

# Interim Report, Q3 2019

November 21, 2019



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# Forward-Looking Statements

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# Agenda

- 01. Update NGAL Pediatrics
- 02. NGAL Awareness
- 03. Financials Q3 2019
- 04. Acute Kidney Injury
- 05. The NGAL Test
- 06. Addressable Market
- 07. About BioPorto



# Highlights of Q3 2019

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- BioPorto to provide additional patient information for pediatric application for US regulatory clearance of The NGAL Test™
- The NGAL Test continues to deliver strong growth in the US - US sales up 29% in Q3 YoY
- Strong support for NGAL at ASN
- Sale of antibodies remained positively affected by higher bulk orders
- FY2019 guidance revised



# 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



Q2-3 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

- 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

Direct sales of FDA cleared test



# Pediatric FDA application process to offer insight into adult

## Pediatrics



1 in 4  
critically ill children  
affected with AKI<sup>2</sup>

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<sup>1</sup>

Predict AKI Risk in  
Intensive Care Setting

- Plasma sample
- Predict Stage 2/3 AKI

Ongoing enrollment of patients  
for FDA clinical study

## 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

# AWARE Study Design

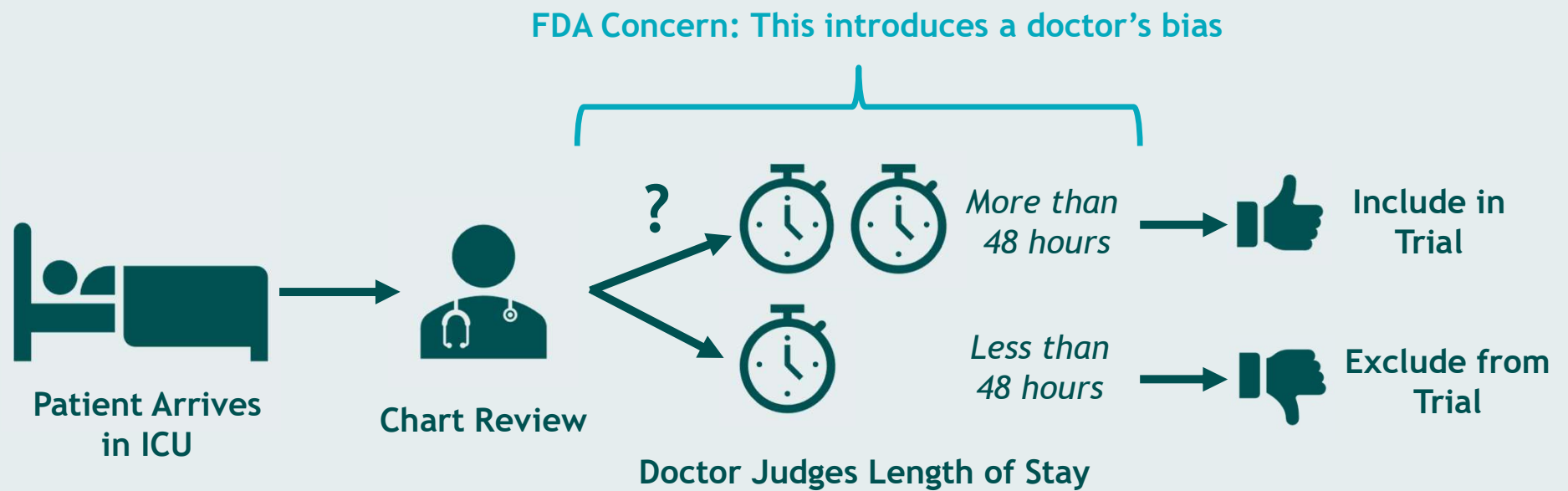
- Goal of the AWARE study was to select patients who were sicker and therefore more at risk of Acute Kidney Injury (AKI)
- They only included patients who the doctor judged would still be in the intensive care unit (ICU) 48 hours after admission
- Our product claim has to mirror the data submitted, and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





The FDA Challenge

# AWARE Study Design





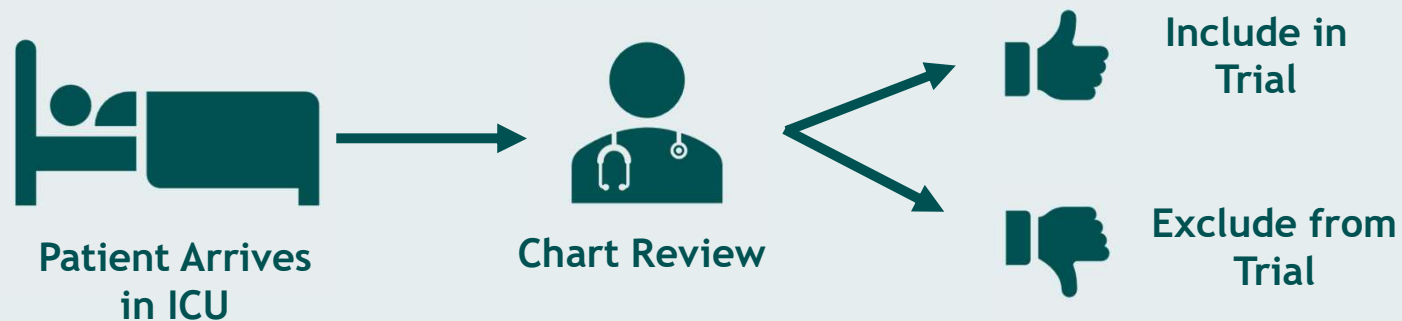


*Next Steps*

## Additional Data Collection

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





# NGAL at Kidney Week 2019

- In November, BioPorto participated on world's premier nephrology meeting, called Kidney Week, arranged by the American Society of Nephrology in Washington D.C.
- Consistent interest for NGAL as an early biomarker for AKI in critically ill patients among attendees
- NGAL was highlighted in two oral presentations, sixteen posters and abstracts, as well as in many discussions with thought leaders



NGAL is well researched; over 2,000 peer-review publications in last decade



## Substantial KOL Support



**Dr. Peter McCullough**  
*Baylor*

“The incorporation of a structural biomarker indicating active kidney damage, such as NGAL, will greatly enhance our understanding of AKI/CKD and allow us to devise prevention and management strategies.”



**Dr. Jonathan Barash**  
*Columbia*

“The use of NGAL in patients with elevated serum creatinine levels provides valuable clinical information to identify patients more likely to have sustained AKI.”



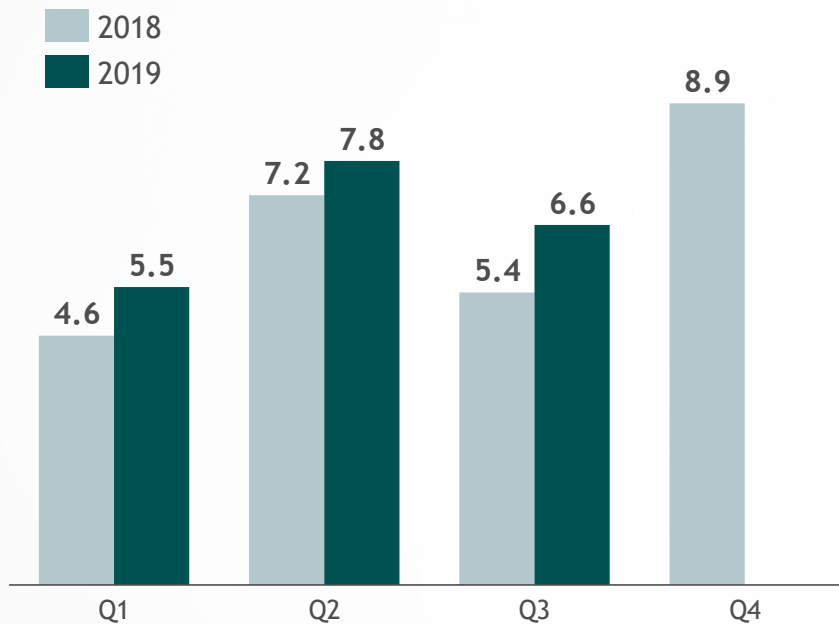
**Dr. Prasad Devarajan**  
*Cincinnati Children's*

“At CCH we firmly believe that the implementation of NGAL as an early predictive biomarker of AKI severity after cardiopulmonary bypass surgery in our pediatric patients has significant clinical impact.”

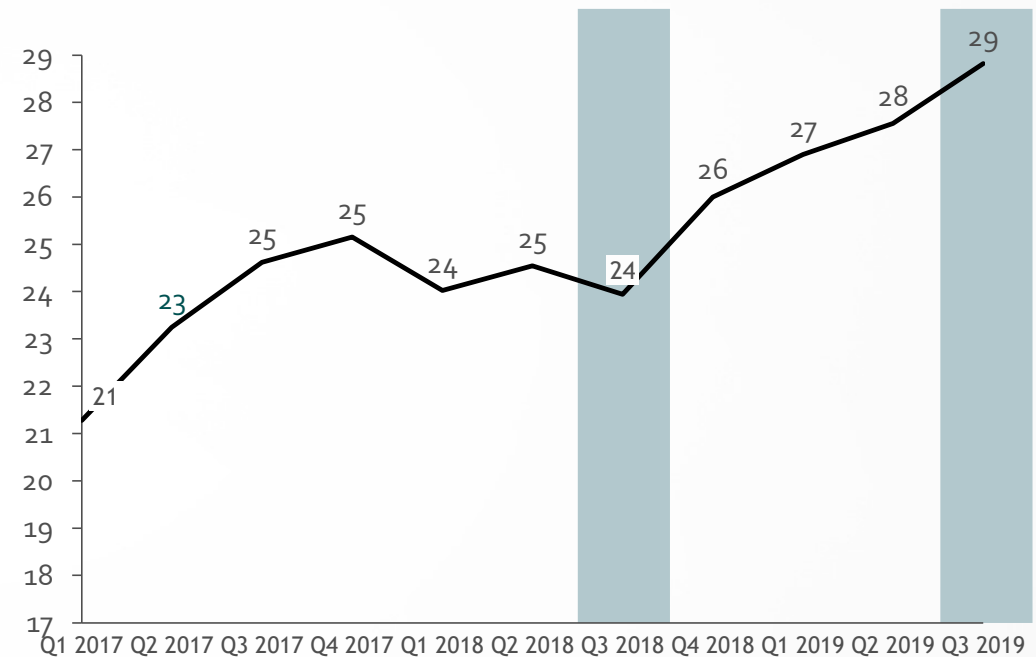


# Growth continues - Q3 2019 revenue up 29% YoY

Revenue by Quarter (DKKm)



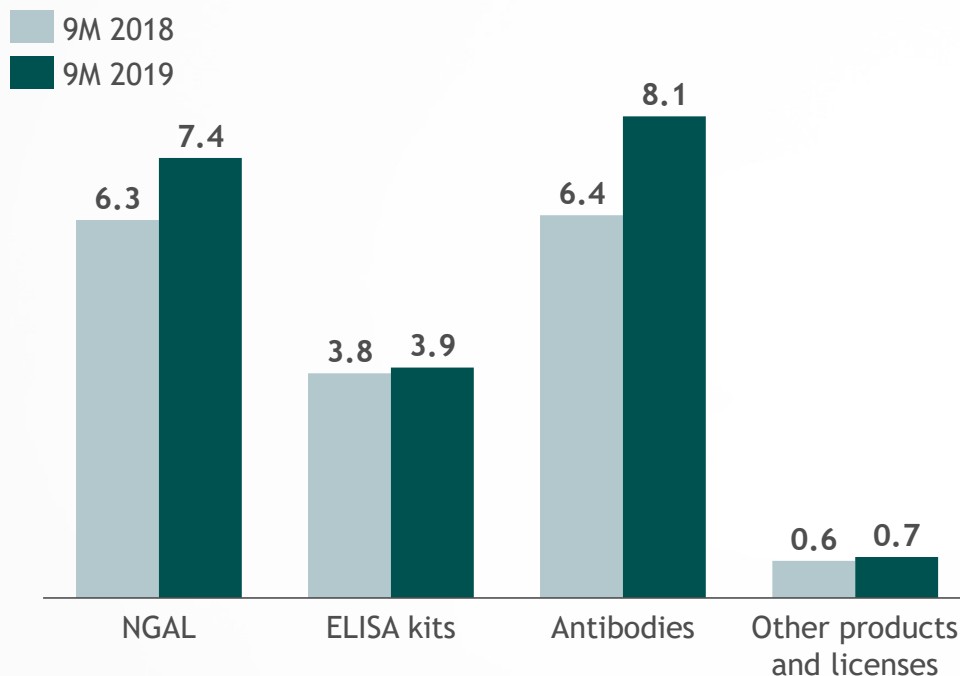
Revenue by Quarter (LTM, DKKm)



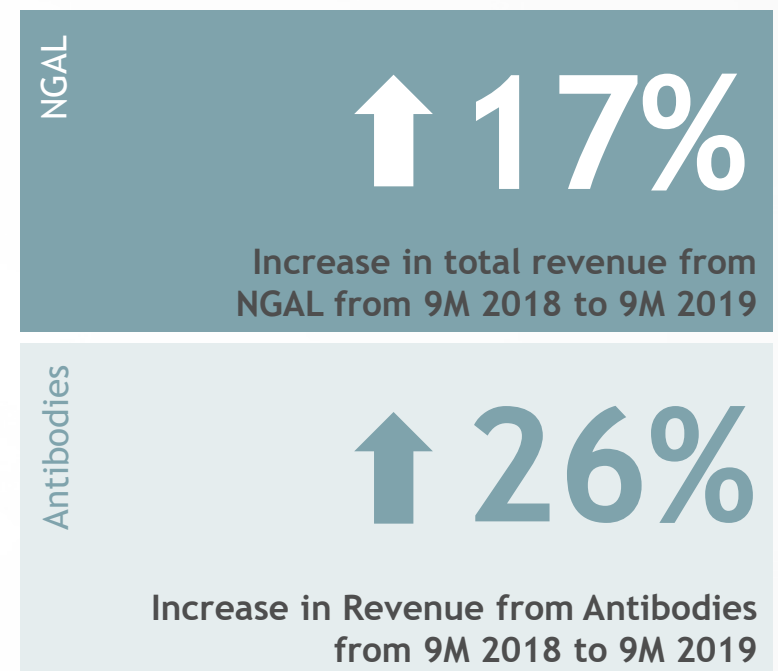


# Increasing RUO sales and continued solid antibody revenue development

## Revenue by Product Category (DKKm)



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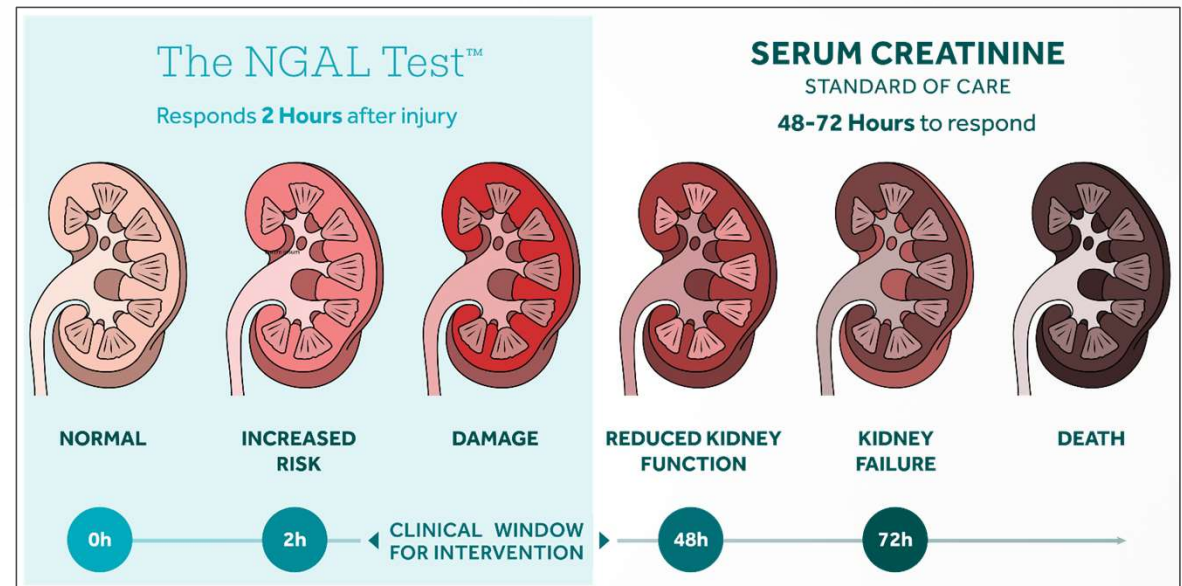




## Standard of Care is Slow and Non-Specific

The NGAL Test is a tool to aid in the risk assessment of AKI in critically ill patients.

As a marker that responds within 2 hours of kidney injury, NGAL can provide a faster assessment of AKI risk - two to three days faster than serum creatinine - and is specific to kidney injury.





## *AKI management challenges*

# Creatinine is delayed and non-specific

### Delayed and dampened

Serum creatinine (sCr) shows a marked delay following kidney injury

- sCr peaks **48-72 hours after** kidney injury
- **>50% of kidney function** can be lost due to an acute insult without any change in sCr

### Non-specific for AKI

A marker of glomerular filtration, sCr cannot differentiate structural AKI from volume-responsive pre-renal azotemia<sup>1</sup>

- As a functional marker, sCr is affected by fluid overload
- **21%** of biopsy-proven cases of AKI did not meet KDIGO sCr-based definition<sup>2</sup>
- **43%** of patients with AKI using NGAL would have been classified as non-AKI with sCr alone<sup>3</sup>

### Influenced by non-renal factors

Serum creatinine levels are influenced by factors independent of kidney structure or function:

- Muscle mass
- Nutritional status
- Age
- Gender



Early identification of AKI risk

# NGAL Biomarker Integrated with Creatinine

	No Injury	Structural Injury	
No Functional Change	<div><div>⊖ NGAL</div><div>⊖ Creatinine</div></div> <div>NORMAL</div>	<div><div>⊕ NGAL</div><div>⊖ Creatinine</div></div> <div>SUBCLINICAL AKI VALUE OF NGAL ⊕ Identifying risk of AKI early increases vigilance, may enable more rapid interventions, such as fluid management and Rx decisions</div>	<b>Cause:</b> AKI due to tubular damage <b>Initiate:</b> Early patient risk stratification, consult KDIGO-based management guidelines
Functional Change	<div><div>⊖ NGAL</div><div>⊕ Creatinine</div></div> <div>REVERSIBLE, FUNCTIONAL AKI VALUE OF NGAL ⊖ Provides more flexibility in fluid management decisions. May inform clinical decision making leading to improved use of hospital resources.</div>	<div><div>⊕ NGAL</div><div>⊕ Creatinine</div></div> <div>DAMAGE ASSOCIATED AKI VALUE OF NGAL ⊕ Rising 2-3 days faster than sCr, NGAL provides early risk assessment of Stage 2/3 AKI and increased odds of needing RRT</div>	

**Cause:** Renal hypoperfusion/volume depletion  
**Initiate:** Volume restoration/ hemodynamic stabilization

Adapted from: Murray PT, Mehta RL, Shaw A, et al. Potential use of biomarkers in acute kidney injury: report and summary of recommendations from the 10th Acute Dialysis Quality Initiative consensus conference. *Kidney Int.* 2014;85(3):513-521 and Stanski N, Menon S, Goldstein SL, Basu RJ. Integration of urinary neutrophil gelatinase-associated lipocalin with serum creatinine delineates acute kidney injury phenotypes in critically ill children. *Journal Critical Care.* 2019;53:1-7.





Clinical utility of NGAL biomarker

## Identify Specific AKI Phenotypes

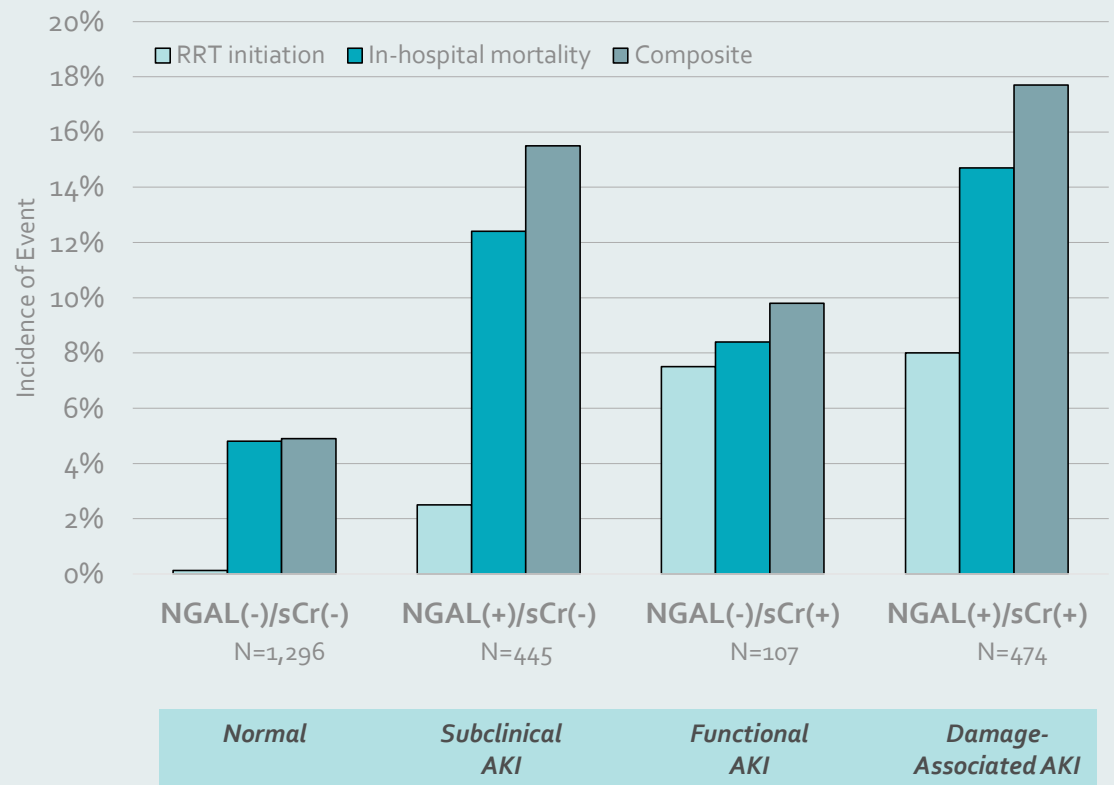
This 2011 multicenter pooled analysis of prospective studies evaluated data from 2,322 critically ill adults from 10 prospective observational studies of NGAL showed:

***“In the absence of diagnostic increases in serum creatinine, NGAL detects patients with likely subclinical AKI who have an increased risk of adverse outcomes.”***

Haase M et al. The outcome of neutrophil gelatinase-associated lipocalin-positive subclinical acute kidney injury: a multicenter pooled analysis of prospective studies. *J Am Coll Cardiol.* 2011;57(17):1752–1761.

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Incidence of RRT & Mortality by Biomarker Status





*The NGAL Test\**

# Benefits Across the Healthcare Ecosystem



## Patients

- Faster identification of AKI risk
- Earlier interventions to limit kidney damage
- Fewer missed cases of AKI



## Providers

- Better triage decisions
- Avoid unnecessary tests/therapies
- Faster feedback on interventions
- Avoid false negative diagnoses



## Core Lab

- Runs on automated analyzers
- Fast processing time, simple set up
- Matrix flexibility (blood or urine)
- Low cost per test (\$20)



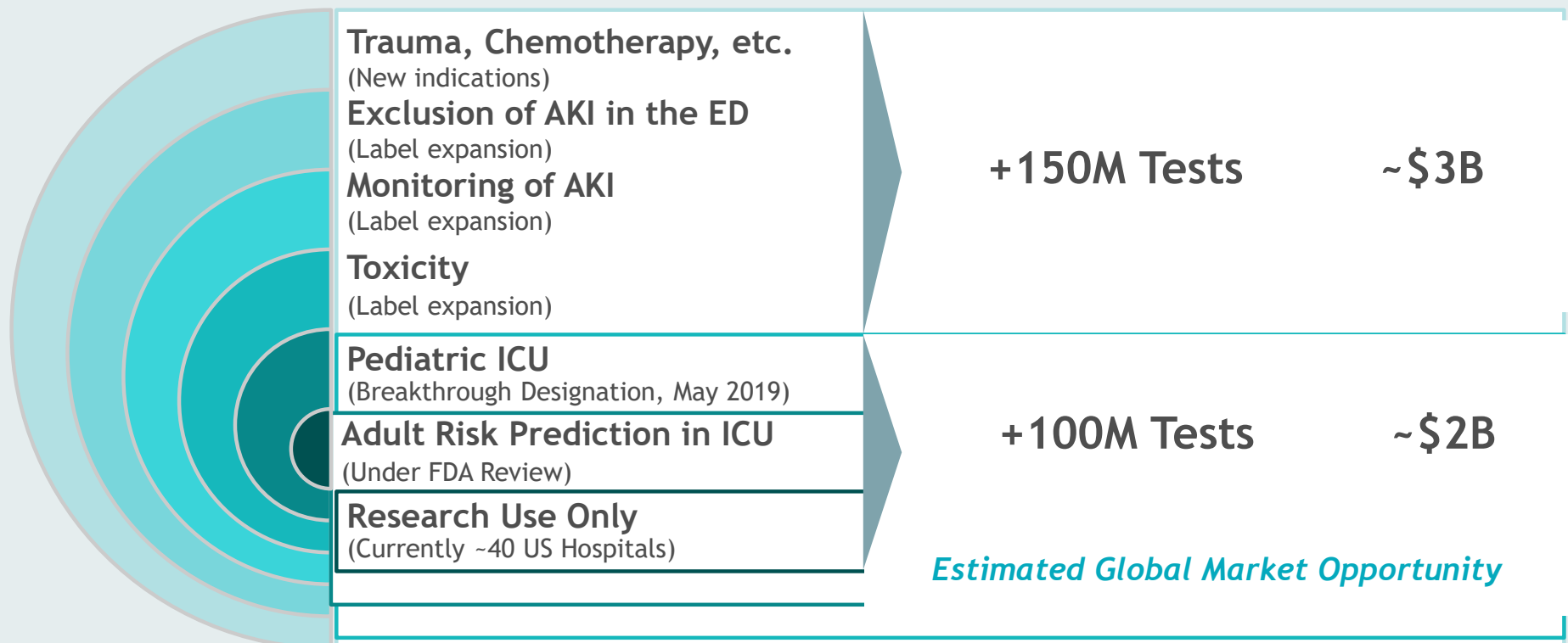
## Hospitals

- Reduce morbidity and mortality
- Fewer patients needing RRT
- Shorter lengths of stay
- Reduced cost per patient



*The NGAL Test\**

# Addresses a Significant Unmet Need





*Clinical, regulatory and commercial*

# Targeted 2019 Milestones

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- Commence collection of additional patient data for FDA application of The NGAL Test for pediatrics
- Supplementary data to FDA to support clearance of The NGAL Test in adults
- Review new opportunities for NGAL and antibody library; define pipeline of targeted assays and biomarkers
- Build RUO sales and awareness of AKI and NGAL in the US ahead of launch





# Financial Projections for 2019

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Revenue

**Approx.  
DKK29m**

EBIT loss

**Approx.  
DKK70m**



# Investment Highlights

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## Platforms

- Antibody -> Assay -> Actionable Biomarker Repeatable development path
- Robust academic & research relationships
- \$4m revenues in 2018

## 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

- Two FDA Applications pending
- Proprietary NGAL Test with extensive studies
- Experienced international management team

# Financial calendar 2020

February 26, 2020

Annual Report 2019

May 7, 2020

Q1 2020 Results

August 19, 2020

Q2 2020 Results

November 18, 2020

Q3 2020 Results

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# About BioPorto

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*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 in Chicago, and is listed on the NASDAQ Copenhagen stock exchange [CPH:BIOPOR].*



## Antibody Library

- 150+ Abs in significant disease states
- Steady source of revenue (275+ customers in 40+ countries)
- Insight into high value diagnostic targets



## Assay Development

- Technical expertise: ELISA kits, automated assays & rapids
- Partnerships with key academic researchers & institutions
- Production/scale up partnerships



## Actionable Biomarkers

- Novel markers that address unmet clinical needs
- Thought leader supported, IP protected
- Expertise & partnerships needed to drive awareness/education