Interim Report, Q3 2019

November 21, 2019





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Agenda

- o1. Update NGAL Pediatrics
- 02. NGAL Awareness
- o3. Financials Q3 2019
- o4. Acute Kidney Injury
- o₅. The NGAL Test
- o6. Addressable Market
- o7. About BioPorto



Highlights of Q3 2019

- 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



US Regulatory Update



Further Patient Data to be Collected for Application



Oct. 2018

Retrospective study for risk assessment in pediatrics initiated



Q2-3 2019

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



Q2 2020

Enhanced FDA submission planned

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

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)

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

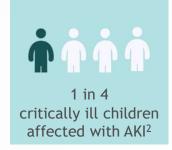
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Pediatric FDA application process to offer insight into adult

Pediatrics

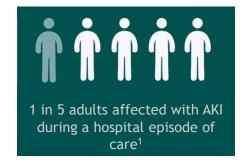


Predict AKI Risk in Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

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

Adults



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

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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.



AWARE Study Design

- Goal of the AWARE study was to select patien ts who were sicker and therefore more at ris k 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 sub mitted, and FDA asked, "how can a doctor k now who will be in the ICU after two days?"

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 From the Center for Acute Care Nephrol injury have been described in single-center and retrospective studies. We conducted a multinational, prospective study involving patients admitted to pediatric ducted a multinational, prospective study involving patients admitted to pediatric den's Hospital Medical Center, Cincinnati; intensive care units to define the incremental risk of death and complications. associated with severe acute kidney injury.

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 Green Rephrology, Cincinnati Children's 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 stuart.goldstein@cchmc.org. 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.

A total of 4683 patients were evaluated; acute kidney injury developed in 1261 pa- This article was published on November 18, tients (26.9%; 95% confidence interval [CI], 25.6 to 28.2), and severe acute kidney 2016, at NEJM.org. injury developed in 543 patients (11.6%; 95% Cl, 10.7 to 12.5). Severe acute kid- DOI: 10.1055/NEJMoa1611391 ney injury conferred an increased risk of death by day 28 after adjustment for 16 Coppight © 2025 Manuschamts Medical Society 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 renalreplacement 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.

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 Clinical Trials.gov number, NCT01987921.)

of Critical Care (R.K.B.), Cincinnati Chil-Qatar (A.K.); and the Department of Crit-ical Care Medicine, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Canada (S.M.B.). Address reprint requests Hospital Medical Center, 3333 Burnet Ave., MLC 7022, Cincinnati, OH 45229, or at

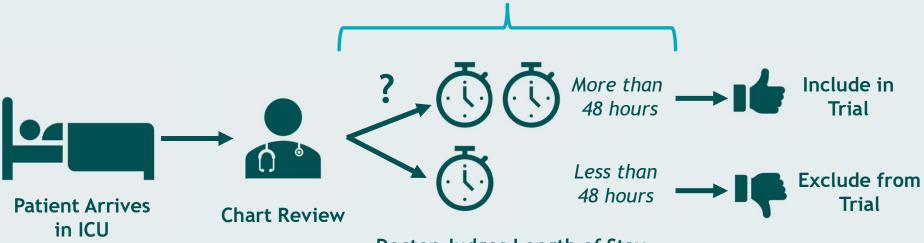
*A complete list of investigators in the Assessment of Worldwide Acute Kidney Injury, Renal Angina, and Epidemiology (AWARE) study is provided in the Supple-mentary Appendix, available at NEJM.org.





AWARE Study Design

FDA Concern: This introduces a doctor's bias



Doctor Judges Length of Stay

Next Steps



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





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







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."



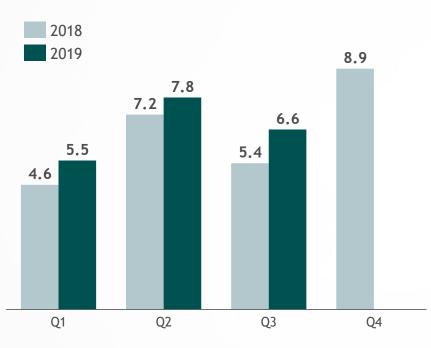
Dr. Prasad Devarajan Cincinnati Children's

"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."

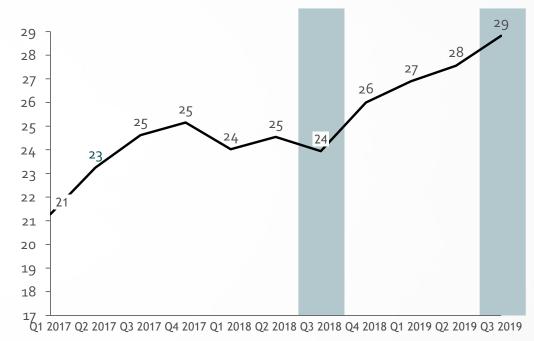


Growth continues - Q3 2019 revenue up 29% YoY

Revenue by Quarter (DKKm)



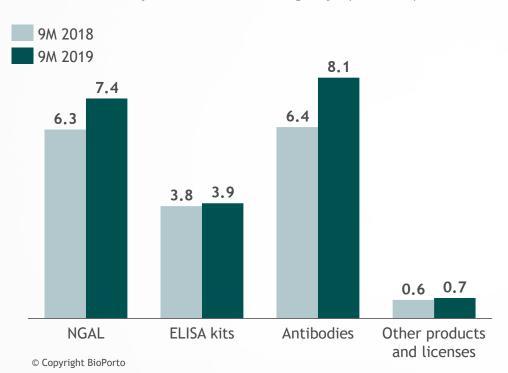
Revenue by Quarter (LTM, DKKm)

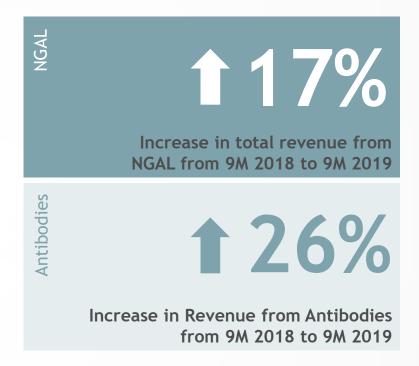




Increasing RUO sales and continued solid antibody revenue development

Revenue by Product Category (DKKm)





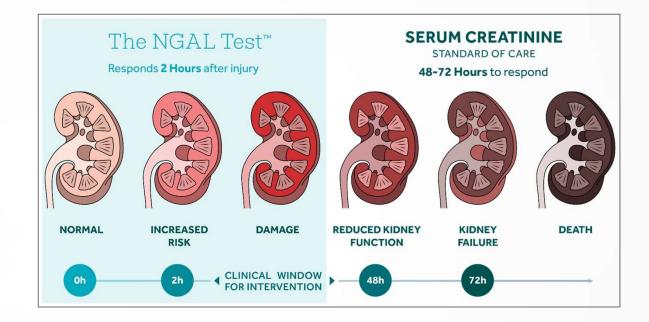
AKI Assessment Tools



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 azotemia¹

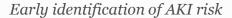
- As a functional marker, sCr is affected by fluid overload
- 21% of biopsy-proven cases of AKI did not meet KDIGO sCr-based definition²
- 43% of patients with AKI using NGAL would have been classified as non-AKI with sCr alone³

Influenced by non-renal factors

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

- Muscle mass
- Nutritional status
- Age
- Gender

¹⁾ Ciccia E, Devarajan P. Pediatric acute kidney injury: prevalence, impact and management challenges. Int J Nephrol Renovasc Dis. 2017;10:77–84.
2) Chu R, et al. Assessment of KDIGO definitions in patients with histopathologic evidence of acute renal disease. *Clin J Am Soc Nephrol*. 2014; 9(7) 1175-1182. 3) Khawaja S, et al. The utility of neutrophil gelatinase-associated Lipocalin as a marker of acute kidney injury in critically ill patients. *Biomark Res*. 2019;7:4.





NGAL Biomarker Integrated with Creatinine

		No Injury		Structural Injury		
	No Functional Change	NGALCreatinine	NORMAL	+ NGAL - Creatinine	SUBCLINICAL AKI VALUE OF NGAL ⊕ Identifying risk of AKI early increases vigilance, may enable more rapid interventions, such as fluid management and Rx decisions	Cause: AKI due to tubular damage Initiate: Early patient risk stratification, consult KDIGO-based management guidelines
	Functional Change	NGALCreatinine	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.	+ NGAL+ Creatinine	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	

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

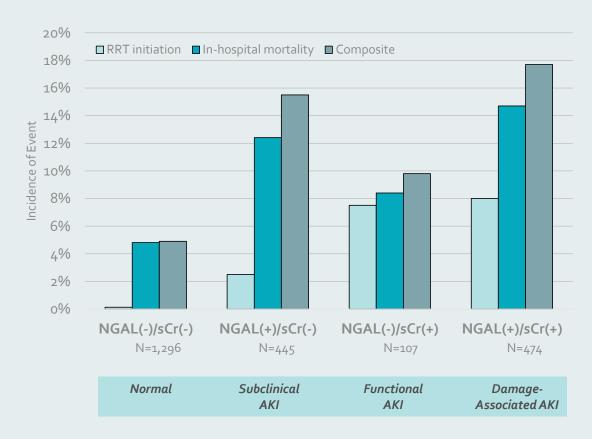
This 2011 multicenter pooled analysis of prospective studies evaluated data from 2,322 critically ill adults from 10 prospective observational studies of NGAL showed:

"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.



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 is pending US FDA 510(K) clearance.

The NGAL Test*



Addresses a Significant Unmet Need

Trauma, Chemotherapy, etc. (New indications) Exclusion of AKI in the ED (Label expansion) +150M Tests ~\$3B Monitoring of AKI (Label expansion) **Toxicity** (Label expansion) Pediatric ICU (Breakthrough Designation, May 2019) ~\$2B +100M Tests Adult Risk Prediction in ICU (Under FDA Review) Research Use Only (Currently ~40 US Hospitals) **Estimated Global Market Opportunity**

^{*}The NGAL Test is pending US FDA 510(K) clearance.

Clinical, regulatory and commercial



Targeted 2019 Milestones

- 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

Approx. DKK29m

Approx.
DKK70m

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Investment Highlights

Platforms

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

Commercialization

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

Broad Target Market

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

Execution

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

Financial calendar 2020

February 26, 2020

May 7, 2020

August 19, 2020

November 18, 2020

Annual Report 2019

Q1 2020 Results

Q2 2020 Results

Q3 2020 Results

Contact:
Ole Larsen (CFO)
ol@bioporto.com







About BioPorto

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