



BioPorto A/S

CEO Peter M Eriksen presenting @ Biotech Showcase

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About BioPorto A/S

BioPorto is an in vitro diagnostics company that uses our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers.

Antibody Library

- 400-800 Abs in significant disease states
- Steady source of revenue (275+ customers in 40+ countries)
- Insight into high value diagnostic targets

Assay Development

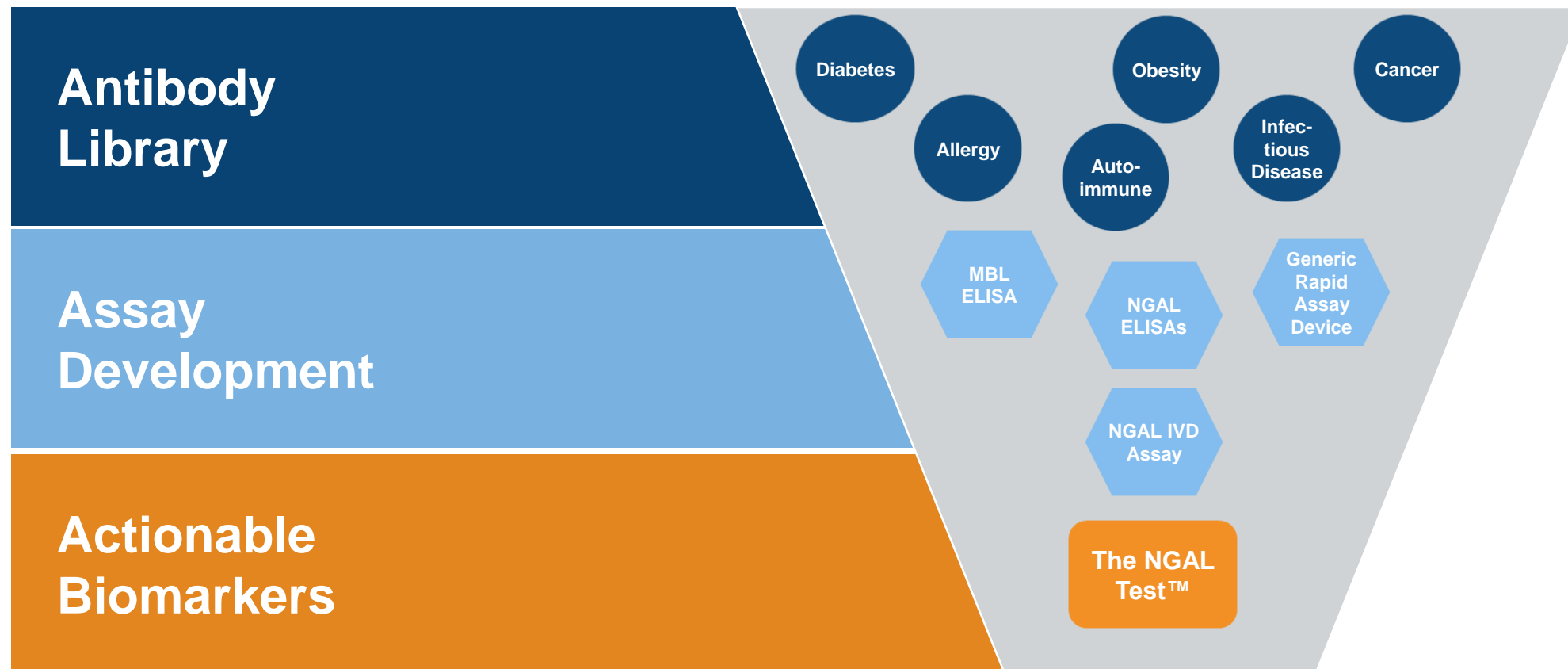
- Technical expertise: ELISA kits, automated assays & rapids
- Partnerships with key academic researchers & institutions
- Production/scale up partnerships

Actionable Biomarkers

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

Founded 2000, headquartered in Copenhagen, Denmark; listed on NASDAQ CPH [Ticker:BIOPOR]

BioPorto's Development Platform



How The NGAL Test Can Improve 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.”



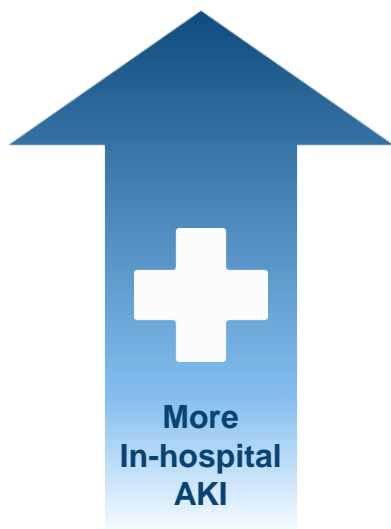
AKI: A Major Public Health Concern

AKI

230% Increase
in 10 Years¹

2 Million Deaths
Each Year²

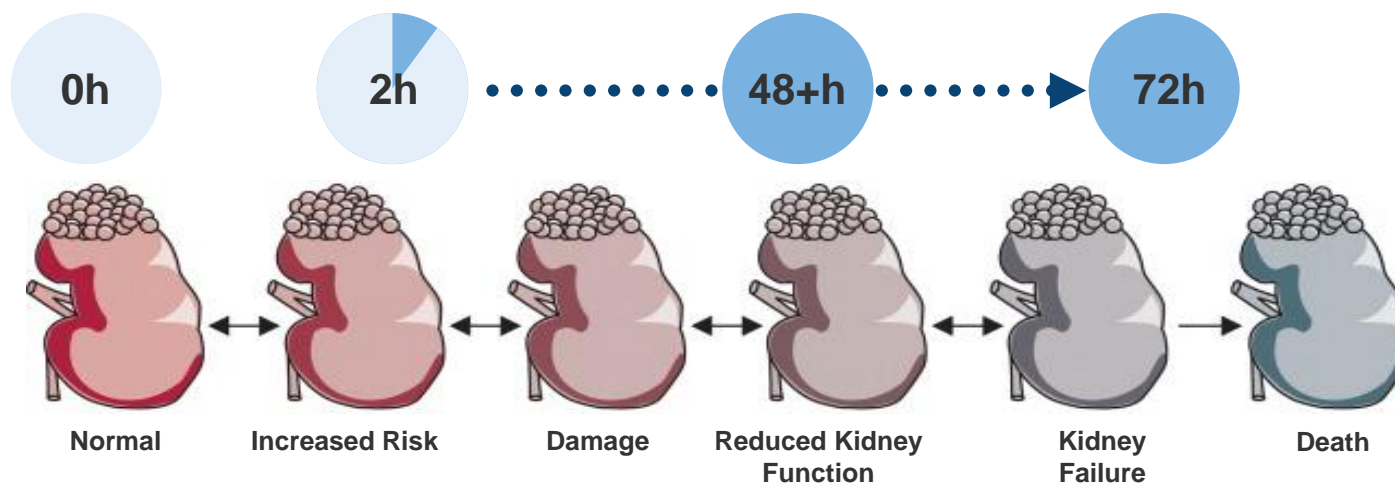
\$10 Billion Increase
in US Hospital Costs³



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

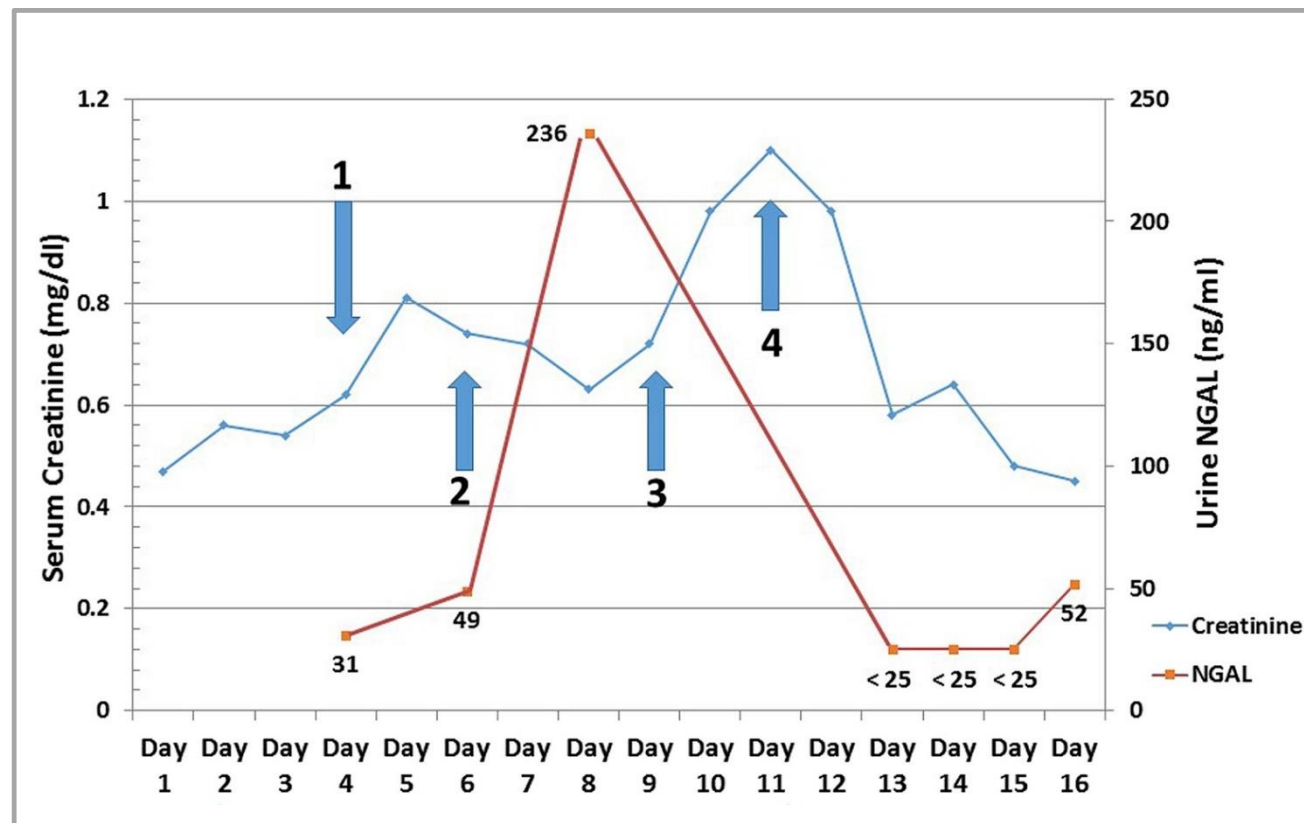
within 2 hours

Actionable Results 46-70h Sooner

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

Case Study: NGAL Monitoring 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.

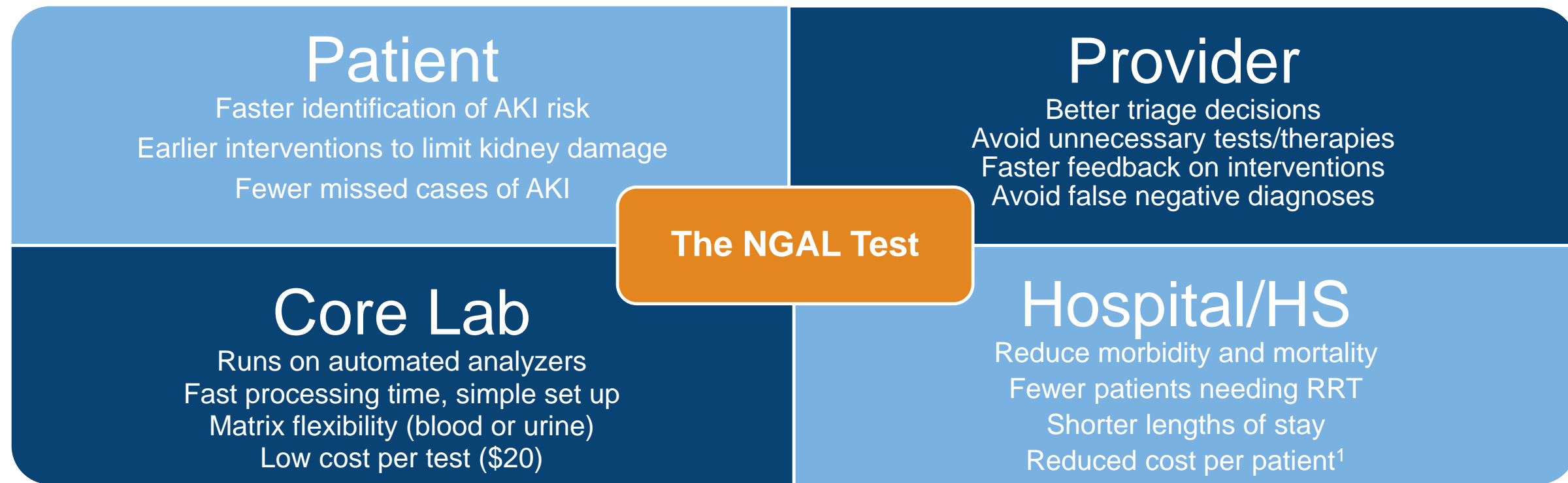
This proportion is similar to that identified by troponin in subjects with myocardial injury missed by conventional biomarkers.¹

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.

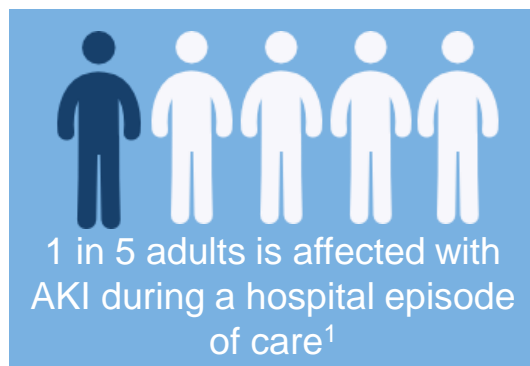
The NGAL Test: Benefits Across the Healthcare Ecosystem



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

Clinical Applications of NGAL

Applications in Adult Populations & Settings



Predict AKI Risk in Intensive Care Setting

- Plasma
- Predict Stage 2 & 3 AKI

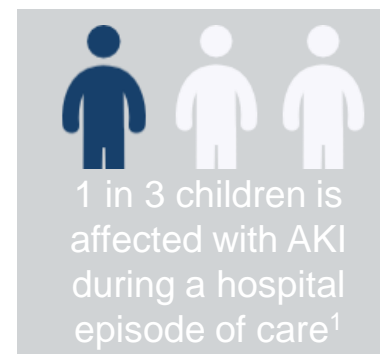
Exclude AKI in Emergency Department

- Plasma
- Rule out AKI to improve triage & care

Monitoring of AKI

- Plasma
- Use NGAL to evaluate efficacy of interventions

Pediatric Indication



Predict AKI Risk in Intensive Care Setting for Pediatrics

- Urine
- Predict Stage 2 & 3 AKI

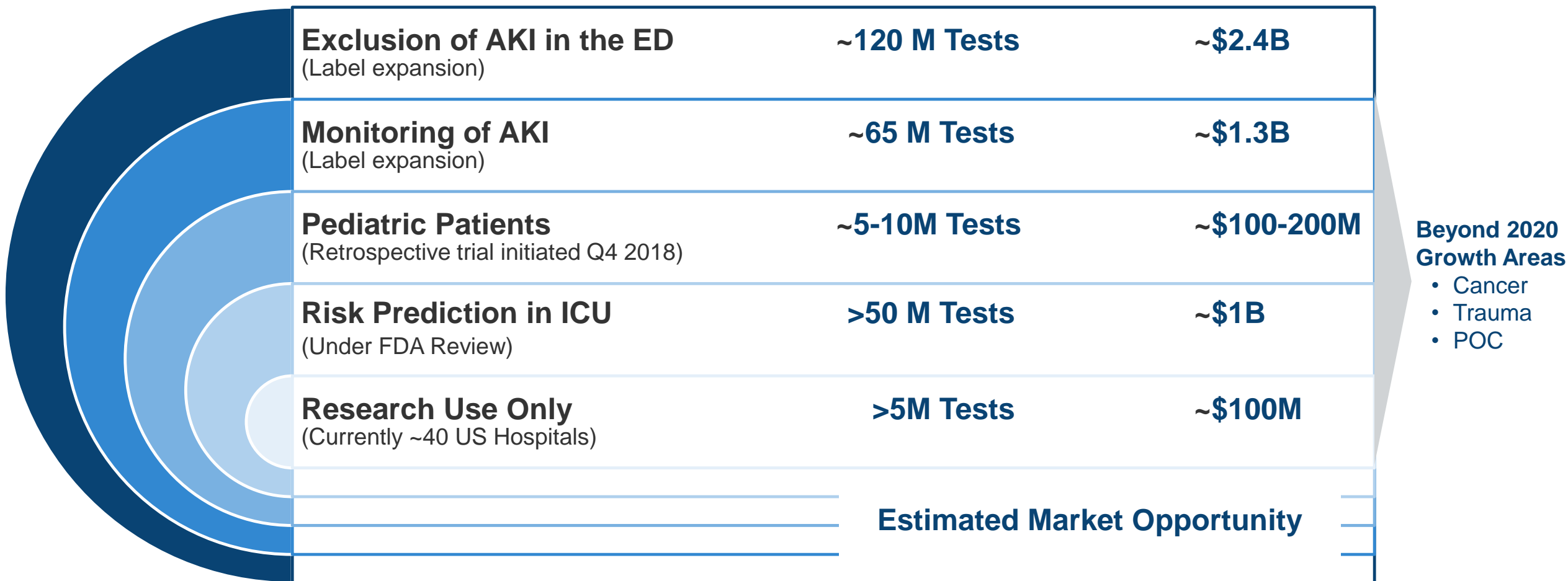
“The limitation in AKI detection may be **limiting doctors’ abilities to get ahead of injury...**”

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

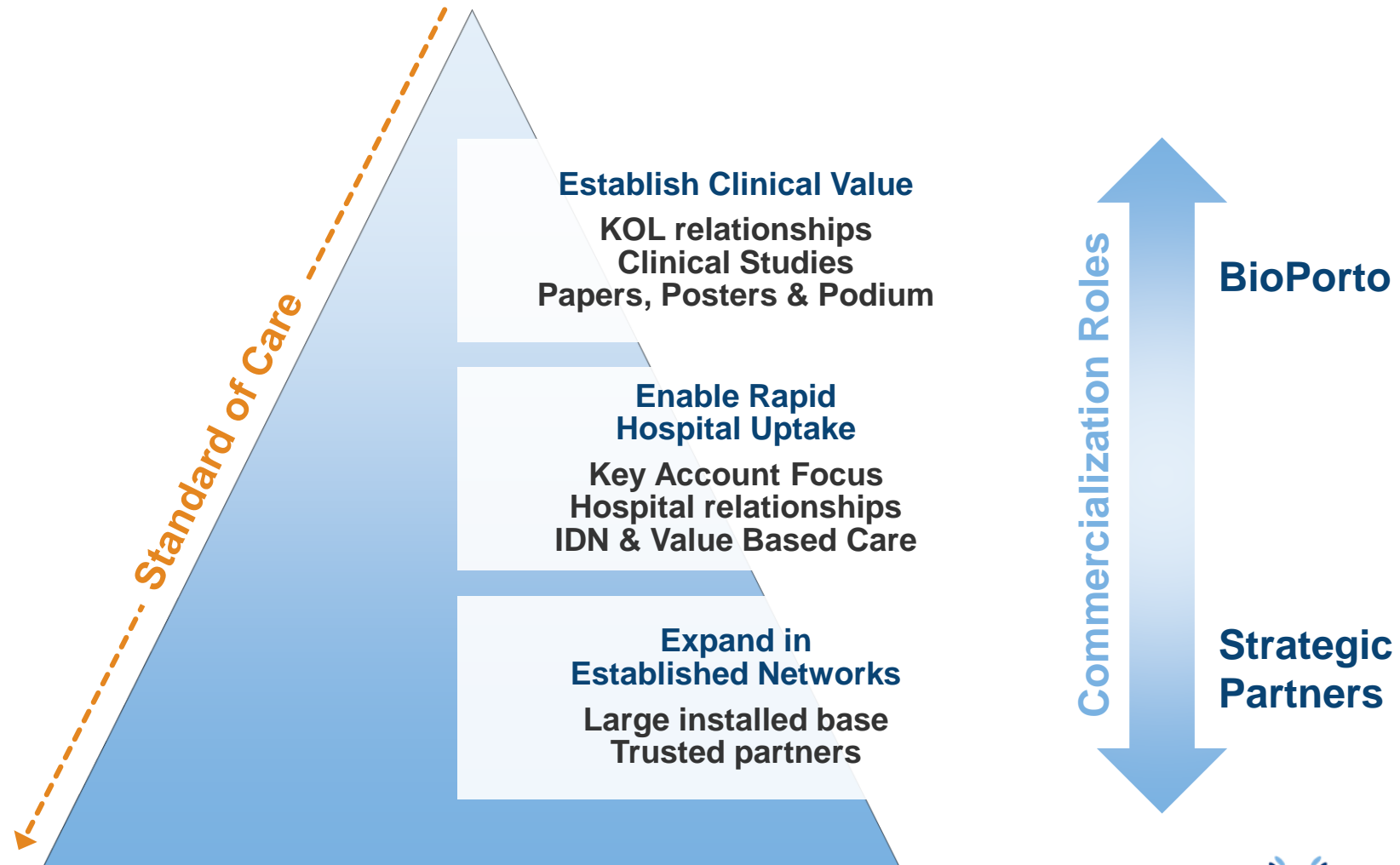
1. Susantitaphong, P et al. World Incidence of AKI: A Meta-Analysis. Clin J Am Soc Nephrol. 2013 Sep;8(9):1482-93.

The NGAL Test: Indications & Opportunities



1. Management estimates; during an average course of illness, 4-5 tests will be used to diagnose AKI
 2. Source: Lameire NH, Bagga A, Cruz D, et al. Acute kidney injury: an increasing global concern. Lancet 2013; 382: (9887) 170-9

Driving Commercialization Through Key Partnerships



2019 Milestones



Clinical and Regulatory

- Supplementary data to FDA to support initial FDA clearance in adults (1H 2019)
- Approval of NGAL (plasma) in adults (2H 2019)
- Submission of urinary NGAL test for pediatric population (1H 2019)
- Approval of NGAL in pediatrics (2019)



Commercial

- Onboard US Commercial Leadership (1H 2019)
- Hire core team of MSLs (1H 2019)
- Prepare with partners for NGAL launch (1H 2019)

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



Thank you