



BIOPORTO A/S

INTERIM REPORT, FIRST QUARTER 2019

MAY 9, 2019

Forward-Looking Statements

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AGENDA

- **Highlights Q1 2019**
- Q1 2019 financial result
- Business development of The NGAL Test
- 2019 milestones and financial guidance



Highlights of Q1 2019

- **Revenue from The NGAL Test™ up 111% in US and 44% globally**
 - Strong increase in revenue from The NGAL Test driven by solid RUO sales in U.S.
 - Large bulk orders drive sales of antibodies up while ELISA kits are down due to market conditions
- **On-track with both the pediatric and adult FDA applications for The NGAL Test**
 - Application for urine-based test in children will be submitted in 1H 2019
 - Enrollment for adult plasma-based study initiated – application with expected regulatory clearance in 2H 2019
- **Paving the road for U.S. post-clearance market entry of The NGAL Test in focus**
 - Build-up in U.S. of organization, 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 up by 50% in 2019

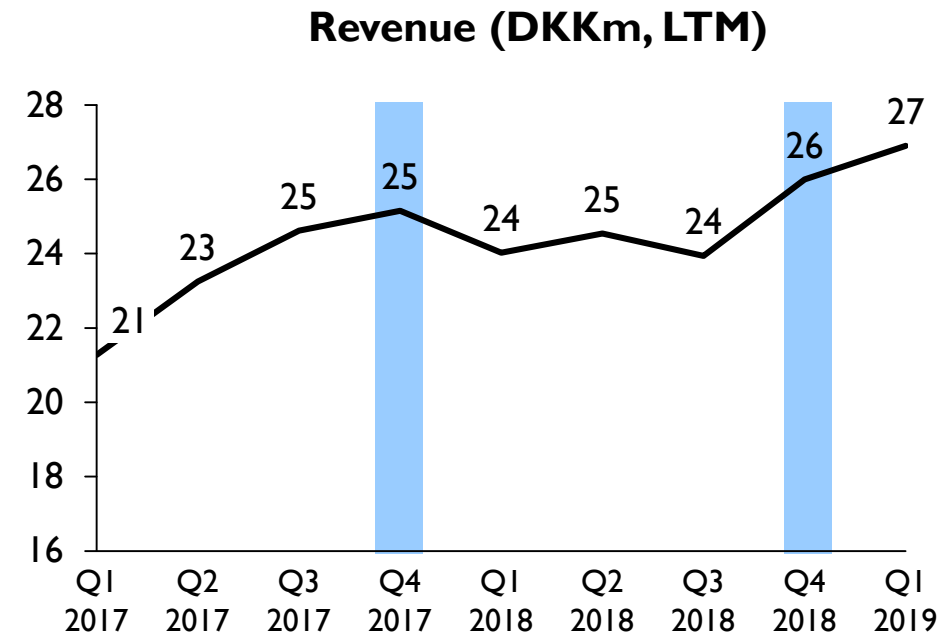
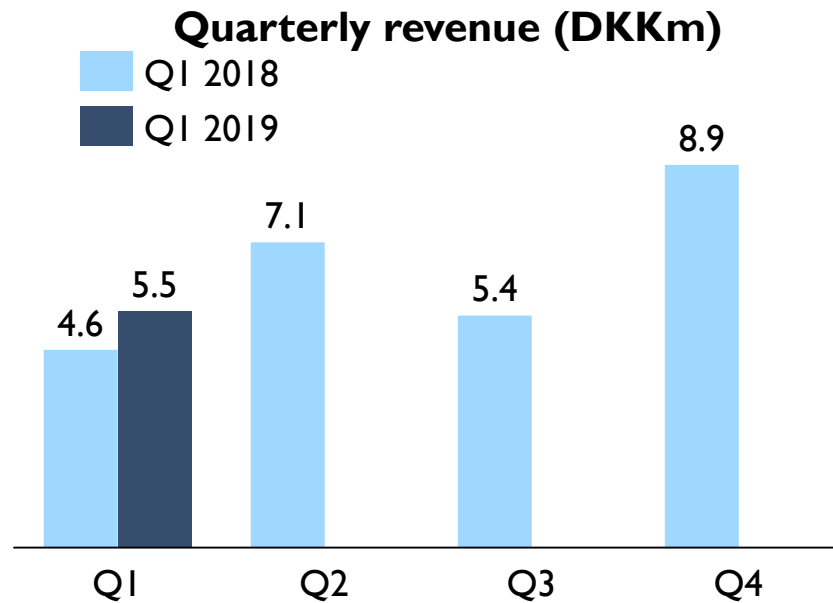
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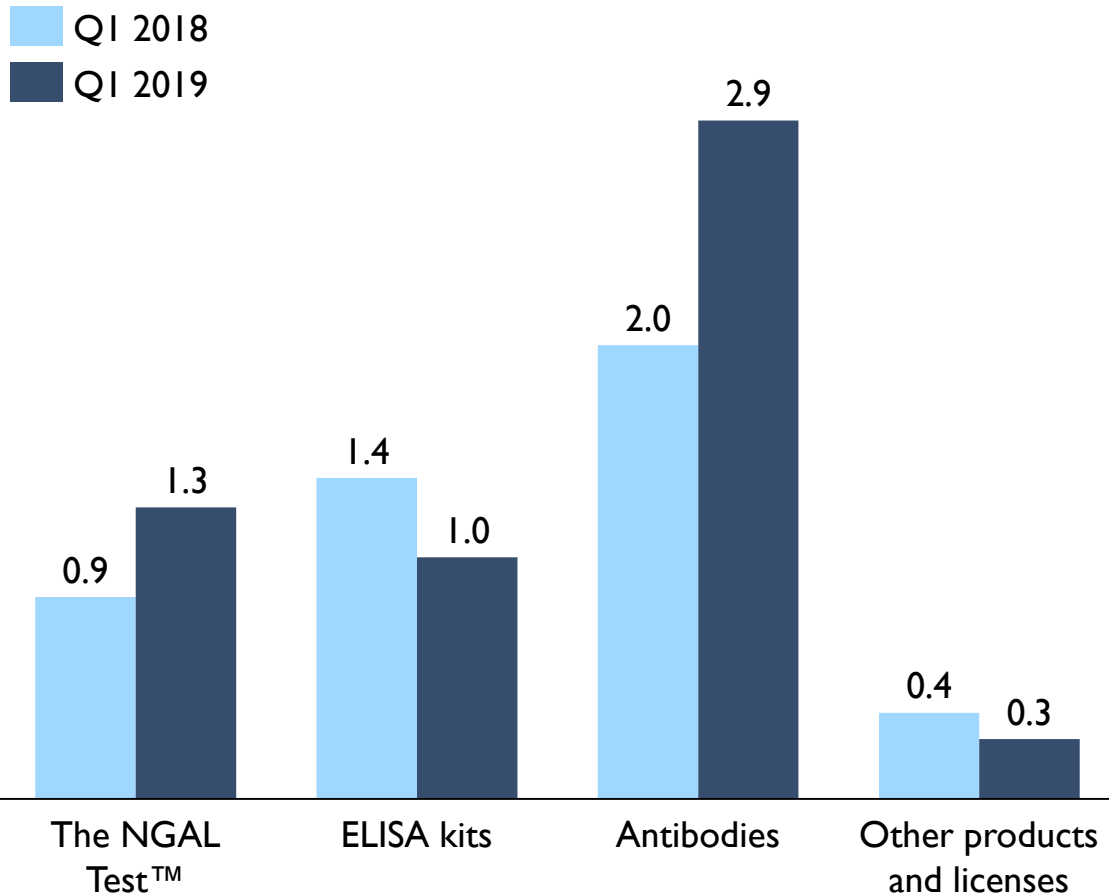
Revenue up 20% in Q1 2019 – EBIT as expected

- Q1 2019 revenue increased to DKK 5.5m from DKK 4.6m last year
- EBIT loss of DKK 17m – on par with expectations as organization ramp-up and clinical study cost impact P&L



US NGAL sales up 111% year over year

Revenue by product category (DKKm)



NGAL

111%

Increase in US revenue from The NGAL Test from Q1 2018 to Q1 2019

Antibodies

49%

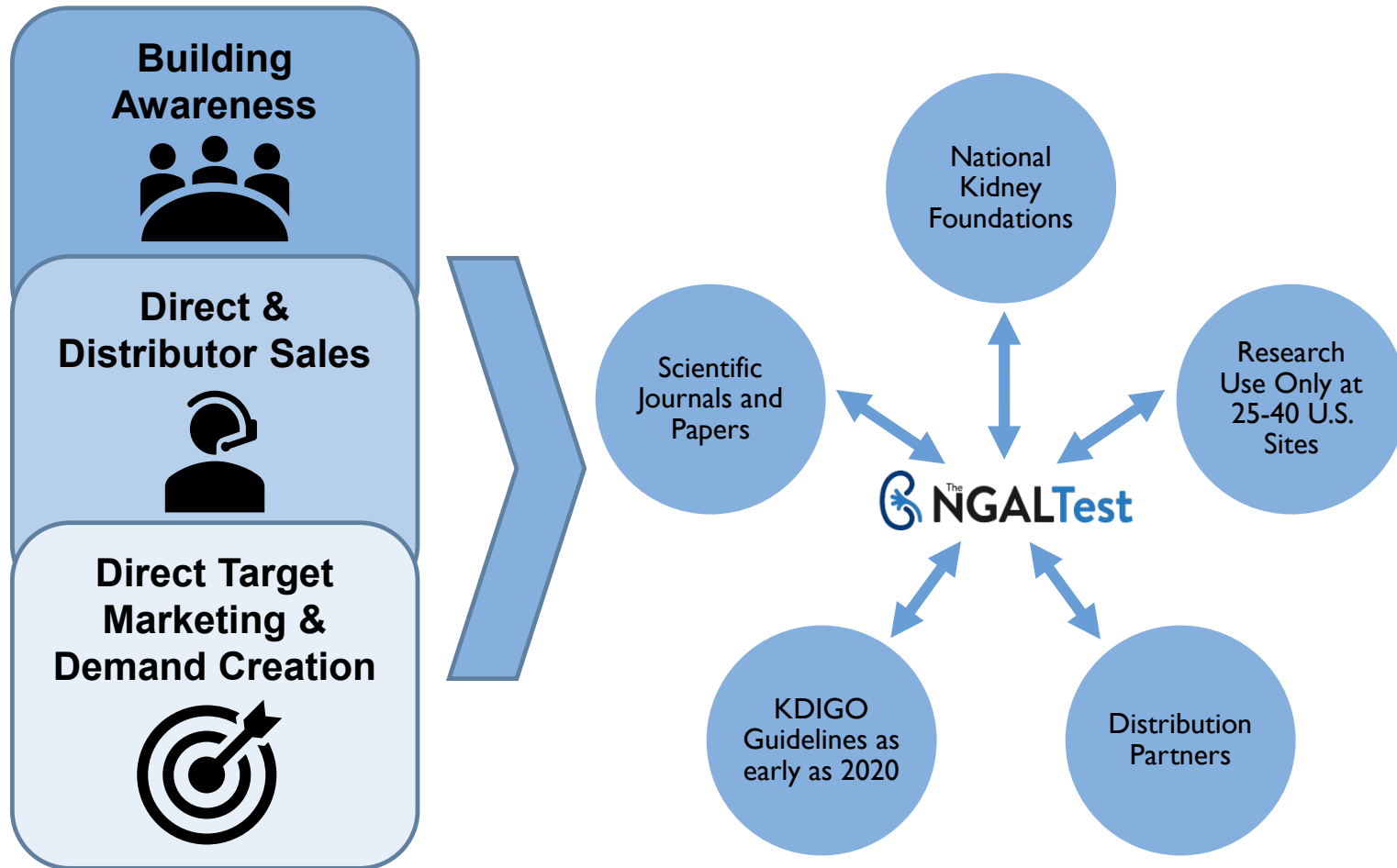
Increase in sales of antibodies from Q1 2018 to Q1 2019

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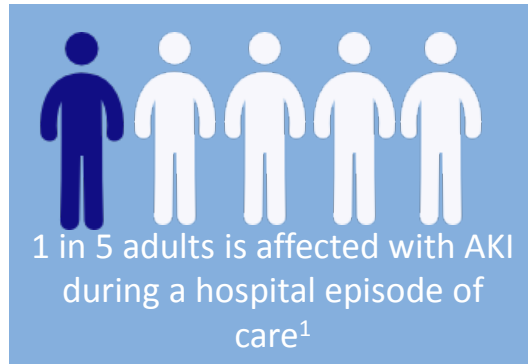
Allocation of considerable resources to U.S. market awareness of NGAL



- U.S. performance result of investment in past years to build awareness of medical need for NGAL as biomarker for safe and efficient evaluation of AKI risk.
- U.S. focus has been on RUO clinics and engagement with KOL and stakeholders to build knowledge of 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.

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.

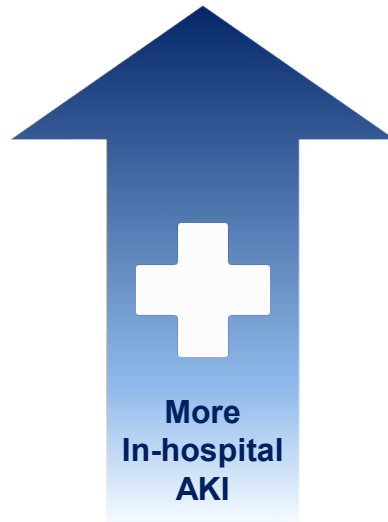
AKI is a Major Public Health Concern

**AKI
in U.S.**

**230% Increase
in 10 Years¹**

**2 Million Deaths
Each Year²**

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

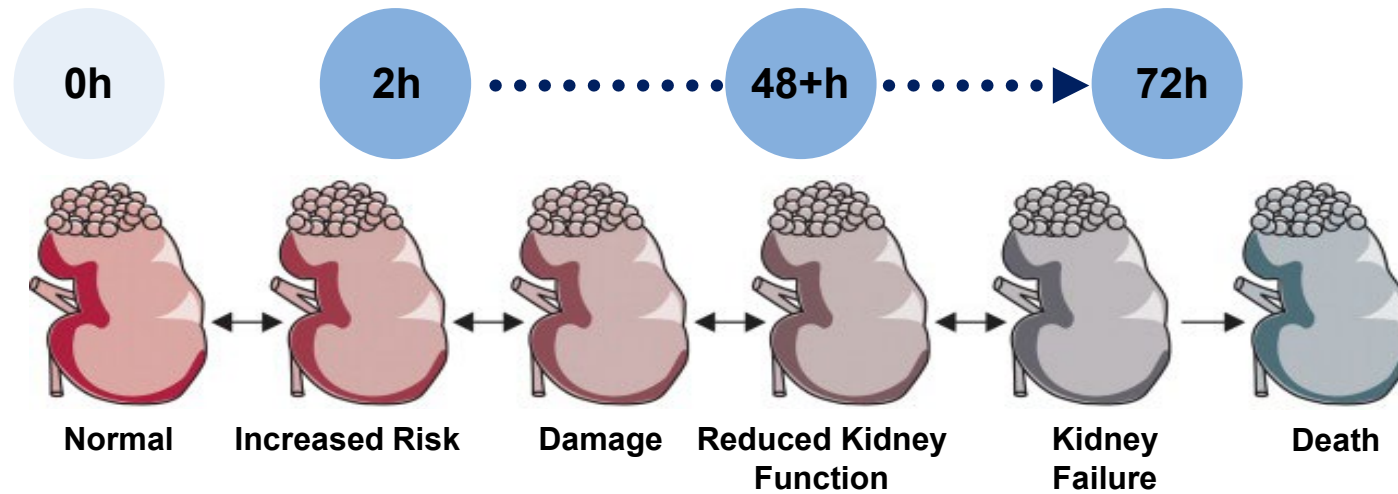


Why? AKI is common, complex and lacking diagnostic tools to help quickly identify kidney injury and aid clinicians in determining the best treatment to preserve kidney function.



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.

Current Standard of Care is Slow and Non-specific



**Serum Creatinine:
Standard of Care**

48-72 hours

The NGAL Test

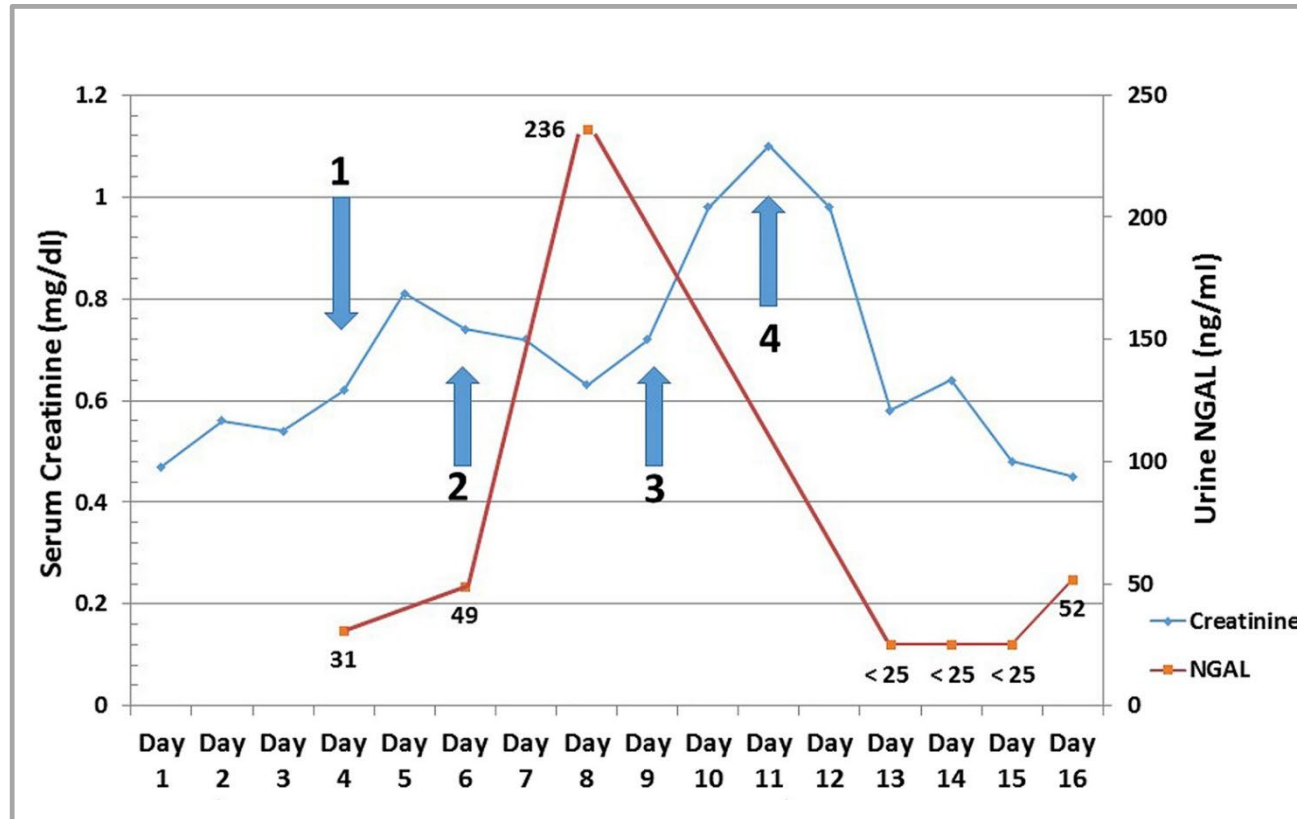
within 2 hours

Actionable Results 46-70h Sooner

*Faster & more specific diagnosis
Shorter length of stay, lower costs
Better patient outcomes*

Case Study: Serial NGAL Testing Improving Care

- **Patient:** 4 mo. old girl in the Cardiac ICU at Cincinnati Children's Hospital with hypoplastic left heart syndrome, respiratory failure & mechanical ventilation.



Case Highlights Corresponding to Numbered Arrows

- 1) After 4 days in the CICU, nephrology was consulted due to rising creatinine levels. Initial uNGAL test is not elevated, suggesting no tubular kidney injury.
- 2) Fluid overload causes placement of dialysis catheter on **Day 6**. Serial uNGAL measurements taken, levels spike on **Day 8**, concurrent creatinine levels were decreasing.
- 3) Patient stops producing urine on **Day 9**
- 4) Fluid challenge: hold dialysis, administer diuretic. Patient responds with brisk production of urine.

In this case example, uNGAL predicted AKI by spiking:

- 1 day before the patient stopped producing urine
- 2 days before creatinine levels spiked

NGAL: An Early Warning System for Kidney Injury

- A small protein expressed in neutrophils and certain epithelia, including the renal tubules
- Produced rapidly by the kidney in response to injury
 - Fastest responding biomarker²
 - NGAL levels increase 48-72 hours before serum creatinine¹
 - Not a functional marker, therefore no need to establish an individual baseline
- Responds in a “dose dependent” manner to injury³
- Well characterized: Over 1000 research papers published over 15 years describing its clinical applications

40%

NGAL detected approximately 40% of patients with probable AKI who were missed by consensus criteria.

This proportion is similar to that identified by troponin in subjects with myocardial injury missed by conventional biomarkers.¹

1) Hasse M et al. The Outcome of Neutrophil Gelatinase-Associated Lipocalin (NGAL)-positive Subclinical Acute Kidney Injury: A Multicenter Pooled Analysis of Prospective Studies. Am Coll Cardiol. 2011 April 26; 57(17): 1752–1761.

2) Alge JL, Arthur JM. Biomarkers of AKI: A Review of Mechanistic Relevance and Potential Therapeutic Implications. Clin J Am Soc Nephrol. 2015 Jan 7; 10(1): 147–155.

3) Devarajan P. Neutrophil gelatinase-associated lipocalin: a promising biomarker for human acute kidney injury. Biomark Med. 2010;4:265–280.

The NGAL Test: Benefits Across the Healthcare Ecosystem

Patient

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

Provider

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

The NGAL Test

Core Lab

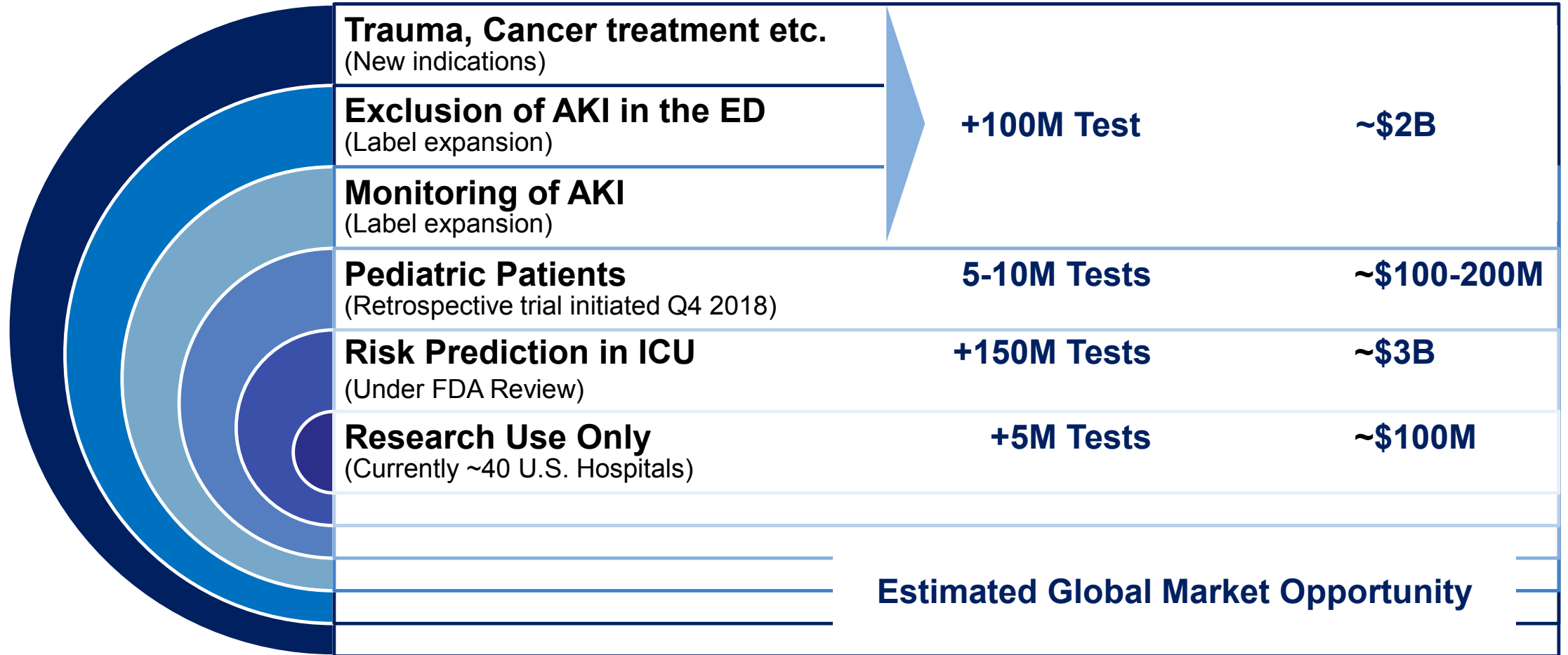
- Runs on automated analyzers
- Fast processing time, simple set up
- Matrix flexibility (blood or urine)
- Low cost per test (\$20)

Hospital/HS

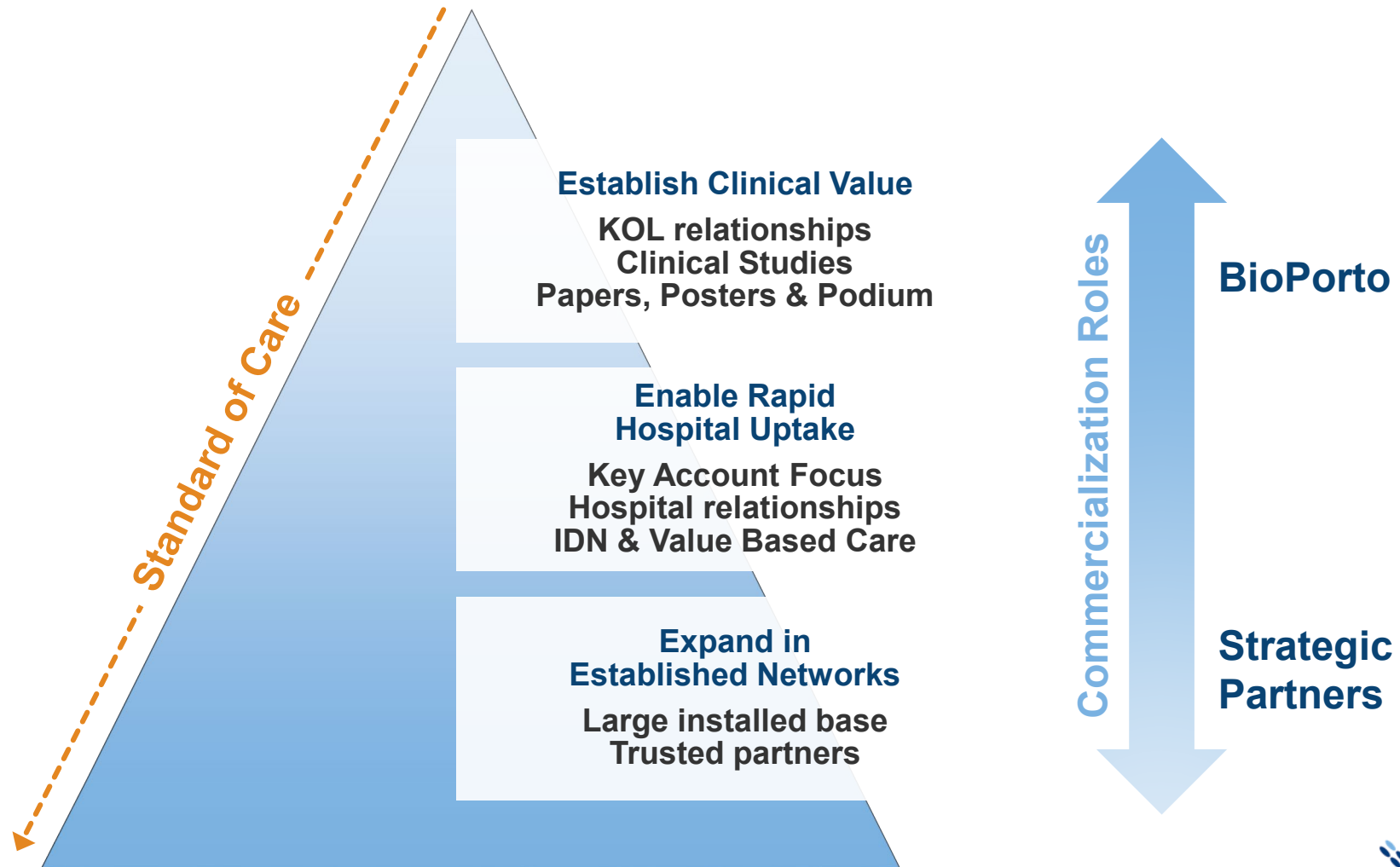
- Reduce morbidity and mortality
- Fewer patients needing RRT
- Shorter lengths of stay
- Reduced cost per patient¹

Reimbursement: Covered as part of inpatient DRG
Intellectual Property: Comprehensive patent protection

The NGAL Test addresses a massive global market



Driving Commercialization Through Key Partnerships



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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 The NGAL Test (urine) 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

\$6m

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

EBIT loss

\$7m

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

Cost for FDA applications

\$1m

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

Underlying assumptions

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

Investment Highlights

Platform

- Antibody → Assay → Actionable Biomarker Repeatable Development Path
- Robust Academic & Research Relationships
- \$4M Revenues in 2018

Broad Target Market

- The NGAL Test Addresses \$5 B AKI Market
- Significant Unmet Diagnostic Needs
- Testing can speed diagnosis, saving costs and lives

Commercialization

- Partnerships Secured with Roche & Siemens
- Reimbursement through DRG codes
- Strong Support from Key Opinion Leaders

Execution

- 2 FDA Clearances expected in 2019
- Proprietary NGAL Test with Extensive Studies
- Experienced Management Team



BIOPORTO A/S

FINANCIAL CALENDAR 2019

MAY 9	Q1 2019 FINANCIAL RESULTS
AUGUST 15	Q2 2019 FINANCIAL RESULTS
NOVEMBER 7	Q3 2019 FINANCIAL RESULTS

