



BIOPORTO A/S

ANNUAL REPORT 2018

FEBRUARY 22, 2019



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AGENDA

- **Highlights from 2018**
- 2018 financial result
- Business development of The NGAL Test™
- 2019 milestones and financial guidance



Highlights of 2018

- **Revenue from The NGAL Test™ up 43% - total revenue of DKK 26m**
 - Strong increase in revenue from The NGAL Test™ driven by solid RUO sales in U.S. (up by 80% YoY)
 - Antibody and ELISA kits revenue down due to market conditions and lower bulk orders
- **Two separate FDA applications for The NGAL Test™ in process**
 - Application for adult plasma-based test with expected regulatory clearance in 2H 2019 and application for urine-based test in children will be submitted in 1H 2019
- **Paving the road for U.S. post-clearance market entry of The NGAL Test™ in focus**
 - Build-up in U.S. of awareness and knowledge continues with strong focus
 - High interest to use NGAL as biomarker in drug development and in new indications
 - Strong increase in sales of The NGAL Test™ will drive revenue to DKK 40m in 2019 (+50% YoY growth)

AGENDA

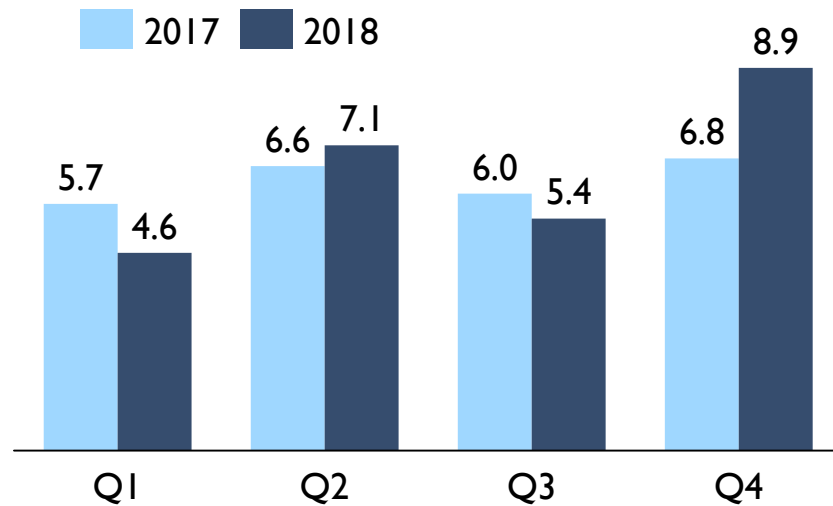
- Highlights from 2018
- **2018 financial result**
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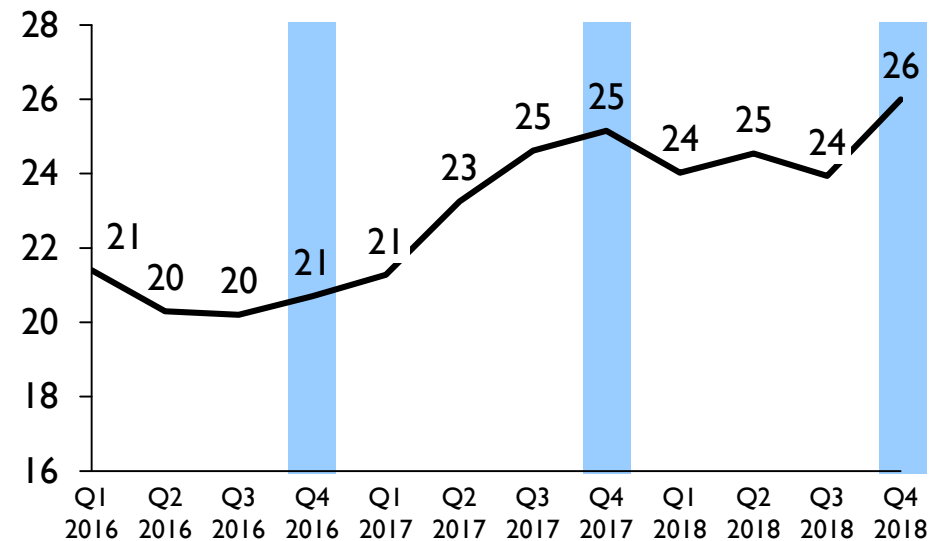
Modest growth after solid Q4 2018

- Revenue up 31% in Q4 2018 driven by strong performance of The NGAL Test™
- For FY2018, revenue totaled DKK 26m – an increase of 3.4% over 2017
 - Guidance of DKK 30m – difference due to unfavorable market conditions and fewer bulk orders in antibodies and ELISA kits

Quarterly revenue (DKKm)

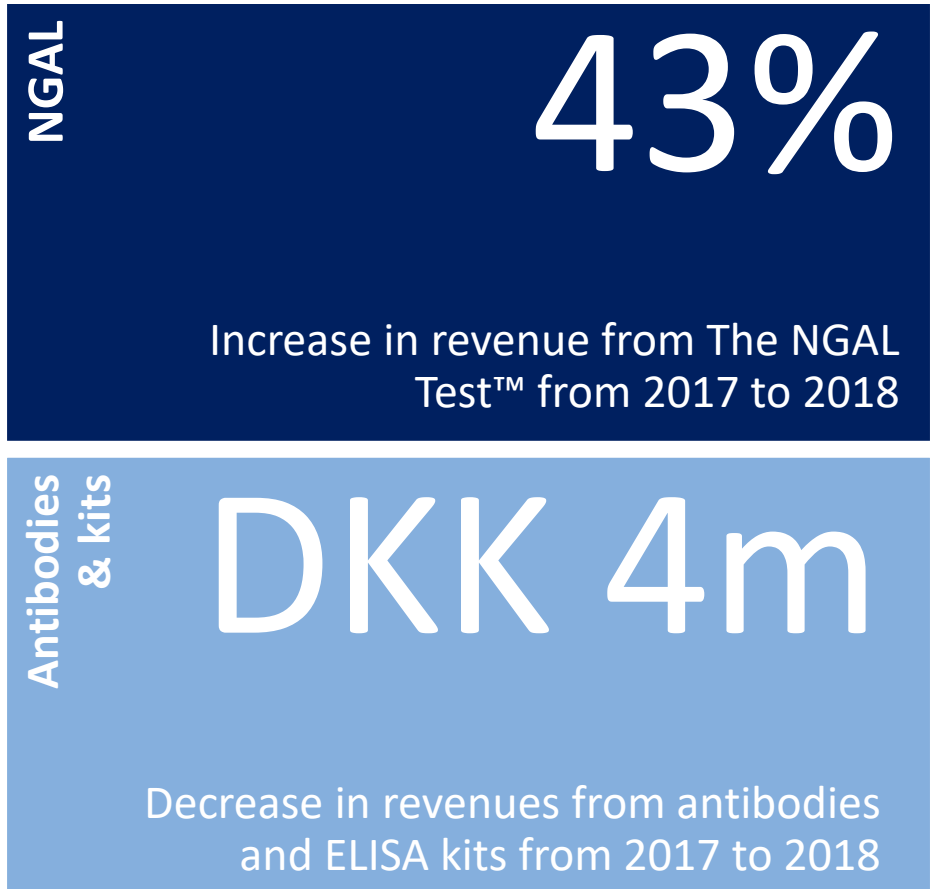
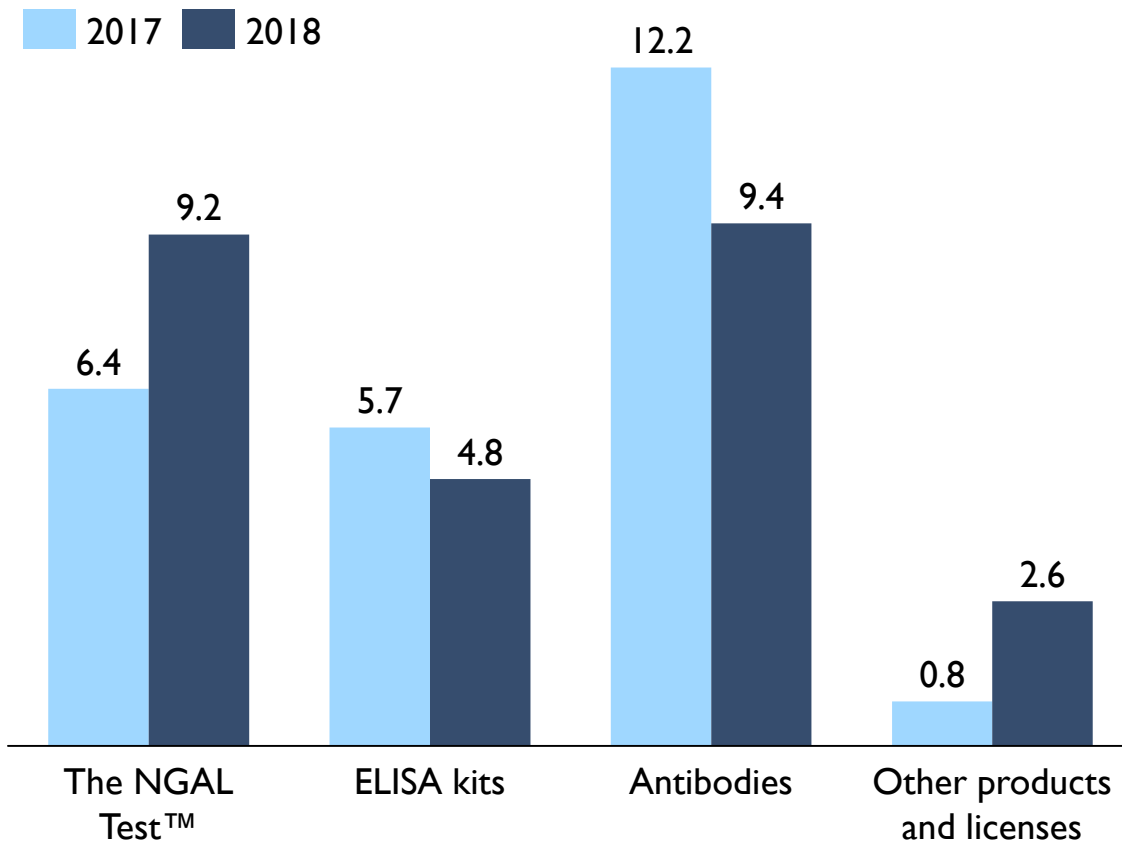


Revenue (DKKm, LTM)



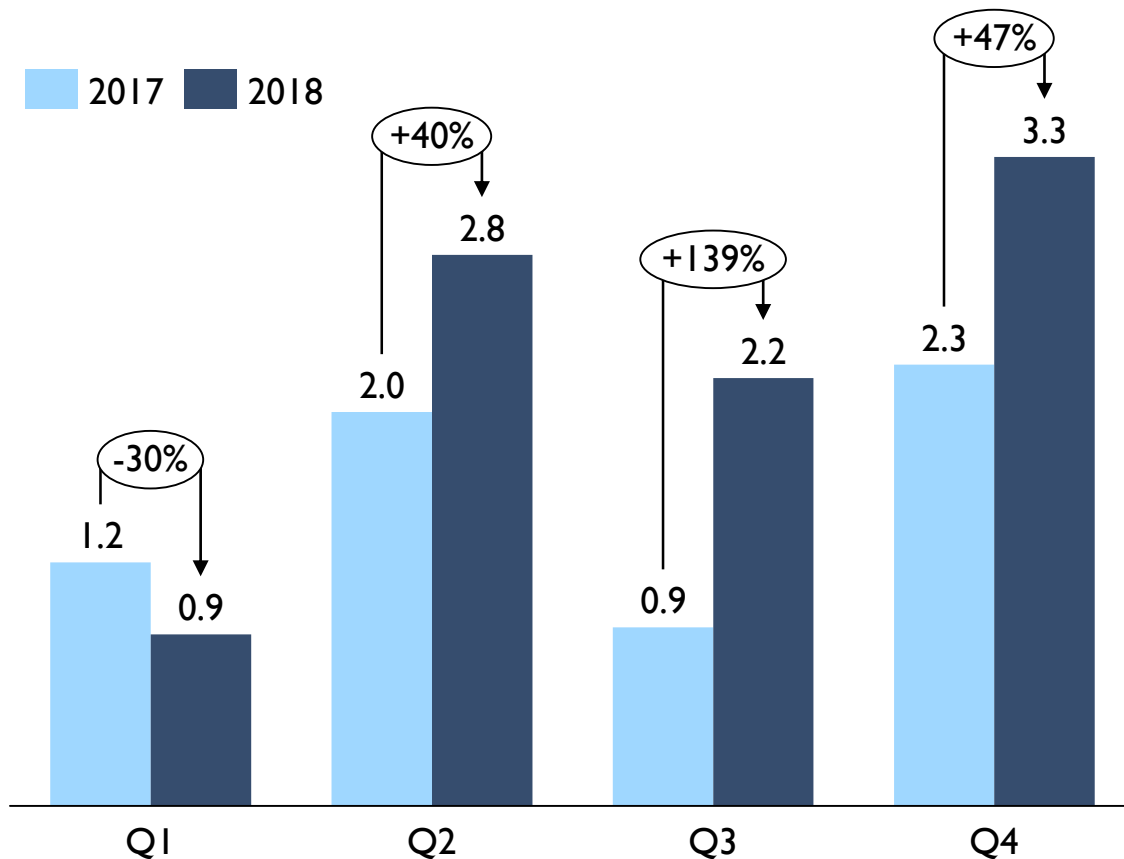
Strong increase in NGAL sales offset by decrease in antibodies/ELISA kits

Revenue by product category (DKKm)



Momentum in revenue from The NGAL Test™ driven by ROU sales in U.S.

Quarterly revenue from The NGAL Test™ (DKKm)



U.S. sales

80%

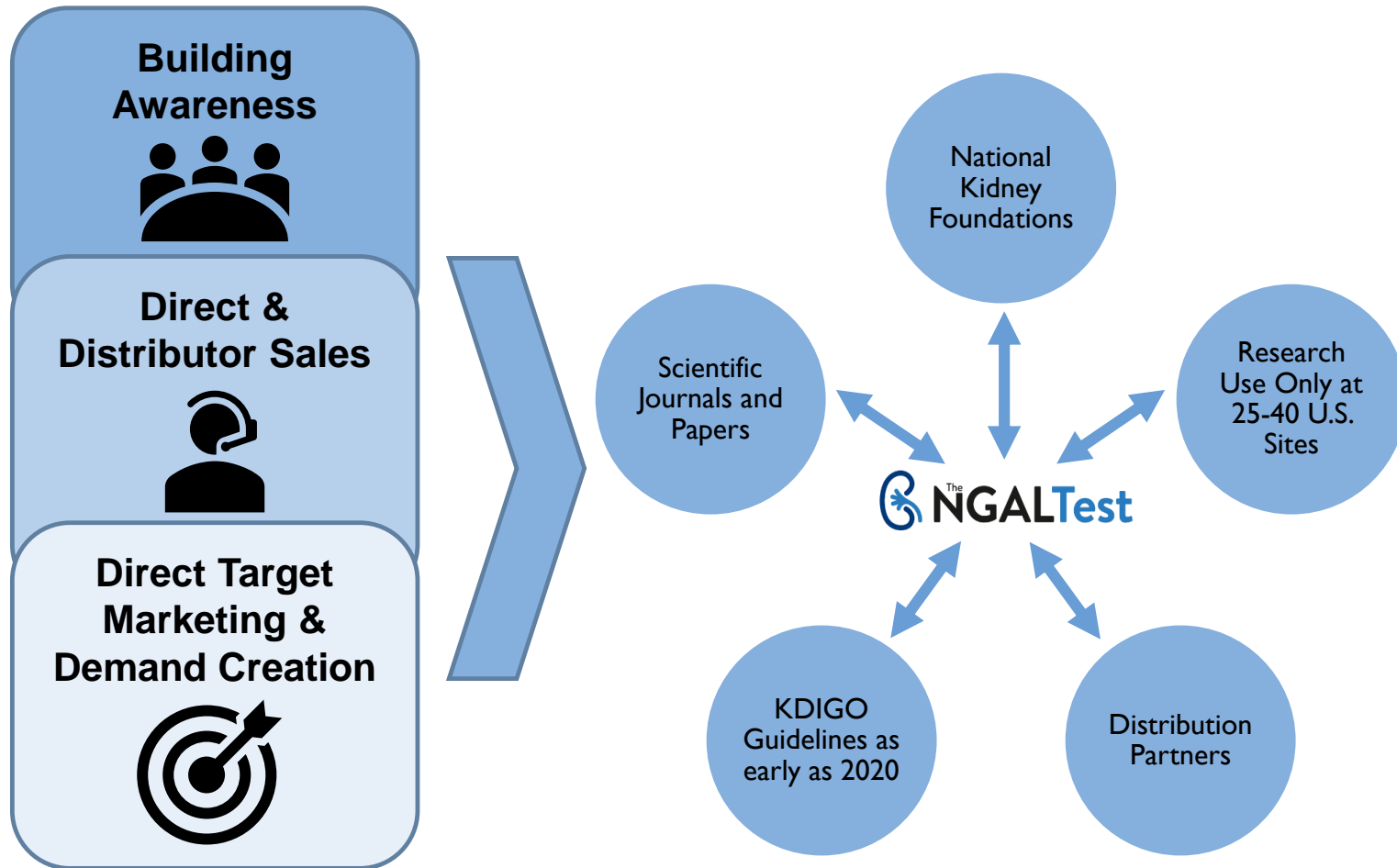
Increase in ROU sales of The NGAL Test™ in the U.S. from 2017 to 2018

Rest of the World

18%

Increase in sales of The NGAL Test™ in ROW from 2017 to 2018

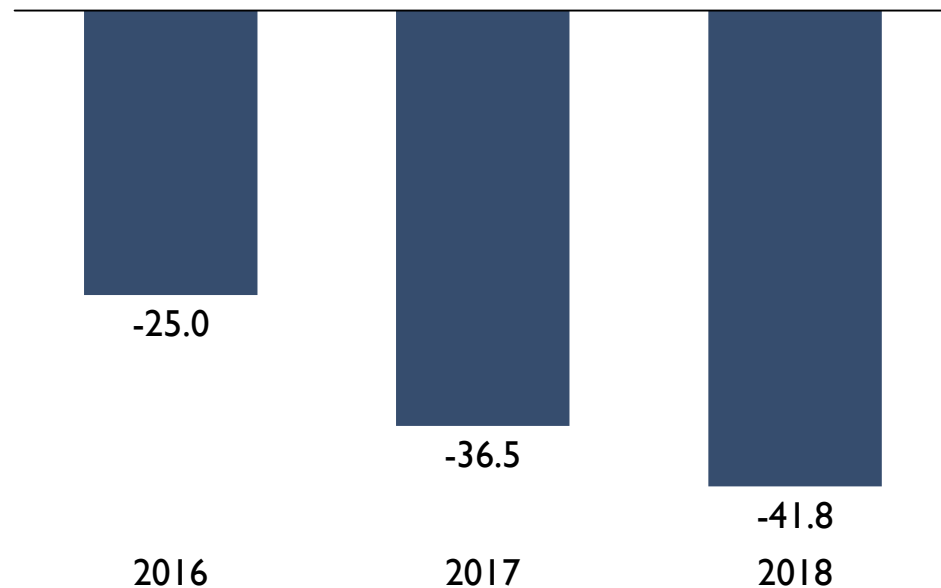
Allocation of considerably resources to U.S. market awareness of NGAL



- U.S. performance result of investment in past years to build awareness of medical need for NGAL as biomarker for safe and efficient diagnosis of AKI.
- U.S. focus has been on RUO clinics and engagement with KOL and stakeholders to build knowledge in patient and health care benefits.
- Number of RUO clinics using the test up from approx. 15 in 2017 to 35 end-2018 – will provide solid basis to increase revenues post FDA clearance.

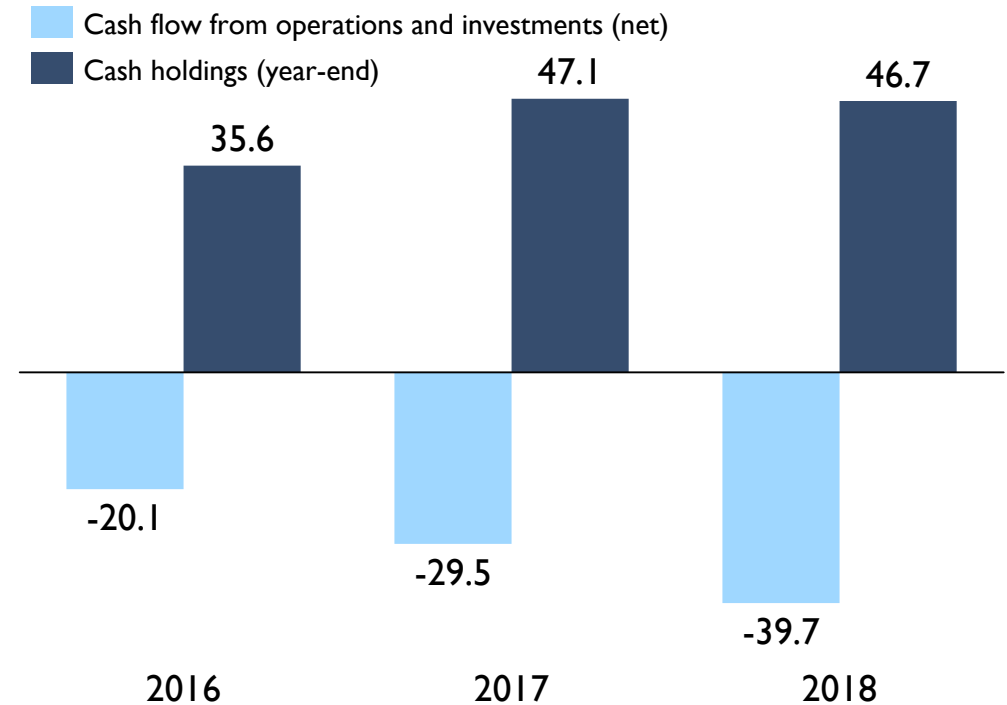
Increased cash burn due to ramp-up of staff and slightly lower GM

EBIT (DKKm)



EBIT effected by higher staff costs, fluctuating exchange rates and changes to product mix.

Cash flow and cash holdings (DKKm)



Solid cash position year-end after successful private placement with DKK 40m in proceeds in Nov. 2018.

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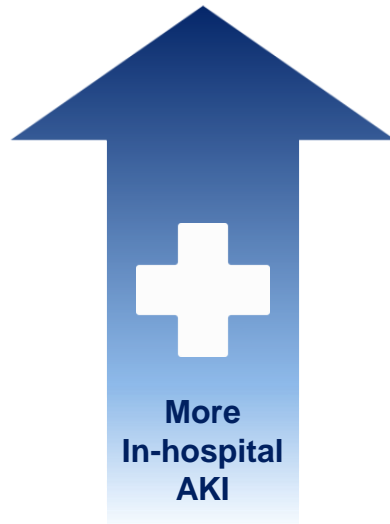
AKI is a Major Public Health Concern

**AKI
in U.S.**

**230% Increase
in 10 Years¹**

**2 Million Deaths
Each Year²**

**\$10 Billion Increase
in U.S. Hospital Costs³**



Why? AKI is common, complex and lacking diagnostic tools to help quickly identify kidney injury and aid clinicians in determining the best treatment to preserve kidney function.



- 1) Increase from 2004-2014 in the rate of AKI hospitalizations among US adults without diabetes. Pavkov ME, Trends in Hospitalizations for Acute Kidney Injury. MMWR Morb Mortal Wkly Rep 2018;67:289–293.
- 2) Murugan R, Kellum JA. Acute kidney injury: what's the prognosis? Nat Rev Nephrol. 2011;7:209–217.
- 3) Chertow G, Burdick E, Honour M, Bonventre J, Bates D. Acute Kidney Injury, Mortality, Length of Stay, and Costs in Hospitalized Patients. J Am Soc Nephrol 16: 3365–3370, 2005.

Strong KOL support for NGAL as mean to improve health care

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

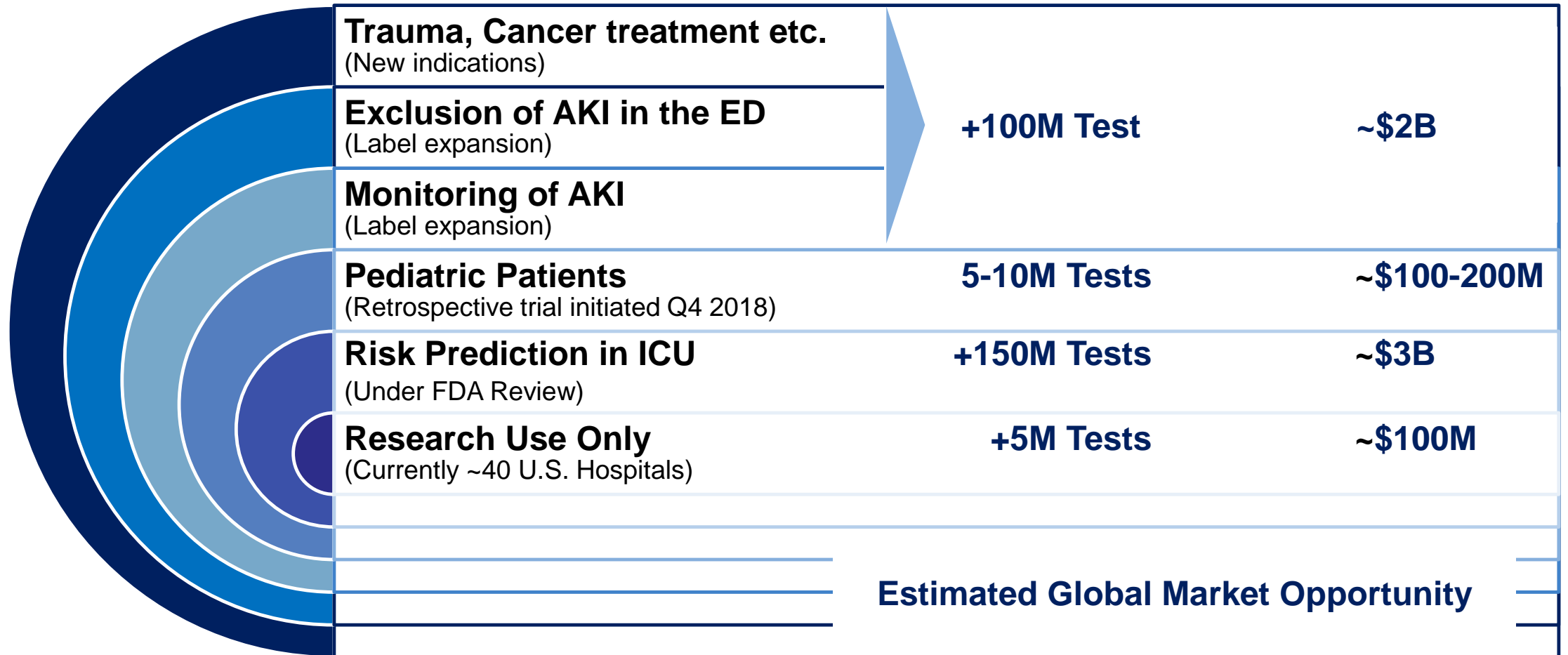
“The use of NGAL in patients with elevated serum creatinine levels provides valuable clinical information to identify patients more likely to have sustained AKI.”

Dr. Prasad Devarajan, Cincinnati Childrens

“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.”



The NGAL Test™ addresses a massive global market



BioPorto submits two separate applications for The NGAL Test™ in 2019

	Adults	Children
Indication	Risk use with AKI	Risk use with AKI
Based on measurements in	Plasma	Urine
Clinical study	Enrolment of up to 200 patients with AKI from 3-5 sites in the U.S.	Retrospective study based on existing US data
Key dates	Expected clearance in 2H 2019	Application expected to be submitted in 1H 2019
Estimated costs in 2019 for study and application	DKK 3.5m	DKK 2.5m

Adult plasma



Additional data with high prevalence to be collected in 2019 to support existing clinical trials

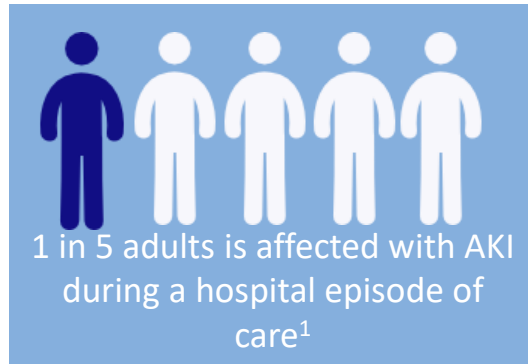
Children urine



Retrospective study for fast and cost efficient process – central testing and validation will allow for fast roll-out to +200 pediatric U.S. hospitals and clinics

Clinical Applications of NGAL

Applications in Adult Populations & Settings



Predict AKI Risk in Intensive Care Setting

- Plasma
- Predict Stage 2 & 3 AKI

FDA clearance expected in 2H 2019

Exclude AKI in Emergency Department

- Plasma
- Rule out AKI to improve triage & care

Will be initiated after FDA clearance of prediction

Monitoring of AKI

- Plasma
- Use NGAL to evaluate efficacy of interventions

Will be initiated after FDA clearance of prediction

Pediatric Indication



Predict AKI Risk in Intensive Care Setting for Pediatrics

- Urine
- Predict Stage 2 & 3 AKI

FDA application expected to be submitted in 1H 2019

“The limitation in AKI detection may be limiting doctors’ abilities to get ahead of injury...”

NGAL is a real-time tool, potentially allowing us to be proactive instead of reactive.”

- Rajit Basu, MD,
Dir. of Research, Critical Care Medicine
Associate Professor of Pediatrics,
Children’s Healthcare of Atlanta

1. Susantitaphong, P et al. World Incidence of AKI: A Meta-Analysis. Clin J Am Soc Nephrol. 2013 Sep;8(9):1482-93.

NGAL Intellectual Property rights further strengthened in 2018

Patents protected until 2024-2028

BioPorto's NGAL Patents			In-licensed NGAL Patents		
<i>Indication</i>	<i>Granted</i>	<i>Pending</i>	<i>Indication</i>	<i>Granted</i>	<i>Pending</i>
NGAL Cutoff	EU, Canada, Australia, S. Korea, China, India, Japan, Singapore, Hong Kong	U.S.	CCH Kidney Dysfunction	U.S.	None
NGAL Exclusion	EU	U.S.	CCH Serum/Plasma	EU, Canada, Australia, Japan	U.S., EU
NGAL Forms	EU	U.S.	CCH Urine	EU, Australia, China, Japan, Mexico, New Zealand	EU, Brazil, Hong Kong
NGAL Trauma	EU, U.S.	U.S.	CCH Chronic	EU	U.S.
NGAL Ratio	EU, U.S.	N/A	CCH Blood	EU	None

Distribution agreement for NGAL with Roche signed in 2018

BioPorto has secured critical distribution agreements with top IVD players to market and sell The NGAL Test



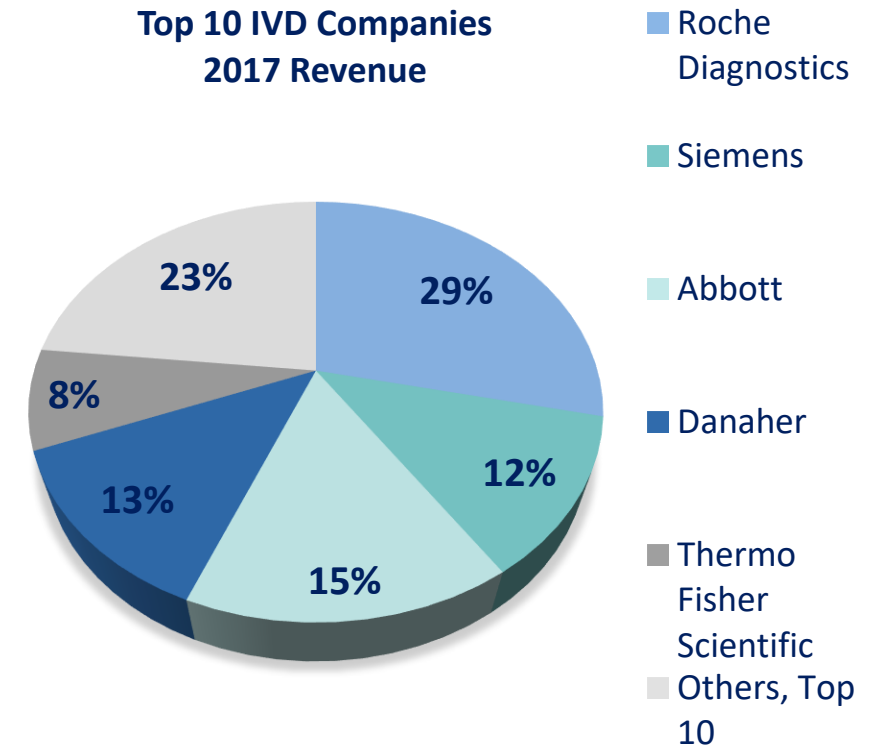
Roche: exclusive global distribution agreement for use of a customized NGAL Test on Cobas c501/c502 systems



Siemens: exclusive global distribution of the NGAL Test on Siemens' BN platforms

Together, BioPortos partners account for an estimated 41% of total revenues of the Top 10 IVD players

Top 10 IVD Companies
2017 Revenue



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Targeted 2019 milestones



Clinical and Regulatory

- Supplementary data to FDA to support initial FDA clearance in adults of The NGAL Test™
- Approval of The NGAL Test™ (plasma) in adults
- Submission of urinary The NGAL Test™ for pediatric population
- Approval of The NGAL Test™ in pediatrics
- Review new opportunities for NGAL and the antibody library to create pipeline of potential new assays and biomarkers



Commercial

- Increase RUO sales and number of customers in U.S.
- Increase awareness of The NGAL Test™ and the NGAL technology
- Strengthen U.S. organization by onboarding U.S. commercial leadership and hire core team of medical liaisons
- Prepare with partners for U.S. launch of The NGAL Test™

Considerably growth in NGAL sales in 2019 will boost revenues

Revenue

DKK 40m

Revenue to increase considerably from increased sales of The NGAL Test™ in U.S. and ROW

Cost for FDA applications

DKK 6m

Expected total cost in 2019 for filing two FDA applications for The NGAL Test™

EBIT loss

DKK 45m

Operating loss at level of 2018 as U.S. organization will be expanded

Underlying assumptions

Guidance for 2019 is based on assumptions of FDA clearance of The NGAL Test™ to adults and children in 2019 and minor decrease in revenue from antibodies (compared to 2018)



BIOPORTO A/S

FINANCIAL CALENDAR 2019

MARCH 18	ANNUAL GENERAL MEETING
MAY 9	Q1 2019 FINANCIAL RESULTS
AUGUST 15	Q2 2019 FINANCIAL RESULTS
NOVEMBER 7	Q3 2019 FINANCIAL RESULTS