Annual Report 2019

March 11th, 2020

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Agenda

01. Highlights from 2019
02. 2019 financial result
03. Regulatory studies
04. 2020 milestones
05. About BioPorto

Highlights from 2019

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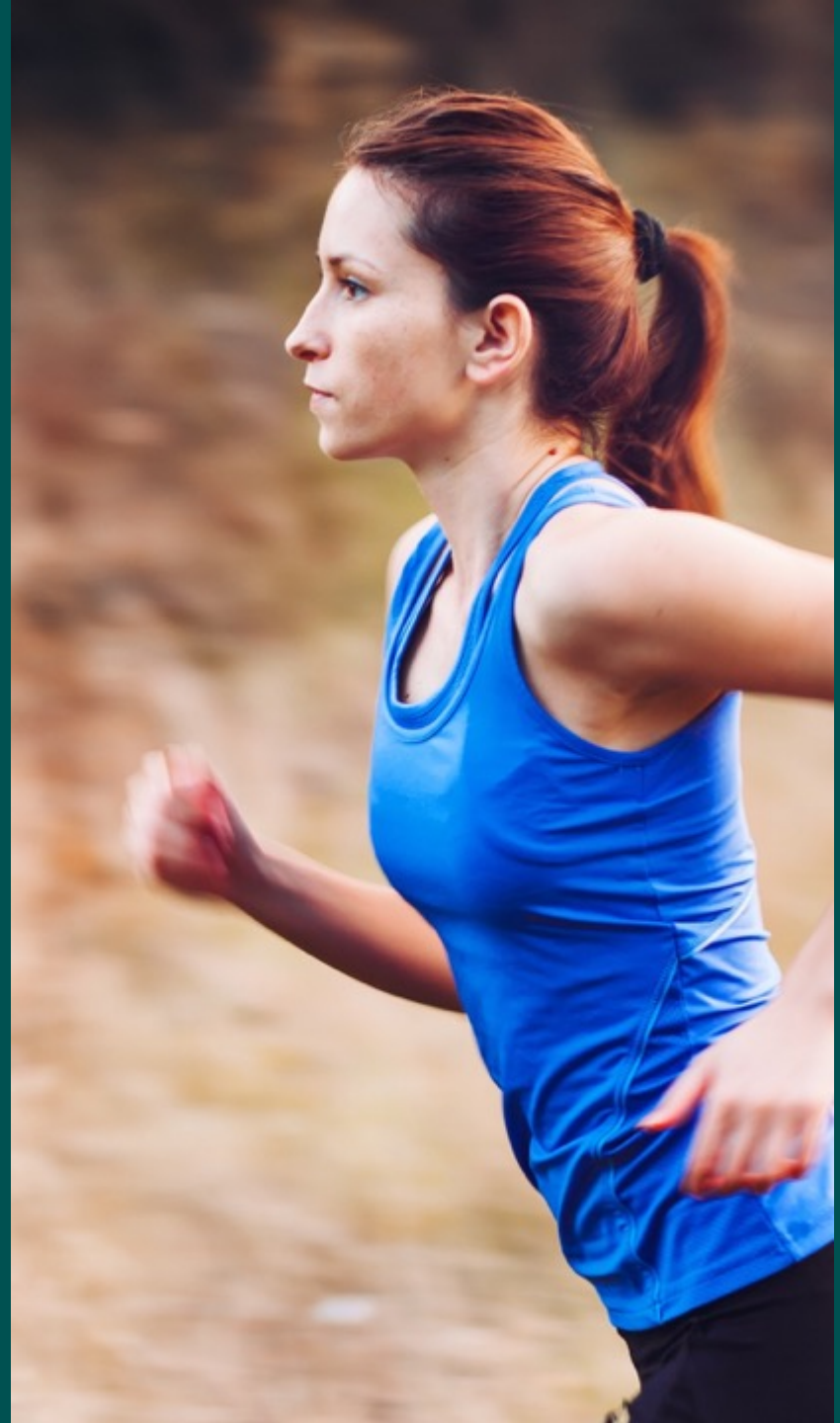
Highlights of 2019

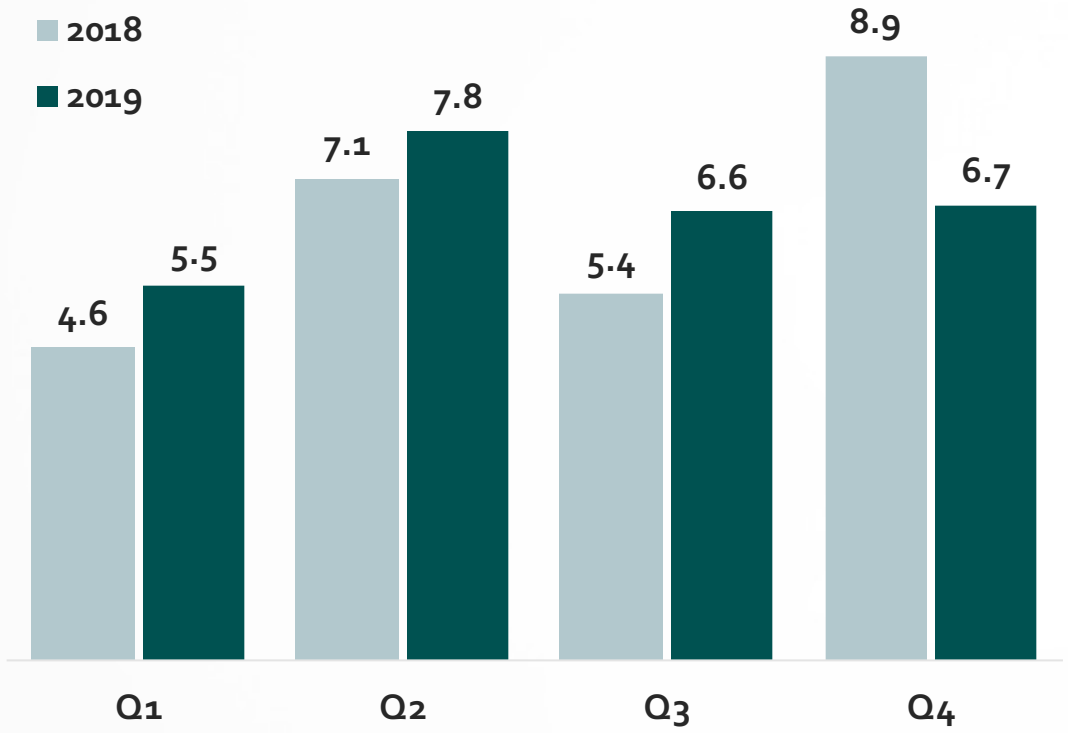
- NGAL product sales up by 14% compared to 2018
- Collecting additional data for the NGAL pediatric clearance with FDA
- Political support and increasing awareness of kidney health in the US
- Strong commercial, clinical and regulatory additions to US organization and Board of Directors
- Successful share capital increases in 2019 – further capitalization in the planning

2019 Financials results

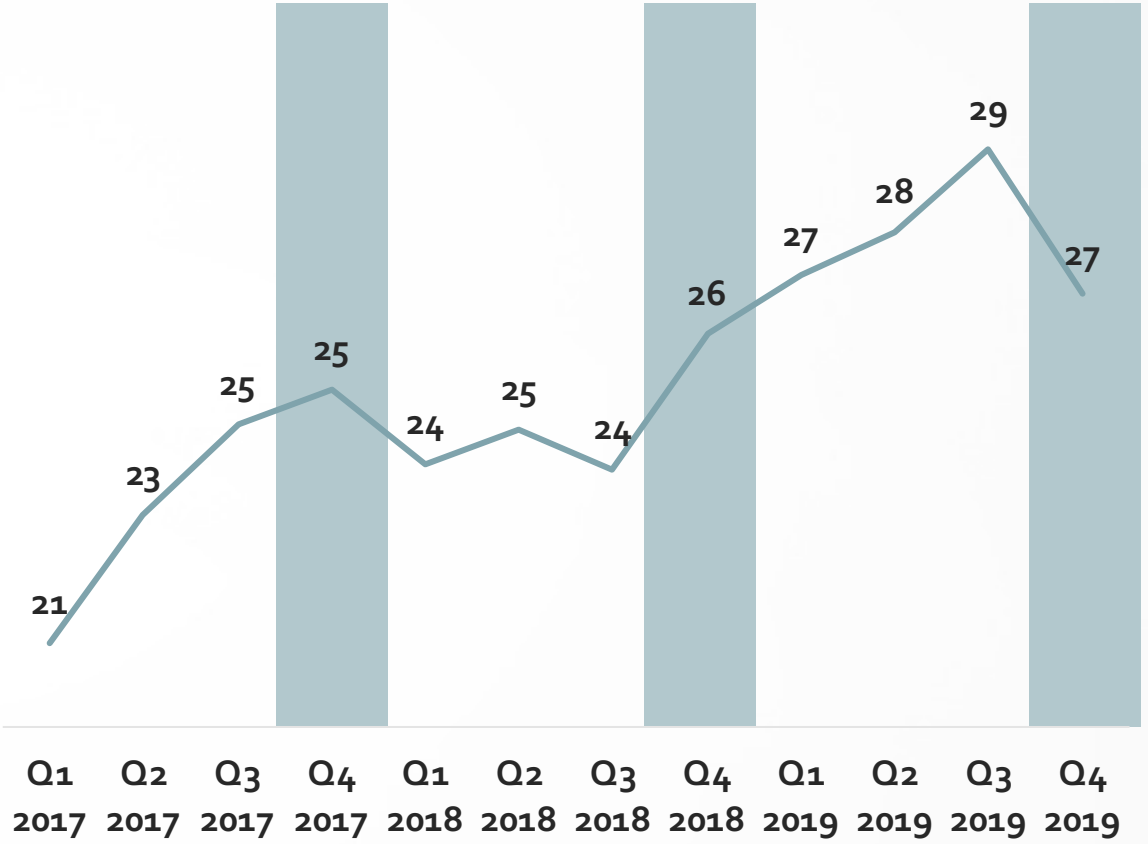


Revenue growth of 2.3% in 2019

Revenue by Quarter (DKKm)

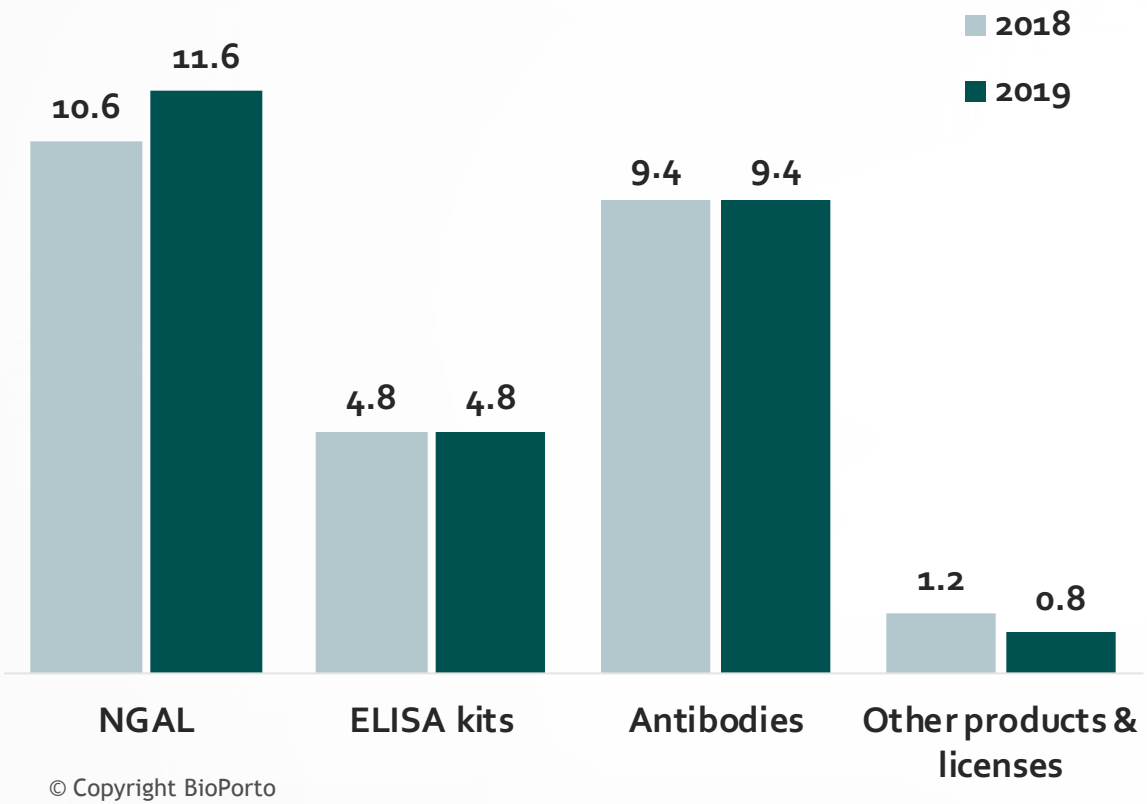


Revenue by Quarter (LTM, DKKm)



NGAL revenue* up 9.4% in 2019

Revenue by Product Category (DKKm)



NGAL

↑ 9%

Increase in total revenue from NGAL sales from 2018 to 2019

Antibodies

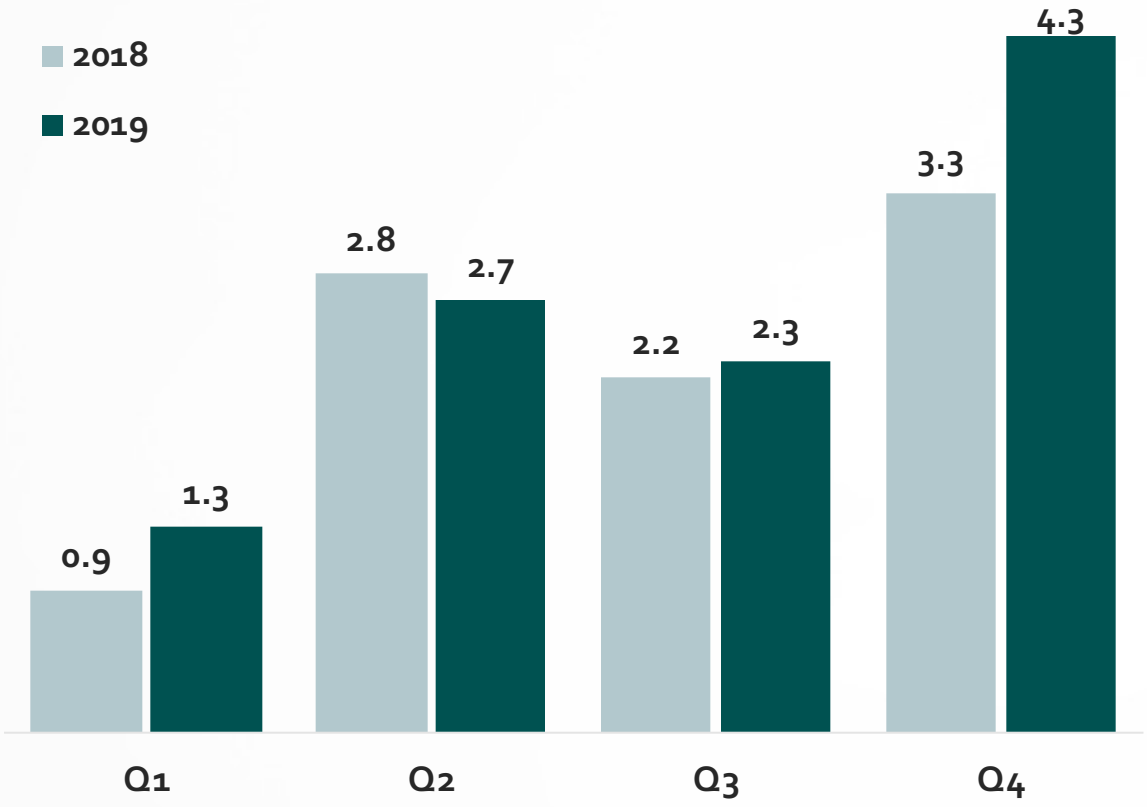
→ 0%

Antibody sales in 2019 at 2018-level due to declining Q4 sales (refocus)

* NGAL product sales and NGAL Other

NGAL product sales up 14% in 2019

NGAL product revenue by quarter (DKKm)



ROW NGAL

↑ 17%

Increase in total revenue from ROW NGAL sales from 2018 to 2019

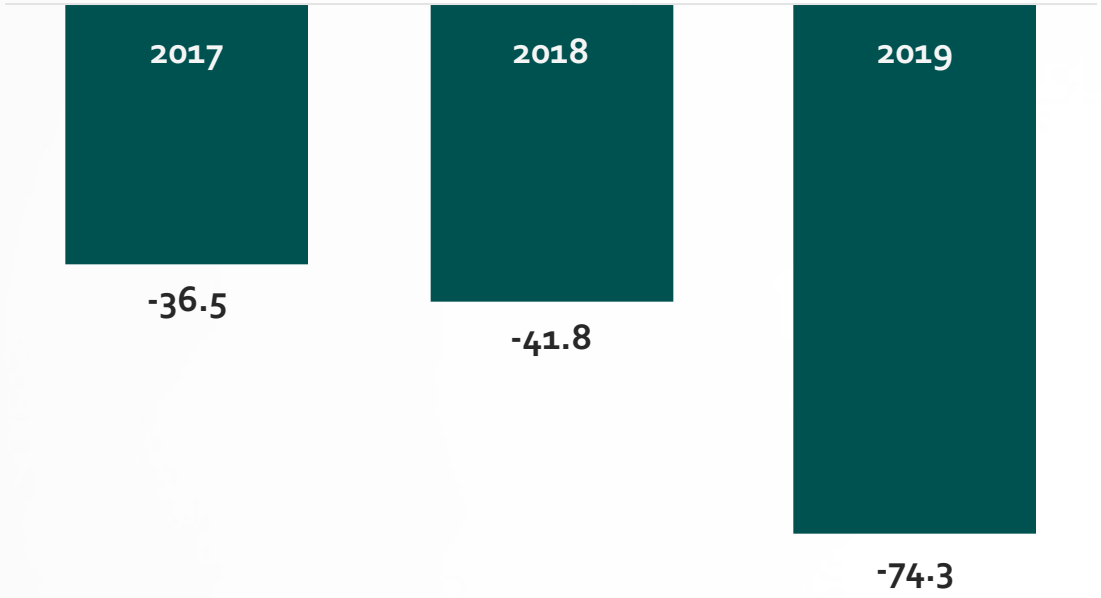
US NGAL

↑ 9%

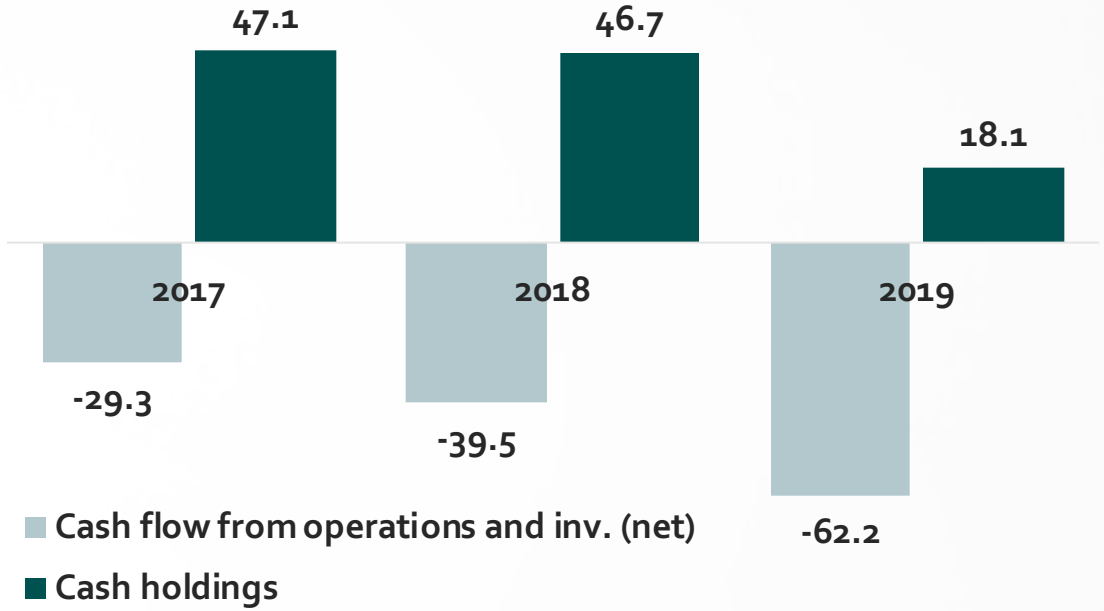
Increase in US RUO sales of NGAL from 2018 to 2019

EBIT on par with expectations - additional financing currently being pursued

EBIT (DKKm)



Cash flows and cash holdings (DKKm)



EBIT loss for 2019 of DKK 74 million in line with guidance

BioPorto is currently pursuing additional financing to strengthen the company's financial position

Regulatory studies

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Pediatric FDA application process to offer insight into adult

Pediatrics

1 in 4
critically ill children affected with AKI[2]

Predict AKI Risk in Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

FDA feedback Nov. 2019, additional data to be submitted Q2 2020

Adults

1 in 5 adults affected with AKI during a hospital episode of care[1]

Predict AKI Risk in Intensive Care Setting

- Plasma sample
- Predict Stage 2/3 AKI

Application to follow pediatric clearance

Additional Indications

- Nephrotoxicity
  - Oncology
  - Cardio
  - Diabetes
  - Transplant
  - Autoimmune
- Therapeutic monitoring
- Diagnosis of AKI
- Point-of-care applications

To initiate following FDA clearance of other indications

1) Susantitaphong, P et al. World Incidence of AKI: A Meta-Analysis. *Clin J Am Soc Nephrol*. 2013 Sep;8(9):1482-93.
2) Kaddourah A, Basu RK, Bagshaw SM, Goldstein SL; Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults, *N Engl J Med*. 2017; 376(1):11-20.

Further Patient Data to be Collected for Application

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

Q2-4 2019

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)

Q2 2020

Enhanced FDA submission planned

Updated regulatory filing

- Revised pediatric application will most likely 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

AWARE Study Design

- Goal of the AWARE study was to select patients who were sicker and therefore more at risk of Acute Kidney Injury (AKI)
- They only included patients who the doctor judged would still be in the intensive care unit (ICU) 48 hours after admission
- Our product claim has to mirror the data submitted, and FDA asked, "how can a doctor know who will be in the ICU after two days?"

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults

Ahmad Kaddourah, M.D., Rajit K. Basu, M.D., Sean M. Bagshaw, M.D., and Stuart L. Goldstein, M.D., for the AWARE Investigators*

ABSTRACT

BACKGROUND
The epidemiologic characteristics of children and young adults with acute kidney injury have been described in single-center and retrospective studies. We conducted a multinational, prospective study involving patients admitted to pediatric intensive care units to define the incremental risk of death and complications associated with severe acute kidney injury.

METHODS
We used the Kidney Disease: Improving Global Outcomes criteria to define acute kidney injury. Severe acute kidney injury was defined as stage 2 or 3 acute kidney injury (plasma creatinine level ≥2 times the baseline level or urine output <0.5 ml per kilogram of body weight per hour for ≥12 hours) and was assessed for the first 7 days of intensive care. All patients 3 months to 25 years of age who were admitted to 1 of 32 participating units were screened during 3 consecutive months. The primary outcome was 28-day mortality.

RESULTS
A total of 4683 patients were evaluated; acute kidney injury developed in 1261 patients (26.9%; 95% confidence interval [CI], 25.6 to 28.2), and severe acute kidney injury developed in 543 patients (11.6%; 95% CI, 10.7 to 12.5). Severe acute kidney injury conferred an increased risk of death by day 28 after adjustment for 16 covariates (adjusted odds ratio, 1.77; 95% CI, 1.17 to 2.68); death occurred in 60 of the 543 patients (11.0%) with severe acute kidney injury versus 105 of the 4140 patients (2.5%) without severe acute kidney injury (P<0.001). Severe acute kidney injury was associated with increased use of mechanical ventilation and renal-replacement therapy. A stepwise increase in 28-day mortality was associated with worsening severity of acute kidney injury (P<0.001 by log-rank test). Assessment of acute kidney injury according to the plasma creatinine level alone failed to identify acute kidney injury in 67.2% of the patients with low urine output.

CONCLUSIONS
Acute kidney injury is common and is associated with poor outcomes, including increased mortality, among critically ill children and young adults. (Funded by the Pediatric Nephrology Center of Excellence at Cincinnati Children's Hospital Medical Center and others; AWARE ClinicalTrials.gov number, NCT01987921.)

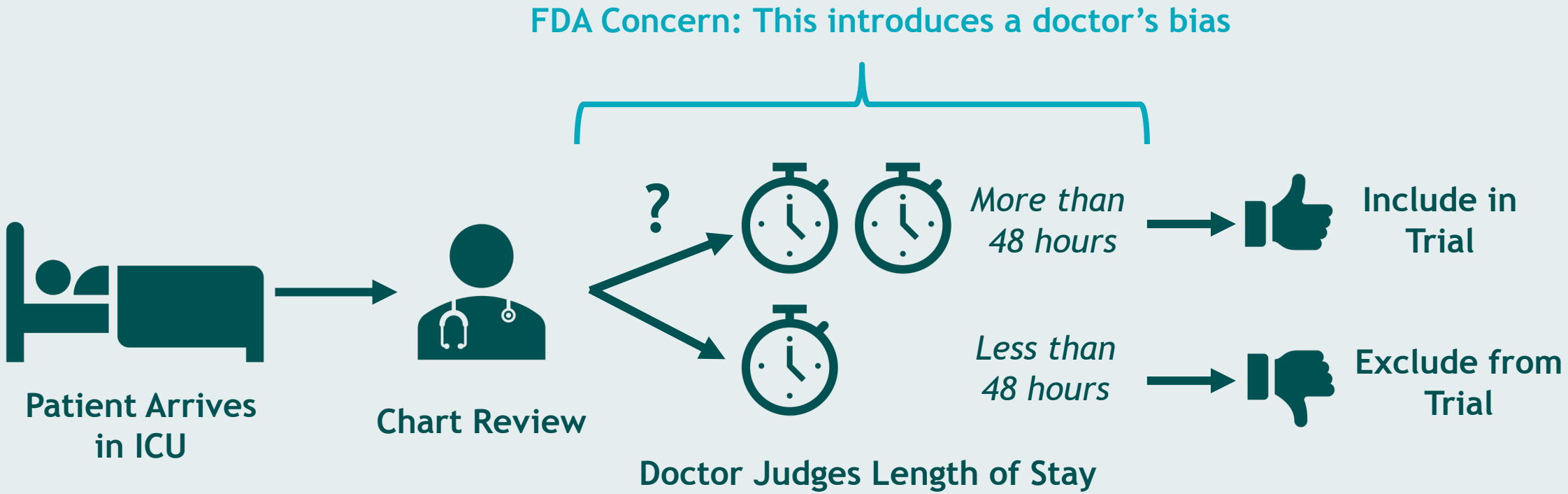
From the Center for Acute Care Nephrology (A.K., R.K.B., S.L.G.) and the Division of Critical Care (R.K.B.), Cincinnati Children's Hospital Medical Center, Cincinnati; Sidra Medical and Research Center, Doha, Qatar (A.K.); and the Department of Critical Care Medicine, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Canada (S.M.B.). Address reprint requests to Dr. Goldstein at the Center for Acute Care Nephrology, Cincinnati Children's Hospital Medical Center, 3333 Burnet Ave., MLC 7022, Cincinnati, OH 45229, or at stuart.goldstein@cchmc.org.

*A complete list of investigators in the Assessment of Worldwide Acute Kidney Injury, Renal Angina, and Epidemiology (AWARE) study is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on November 18, 2016, at NEJM.org.

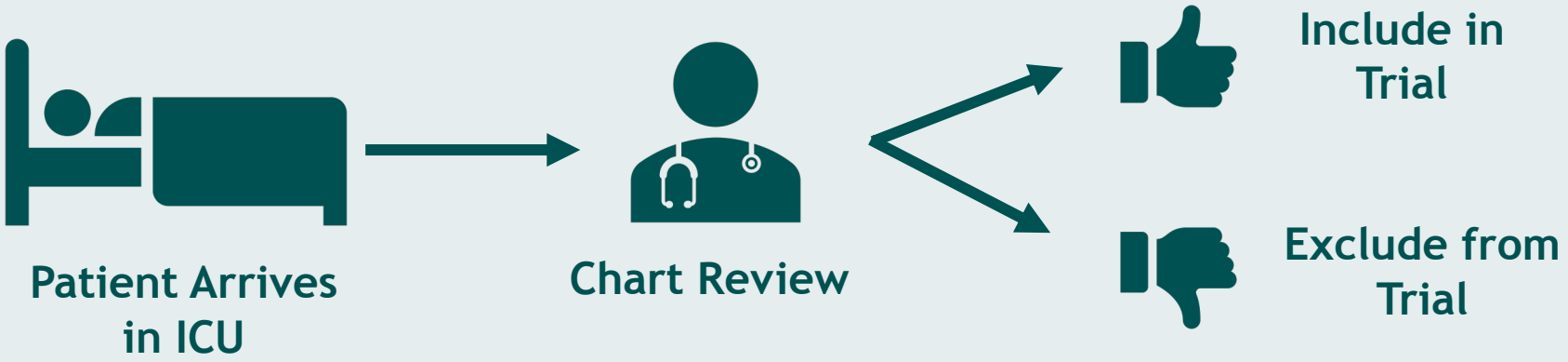
DOI: 10.1056/NEJMoa1611391

AWARE Study Design



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



2020 milestones

Targeted 2020 Milestones

- Commence and finalize collection of additional patient data for pediatric FDA application of The NGAL Test
- Obtain FDA approval of The NGAL Test for pediatrics
- Collect supplementary data to support submission of adult application for The NGAL Test
- Review new opportunities for NGAL and BioPorto's antibody library; define a pipeline of targeted assays and biomarkers
- Grow total revenue by 10%

Financial Projections for 2020

Revenue

Approx. DKK 30m

EBIT loss

Approx. DKK 73m

Focus on collection of additional data for FDA clearance of The NGAL Test and growth in NGAL revenues in 2020. No FDA cleared sales of The NGAL Test included in guidance.

Financial calendar 2020

May 7, 2020	Q1 2020 Results
August 19, 2020	Q2 2020 Results
November 18, 2020	Q3 2020 Results

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