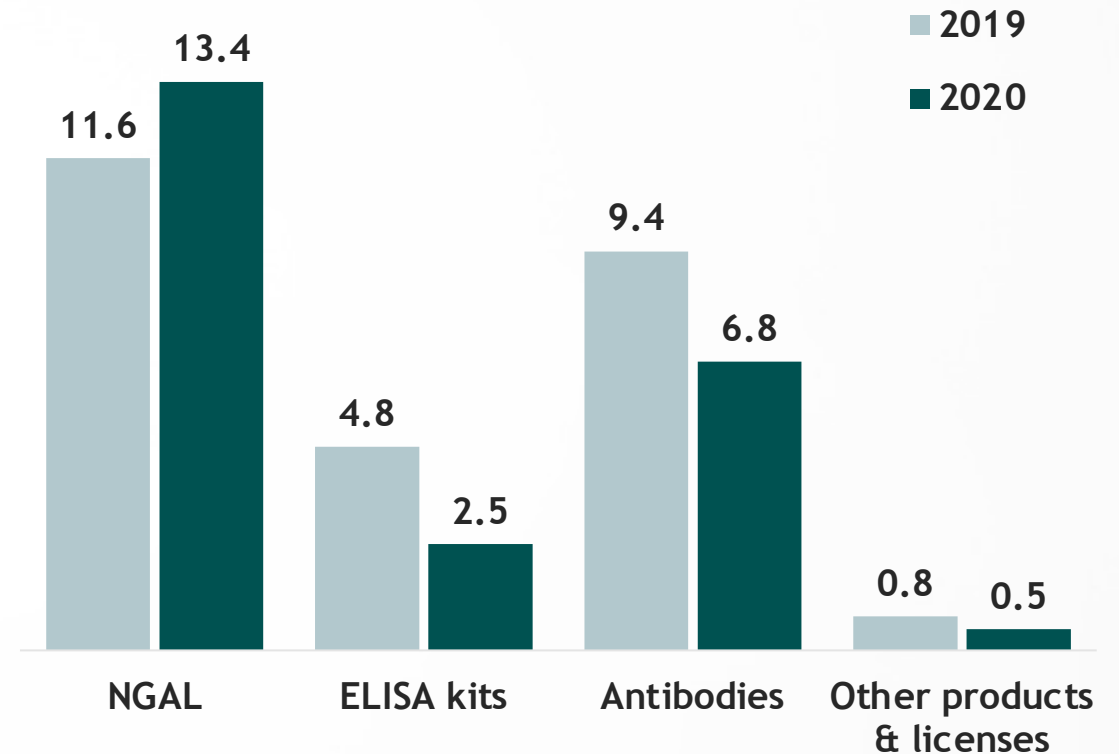


Revenue declined due to anticipated decrease in antibody and ELISA kits sales

Revenue by Quarter (DKKkM)



Revenue by Product Category (DKKkM)





Despite order postponements to 2021, sales of The NGAL Test grew 28% in 2020

US NGAL

↑ 37%

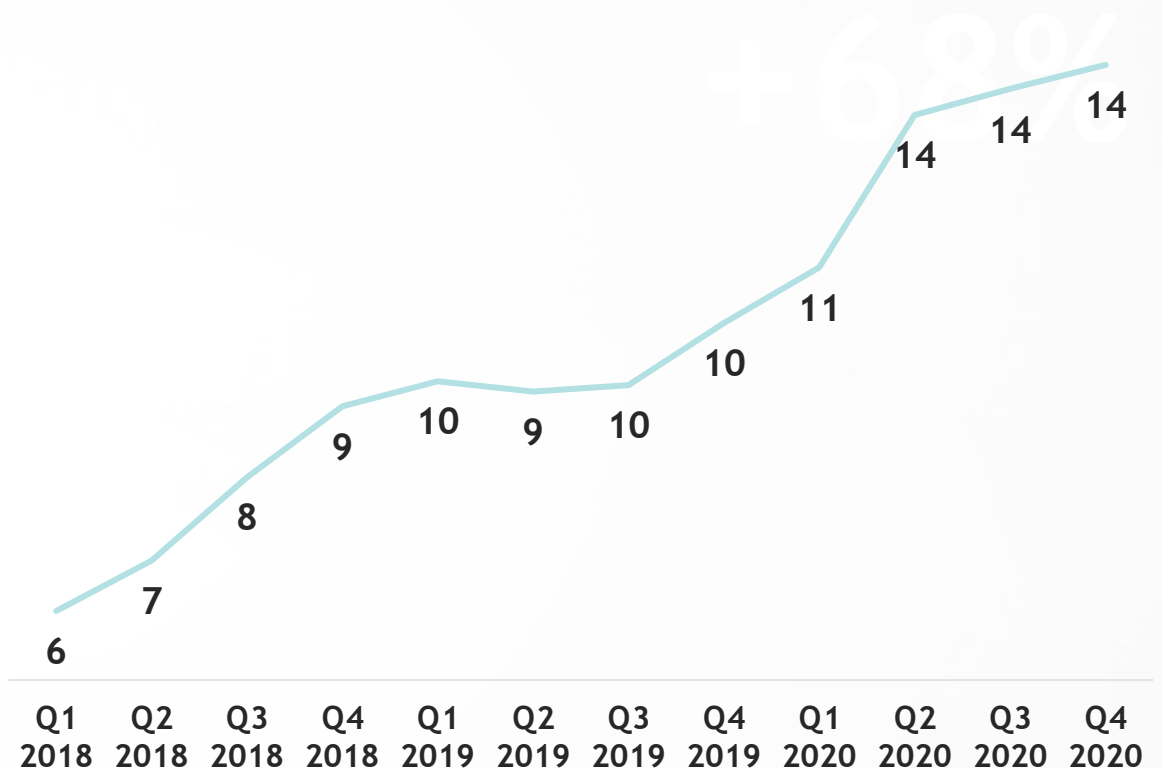
Increase in total revenue from US NGAL sales (RUO) from 2019 to 2020

ROW NGAL

↑ 22%

Increase in ROW sales of NGAL from 2019 to 2020

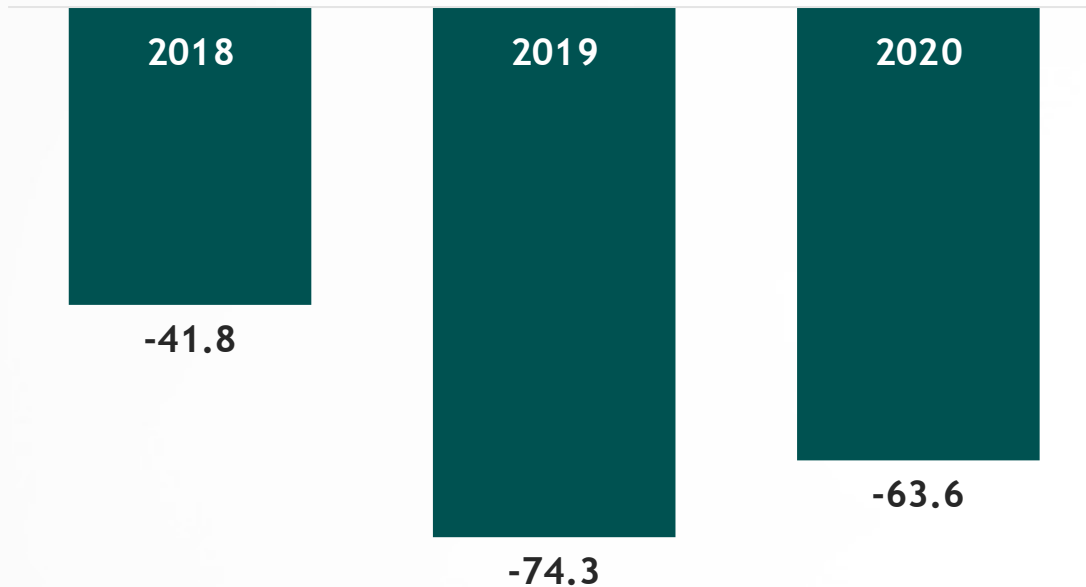
NGAL Product Sales by Quarter (LTM, DKKm)





EBIT loss below expectations as commercial activities and clinical trials were postponed due to COVID-19

EBIT (DKKm)

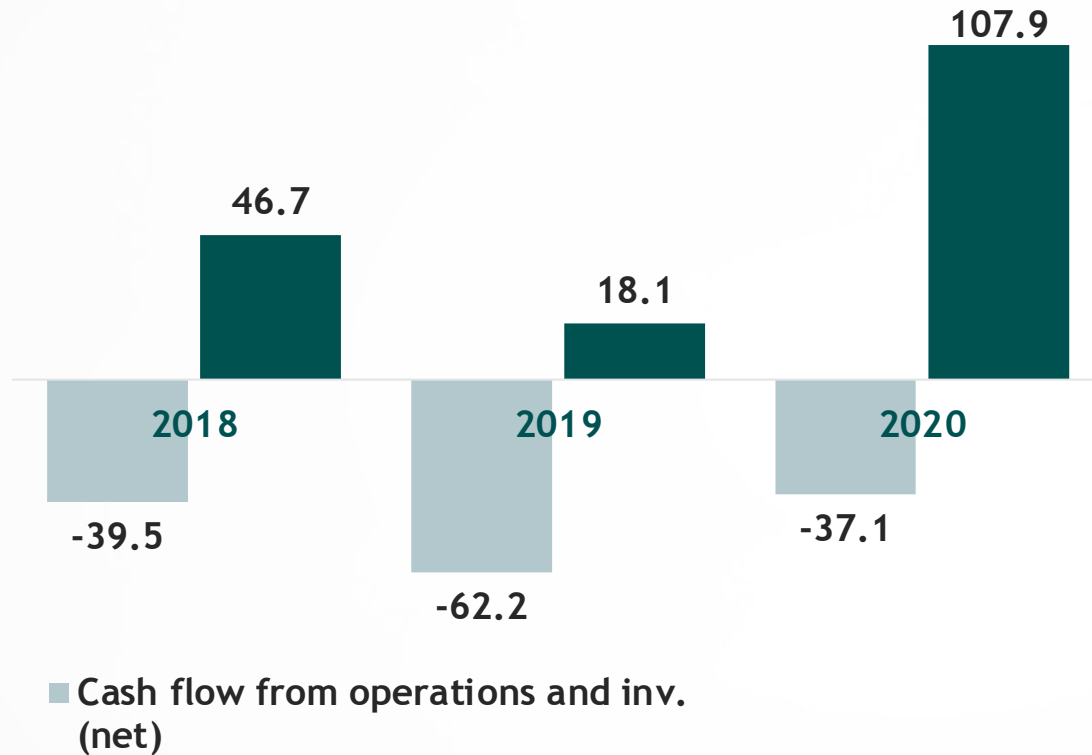


- EBIT loss for 2020 below guidance of DKK 73 million
- COVID-19 pandemic caused US clinical trials for pediatric application to be postponed and hence pushed costs to 2021
- Several commercialization events in late 2020 were cancelled due to the second wave of the COVID-19 pandemic



Cash position strengthened with DKK +130 million in 2020 through two oversubscribed rights issues

Cash flows and cash holdings (DKKm)



October 2020

DKK 93 mill.

Net proceeds from
fully guaranteed rights issue
with pre-emptive rights

April 2020

DKK 38 mill.

Net proceeds from
rights issue with
pre-emptive rights

A Novel Solution

The NGAL Test



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.



Regulatory Strategy for NGAL

Pediatrics



1 in 4 affected with AKI during hospitalization (ICU)³¹

Predict AKI Risk in Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

Finalize collection of data by summer 2021 and submit De Novo application to FDA

Adults



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

Predict AKI Risk in Intensive Care Setting

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

Study planning underway, expect 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 trial enrollment delayed by COVID-19 limiting hospital access

- Prospective trial to establish and validate the performance of The NGAL Test at leading US pediatric hospitals, led by Cincinnati Children's Hospital
 - Pediatric population (≥ 3 months to < 22 years old), urine samples
 - Predict risk of developing moderate to severe AKI (stages 2/3)
- BioPorto's non-hospital studies are being finalized according to schedule.
- Second and third waves of COVID-19 brought restrictions at hospitals and delayed enrollment
- As of March 2021, eight hospitals are enrolling patients; new sites are being added
- Finalize enrollment by summer 2021 and submit De Novo (510k) application to FDA - subject to further COVID-related changes



Children's
of Alabama



BioPorto's gRAD

A Development Platform



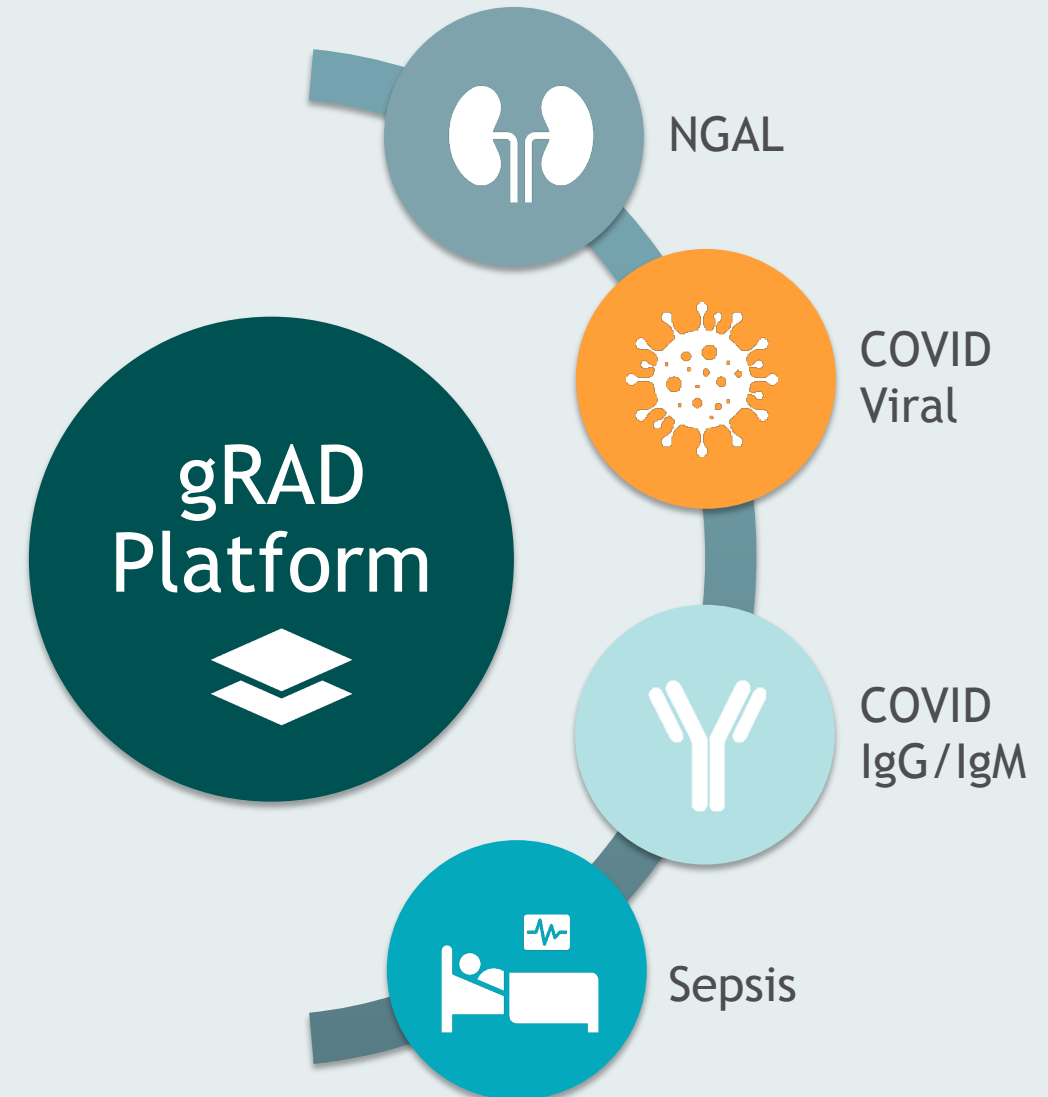


Generic Rapid Assay Device (gRAD) platform

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.





Benefits of BioPorto's gRAD Solution

Fast



Short
incubation time
<15 minutes

Versatile



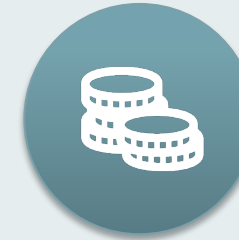
Flexible design
allows different
sample types

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



Major 2020 milestone: NGALds CE marked as first gRAD product

- NGALds is the first assay developed and approved on the gRAD platform
- CE Mark in Europe on December 30, 2020
- A rapid lateral flow test to offer semi-quantitative urine NGAL results without complexity or instrumentation - ideal for outpatient or low-resource settings
- Commercialization of the NGALds will be initialized in Europe through distribution partners and BioPorto's own sales channels
- BioPorto plans to seek regulatory approval for the test in other markets at a later stage

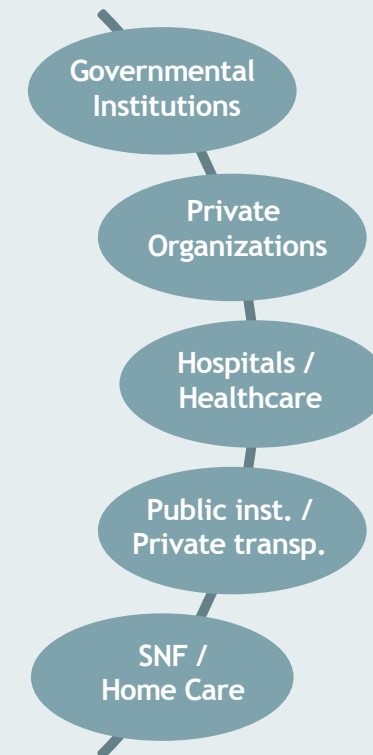




COVID-19 antigen test addresses growing global market

- COVID-19 test for broad scale diagnosis and rapid screening of viral infections in non-laboratory settings
- Test could provide a result in less than 15 minutes and at be offered at a lower price
- Optimally positioned for global health authorities focusing on self-testing and near-patient testing as primary pandemic control mechanisms
- Global demand and importance for broad-based diagnostic tests, such as COVID-19 rapids, will rise exponentially in the coming years

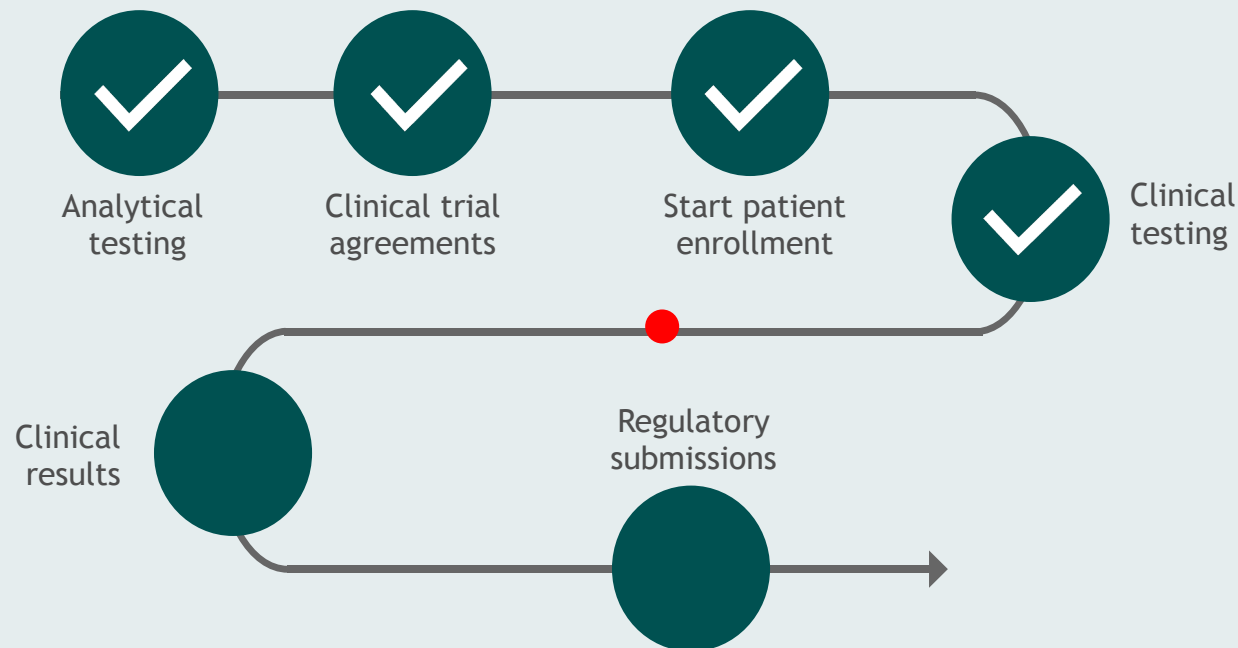
Customer Segments



COVID-19 viral test development process in final stage before EUA request and CE mark



Assay Development Timeline



- Device prototyping and production agreements for 1 million test per month capacity secured
- University of California, Davis (US) will test samples from approx. 150 COVID-19 patients
- After initial issues in the trial, BioPorto is awaiting outcome of the new testing
- If successful, BioPorto will submit an Emergency Use Authorization (EUA) request with the FDA and a CE mark filing in Europe in the second quarter of 2021
- To further support the CE mark application, BioPorto is also evaluating options for conducting additional testing at clinical sites in Europe

2021 milestones





Clinical, regulatory and commercial

Targeted 2021 Milestones

- Finalize collection of additional patient data by summer 2021 and submit FDA application of The NGAL Test for pediatrics
- After submission the focus is on the Clinical Test for The NGAL Test in adults
- If testing is successful, BioPorto will finalize request to FDA for EUA and CE mark in Europe of COVID-19 rapid test by Q2 2021
- Progress development of new rapid assays on gRAD platform
- Grow revenues by 25%





Financial Projections for 2021

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

April 29, 2021

May 12, 2021

August 18, 2021

November 17, 2021

Annual General Meeting

Q1 2021 Results

Q2 2021 Results

Q3 2021 Results

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