# Interim Report, Q1 2020

May 7, 2020





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# Agenda

- o1. Highlights from Q1 2020
- o2. Q1 2020 financial results
- o3. The NGAL Test regulatory studies
- o4. gRAD pipeline: Includes tests for COVID-19
- o5. 2020 milestones

# Highlights







### Highlights from Q1 2020

- NGAL sales up 67% compared to Q1 2019
- FDA dialogue and preparations for additional data collection on track, but enrollment of new patients for US study delayed due to COVID-19 shutdown
- New collaboration with SDU to develop test for active COVID-19 virus based on gRAD technology
- Successful rights issue completed cash position strengthened with DKK 38 million
- Guidance for 2020 maintained

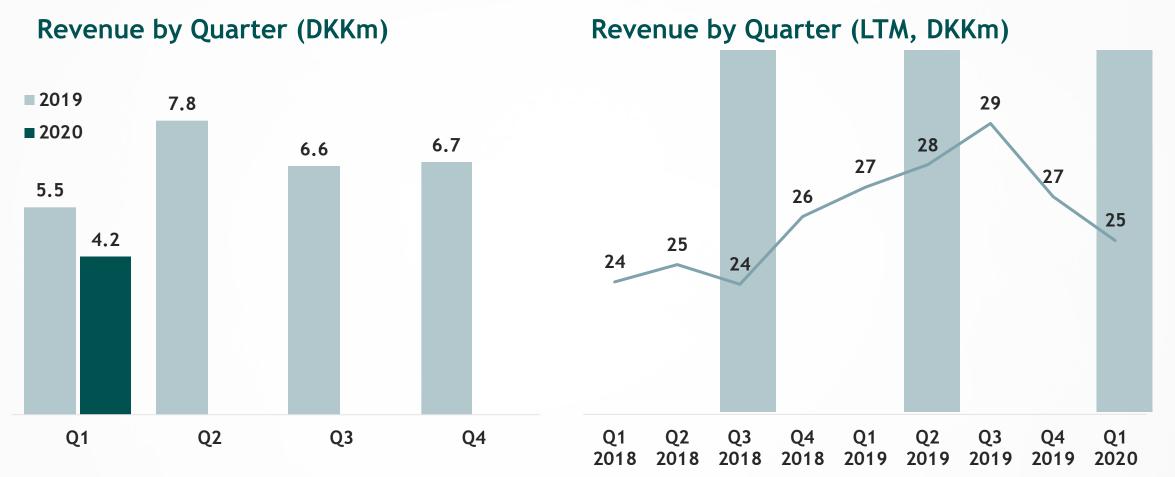
## Q1 2020 Financials





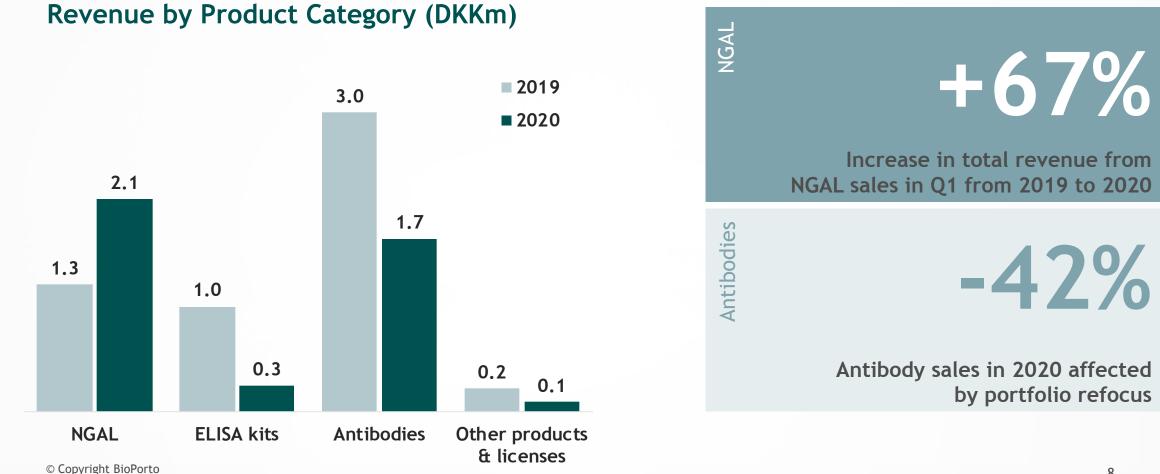


# Change in antibody strategy dilutes NGAL-driven growth in Q1 2020





#### Very satisfactory growth of 67% in NGAL revenue



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### Fully subscribed with proceeds of DKK 40 million

- A total of 24,992,053 new shares offered from March 19, 2020 to April 3, 2020
- Holders of existing shares received one pre-emptive right for each share held seven pre-emptive rights allowed for subscription of one new share against payment of subscription price of DKK 1.60 per share
- Very robust interest binding commitments and guarantees for +70% of the offering
- All new shares were subscribed for and the successful offering yielded gross proceeds of DKK 40 million (net proceeds of approximately DKK 37.5 million)
- Total cash position (after Q1 + net proceeds from rights issue) of DKK 41 million
- Proceeds and cash position will cover BioPorto's financing requirements through September 30, 2020, after which additional funding will be required

### The NGAL Test Regulatory Studies





US Regulatory Update



#### Patient enrollment delayed due to COVID-19 outbreak Submission to FDA expected in 2H 2020

Oct. 2018



Retrospective study for risk assessment in pediatrics initiated

#### Original study (AWARE 2014)

- 4,653 patients tested
- 1,261 developed AKI
- 543 developed severe AKI

Subset of samples re-tested with The NGAL Test

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Application submitted to FDA, reviewed with determination of additional data requirements

#### Strong clinical support for The NGAL Test

- Sensitivity 65.0%
- Specificity 81.8%
- Neg. predictive value 95.4%
- Concern by FDA for clinician bias in underlying dataset (AWARE)

#### 2H 2020 Enhanced FDA submission planned

#### Updated regulatory filing

- Revised pediatric application will be a De Novo 510(k) application
- Additional patient data to be collected in US to address FDA concerns over clinician bias
- Rapid addition of new clin/reg personnel for best-in-class study management

#### Research Use Only sales to US research hospitals



### **Additional Data Collection**

- BioPorto will include all ICU patients who meet our criteria
- This will result in a simpler dataset, and a simpler message for FDA



gRAD pipeline: Includes tests for COVID-19





BioPorto's patented lateral flow development system

### **Proprietary Platform: gRAD**

- BioPorto's patented Generic Rapid Assay Device, gRAD, was developed in 2016 to enable rapid development of lateral flow devices
- gRAD has been used in the development of 3 novel lateral flow tests
- Features of gRAD include:
  - Optimized with two printed lines: a test line for capture antibody, and a control line designed to capture any 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

See how gRAD

works

- Assay incubation time is short, typically 10-15 minutes
- Cost effective, flexible design

Unique opportunity to use gRAD technology for two tests



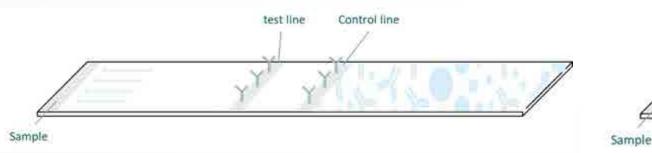
#### **Product Formats**

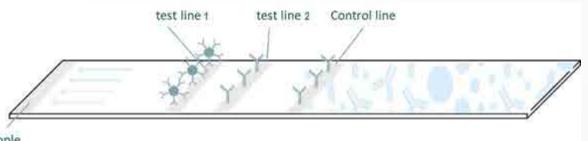
#### Single analyte detection

- Qualitative, semi-quantitative and quantitative detection of analytes
- Flexible sample types: urine, plasma, serum, whole blood, saliva, oro- and nasopharyngeal swabs, synovial fluid
- Improved performance characteristics compared to standard lateral flow tests

#### **Multiplex detection**

- Qualitative, semi-quantitative and quantitative detection of multiple analytes
- Flexible sample types: urine, plasma, serum, whole blood, saliva, oro- and nasopharyngeal swabs, synovial fluid
- Detection of multiple analytes for improved clinical decision making





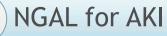


#### **Benefits of BioPorto's Solution**





#### **BioPorto gRAD Pipeline**



Screen for COVID-19 active virus

Test for COVID-19 IgG/IgM

NGAL for Sepsis

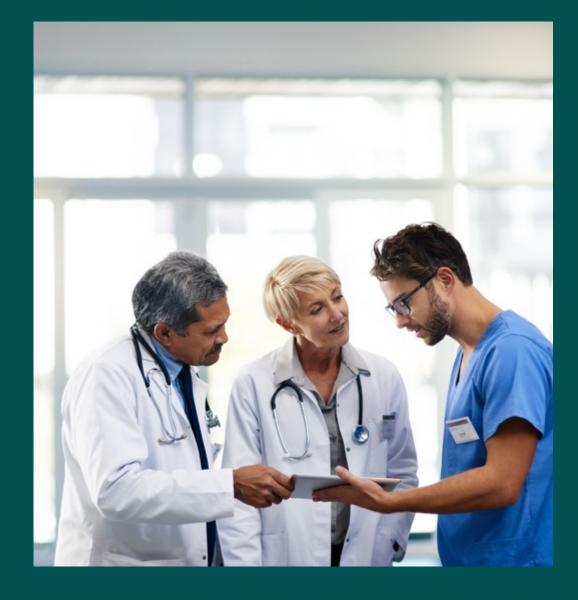
NGAL for Inflammation

NGAL for Blast Lung Injury (triage)

NGAL in veterinary (race horses)



### 2020 milestones









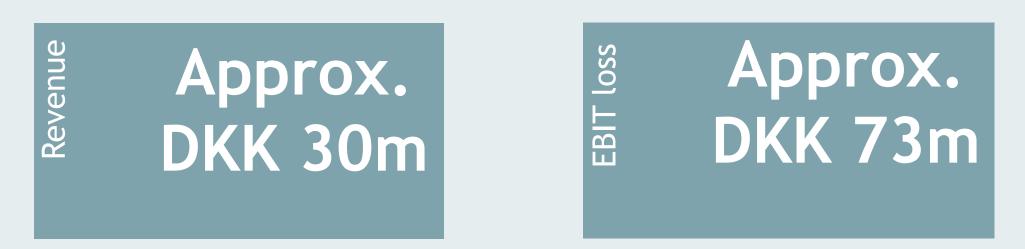
### **Targeted 2020 Milestones**

- 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 the newly discovered coronavirus (SARS-CoV-2) with SDU
- Review new opportunities for NGAL and BioPorto's antibody library
- Grow total revenue by 10%





#### **Financial Projections for 2020**



Growth in sales of The NGAL Test offset to some degree by decline in antibodies and ELISA kits sales. No regulatory sales included in guidance, which is subject to change depending on the development of the global COVID-19 situation.



#### **Investment Highlights**

#### Platforms

- Antibody -> Assay -> Actionable Biomarker Repeatable development path
- Robust academic & research relationships
- \$4m+ revenues in 2020

#### **Broad Target Market**

- The NGAL Test Addresses \$5 bn AKI market
- Significant unmet clinical need
- Testing can improve management, saving costs and lives

### Commercialization

- Partnerships secured with Roche & Siemens
- Reimbursement through DRG codes
- Strong support from Key Opinion Leaders

#### Execution

- Execution of two FDA submissions
- Proprietary NGAL test with extensive studies
- Experienced international management team

# Financial calendar 2020

August 19, 2020Q2 2020 ResultsNovember 18, 2020Q3 2020 Results

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