

Interim Report, first half of 2019

BioPorto
15 August 2019





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Agenda

- 01. Financials H1 2019
- 02. About BioPorto
- 03. Acute Kidney Injury
- 04. The NGAL Test
- 05. Addressable Market
- 06. Approval process



Highlights of first half of 2019

- Q2 sales of NGAL in U.S. up by 43% and in H1 2019 by 23%
- Bulk orders drive sales of antibodies up, while ELISA kits down due to market conditions
- Successful share capital increase adds DKK 36m to liquidity
- Strengthening of organization in U.S. with important new management hires
- Pediatric application submitted in May 2019 – questions received from FDA in mid-July 2019
- Strong clinical and political interest in NGAL as biomarker for AKI





Pediatric Application to be Resubmitted in Q4 2019



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



Q2-4 2019

Breakthrough designation granted and application submitted to FDA

Strong results support potential of The NGAL Test

- Sensitivity 65.0%
- Specificity 81.8%
- Neg. predictive value 95.4%
- Breakthrough device designation granted by FDA, May 2019



FDA clearance expected for pediatric critical care risk assessment

Direct sales

- US organization strengthened with new management and reps
- 200+ dedicated U.S. pediatric hospitals will be addressed directly by BioPorto's commercial team

Research Use Only sales to US research hospitals

Direct sales of FDA cleared test



BioPorto's leadership

International Management Team



Peter Mørch Eriksen
CEO



Ole Larsen
CFO



Jan Kuhlmann
COO



Amy Winslow
President,
BioPorto Diagnostics Inc.

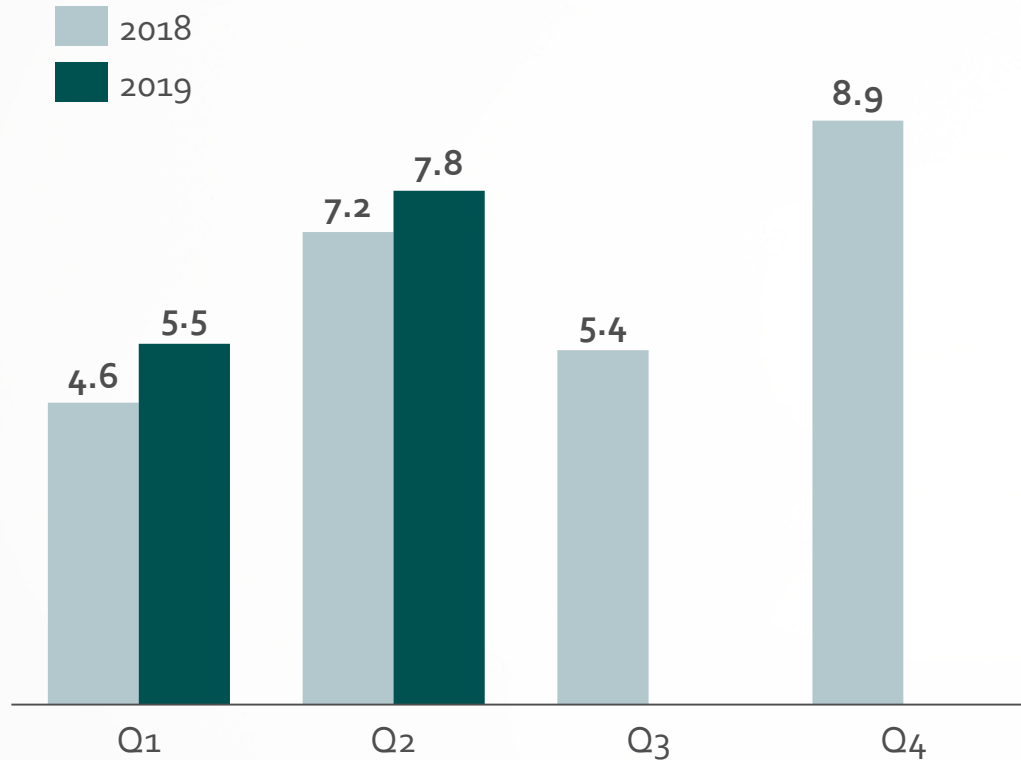


Christopher Bird
CMO, BioPorto Inc.

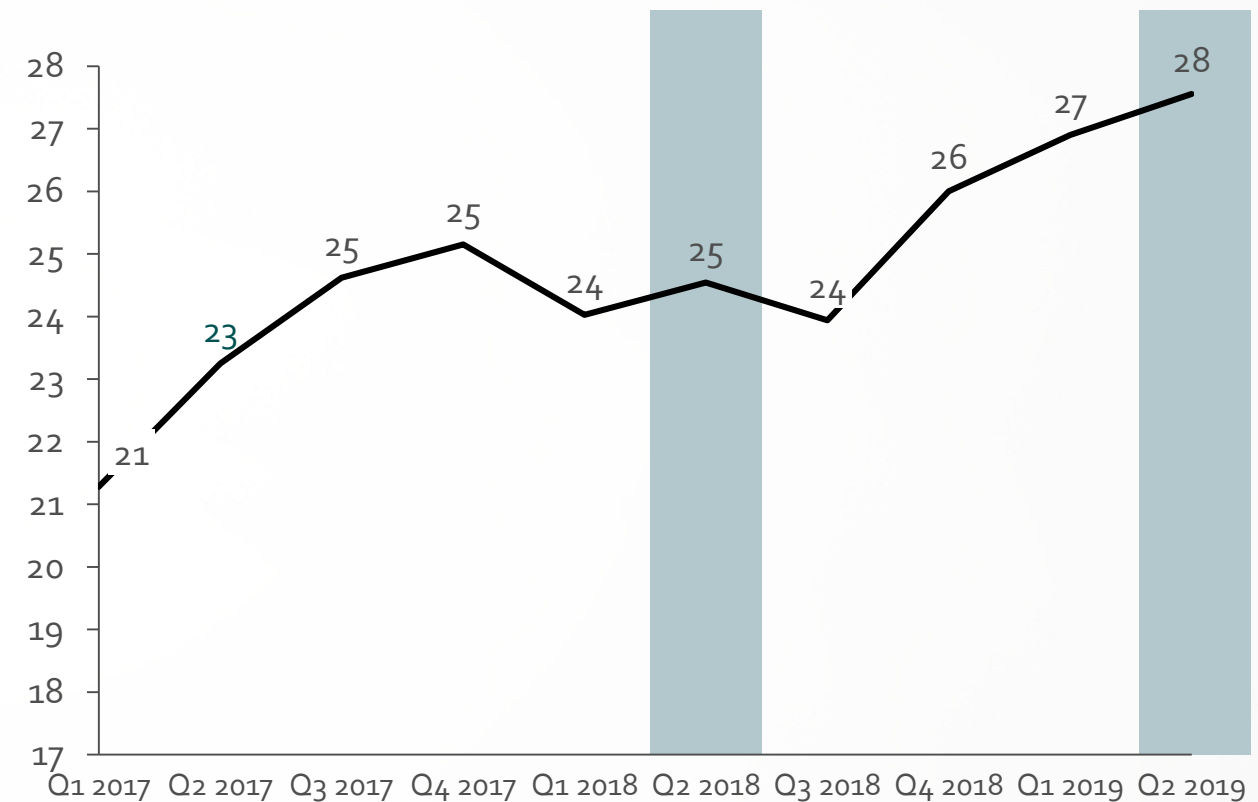


Overall growth in H1 2019 of 13%

Revenue by Quarter (DKKkM)



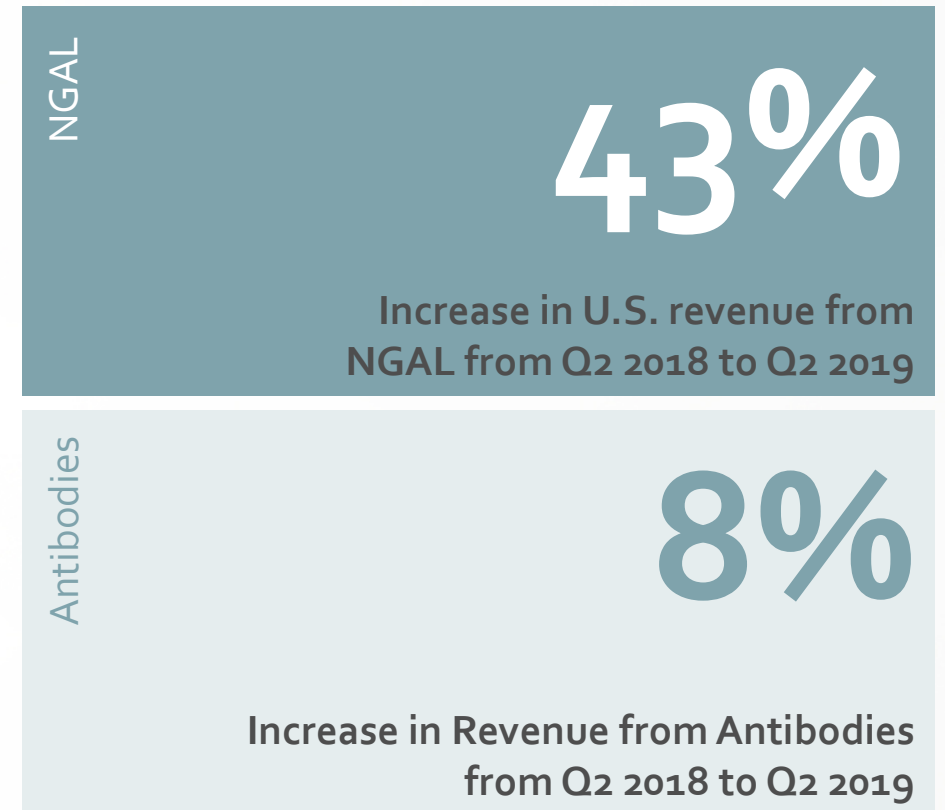
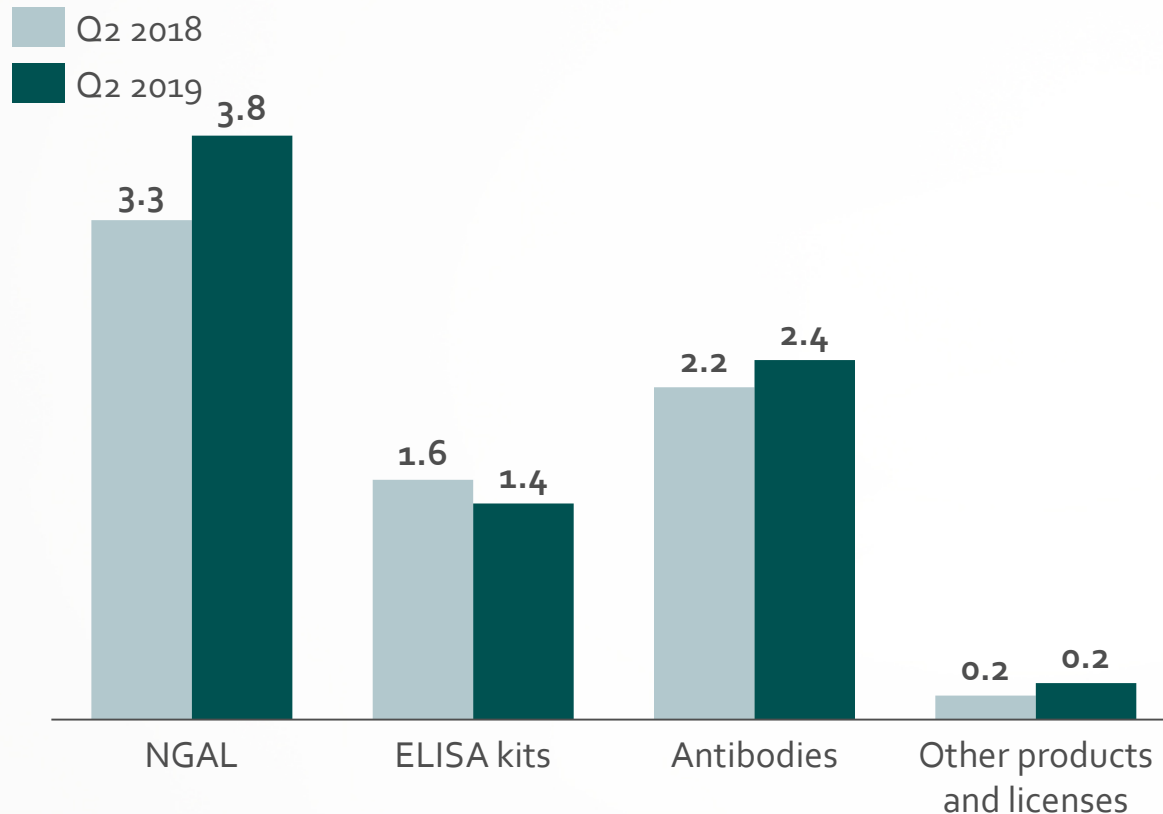
Revenue by Quarter (LTM, DKKkM)





Solid increase in Q2 revenues from NGAL lead by performance in U.S.

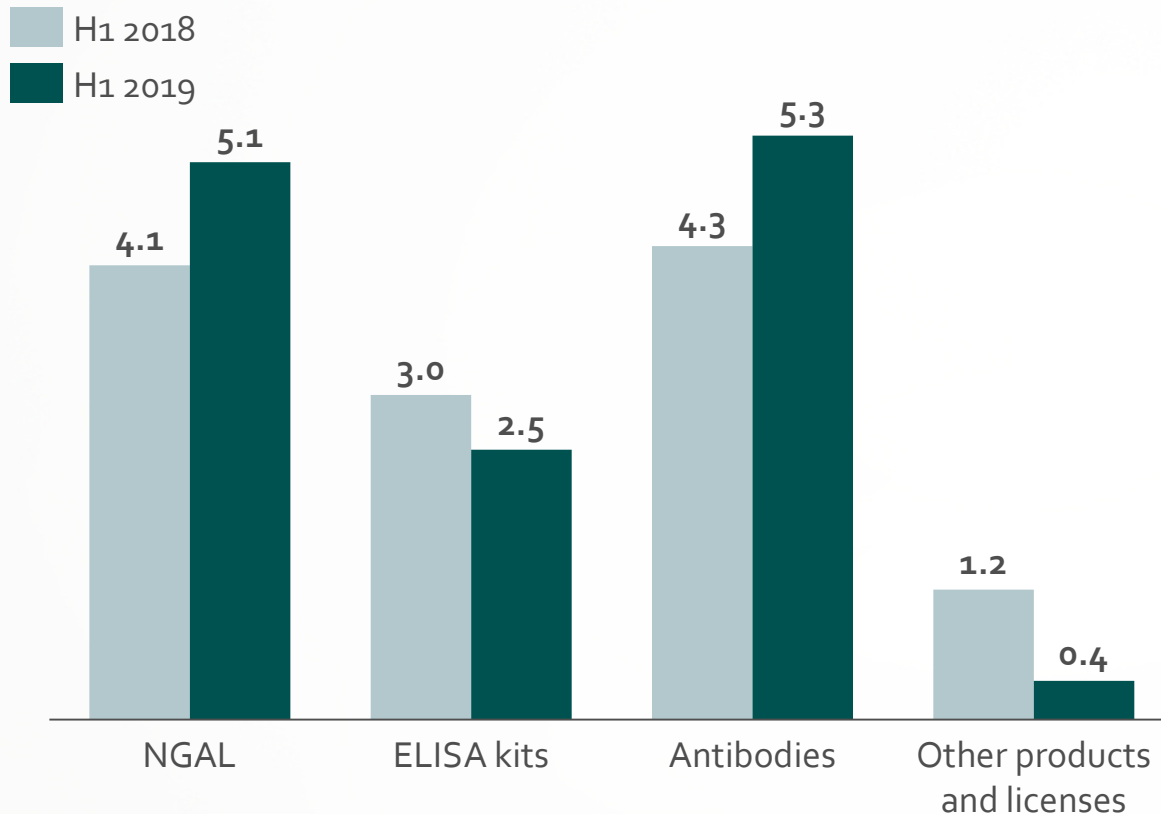
Revenue by Product Category (DKKm)



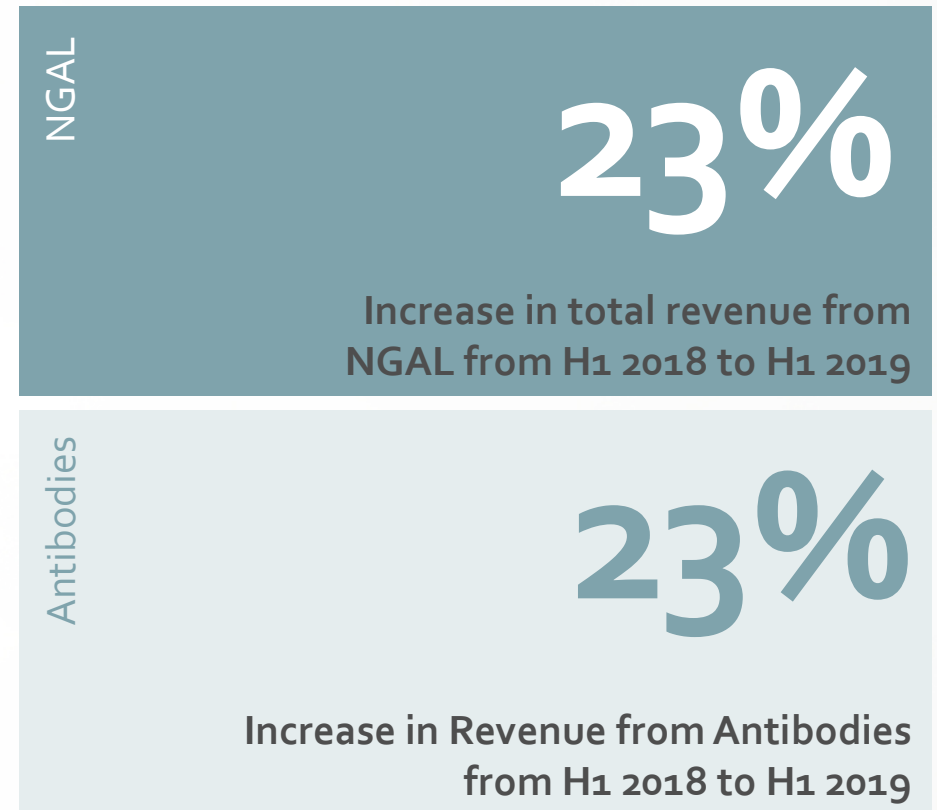


YTD growth driven by higher RUO and license fees on NGAL and strong antibody development

Revenue by Product Category (DKKm)



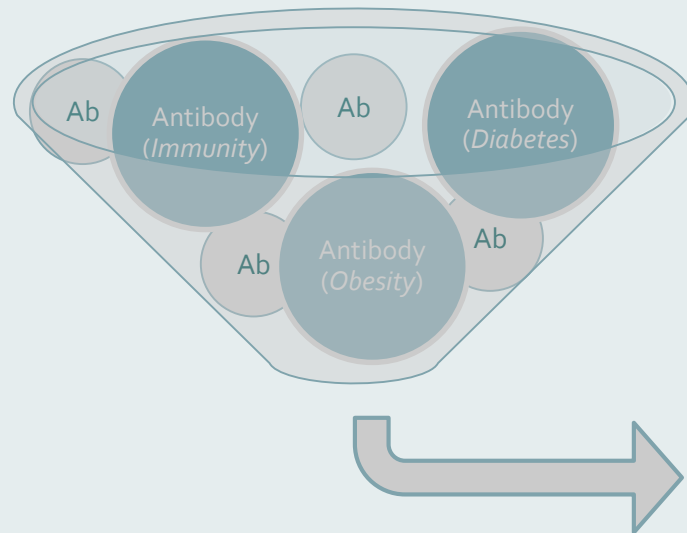
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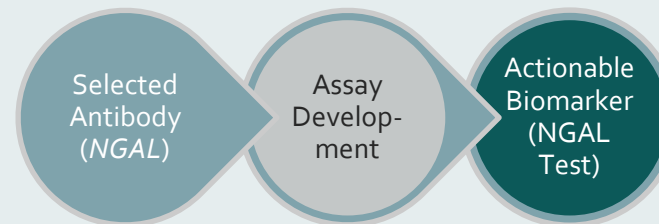


Platform for Growth

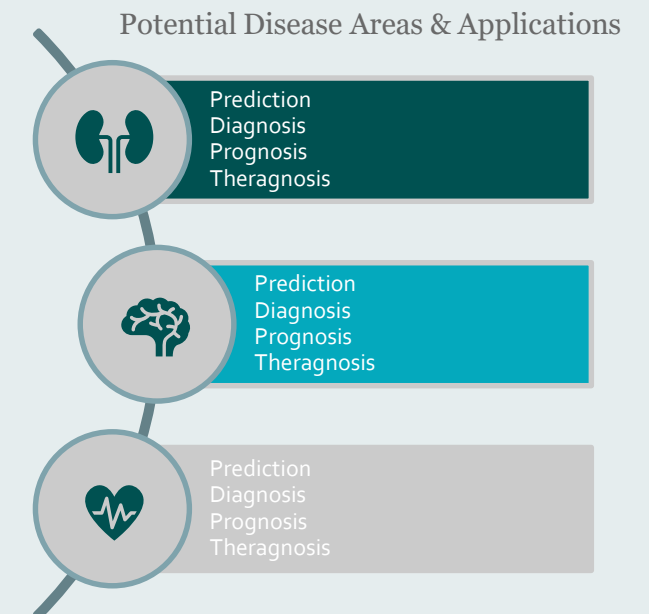
Antibody Library



Assay Development Expertise



Actionable Biomarkers

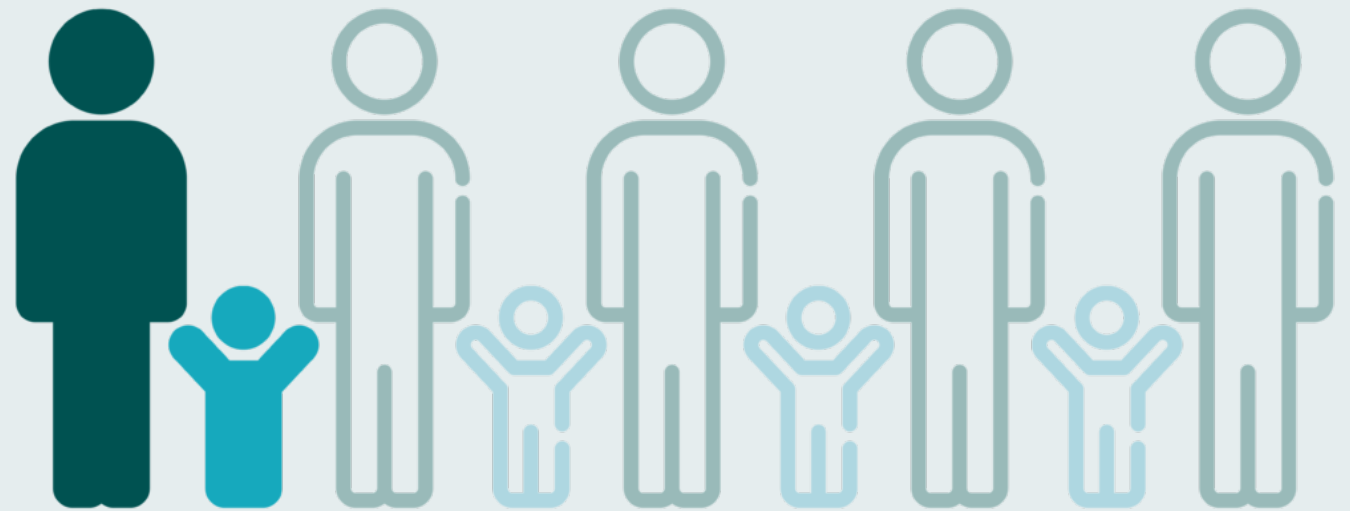




Why Is AKI Important?

Acute kidney injury (AKI) is a rapid loss of kidney function which typically happens as a complication of another serious illness or intervention.

Because pain and other symptoms don't usually occur, AKI can be difficult to identify, but to preserve kidney function it is essential that AKI is detected early and treated promptly.



1 IN 5 ADULTS & 1 IN 4 CHILDREN
IS AFFECTED WITH AKI DURING HOSPITALIZATION^{i,ii}



Acute Kidney Injury (AKI)

A Major Public Health Concern

230%

Increase in 10 years
of in-hospital AKI in
U.S.

2 Million

Deaths worldwide
each year

\$10 Billion

Increase in U.S.
hospital costs

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.



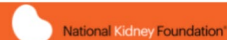
Trump signs Executive Order to improve treatment of kidney disease

Recent Political Focus on Kidney Disease

The New York Times

Trump Proposes Ways to Improve Care for Kidney Disease and Increase Transplants

The administration set ambitious goals to move people out of traditional dialysis and to encourage organ donations.



President Trump Announces Administration's Bold Vision for Transforming Kidney Care

TWEET SHARE PIN SHARE PRINT EMAIL



New York, NY, July 10, 2019—Today President Trump announced a bold vision for transforming kidney care for the estimated 37 million Americans affected by kidney disease. During a speech at the Ronald Reagan International Trade Center attended by National Kidney Foundation (NKF) volunteers, patients, care partners and leadership, government officials and other kidney organizations, the President laid out the Administration's detailed plan



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U.S.

Trump Signs Executive Order on Kidney Disease

President's move encourages kidney transplants, less expensive at-home dialysis treatments



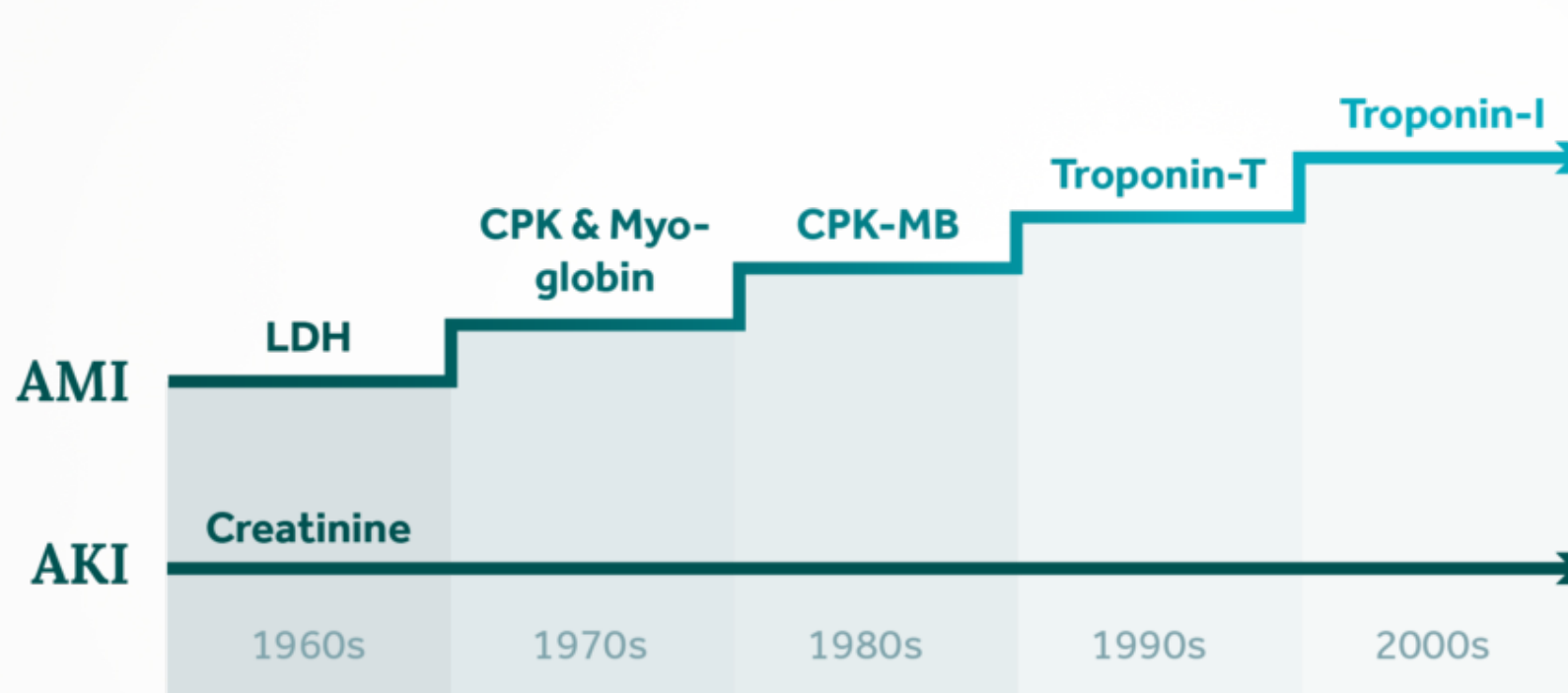
Trump signs executive order aimed at improving kidney disease treatment

BY JESSIE HELLMANN - 07/10/19 02:52 PM EDT



Cardiac biomarkers vs. kidney biomarkers

AMI Validates the Need for AKI Innovation



40% Patients with probable AKI missed by consensus criteria.

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

INTRODUCING
The NGAL Test™
2019

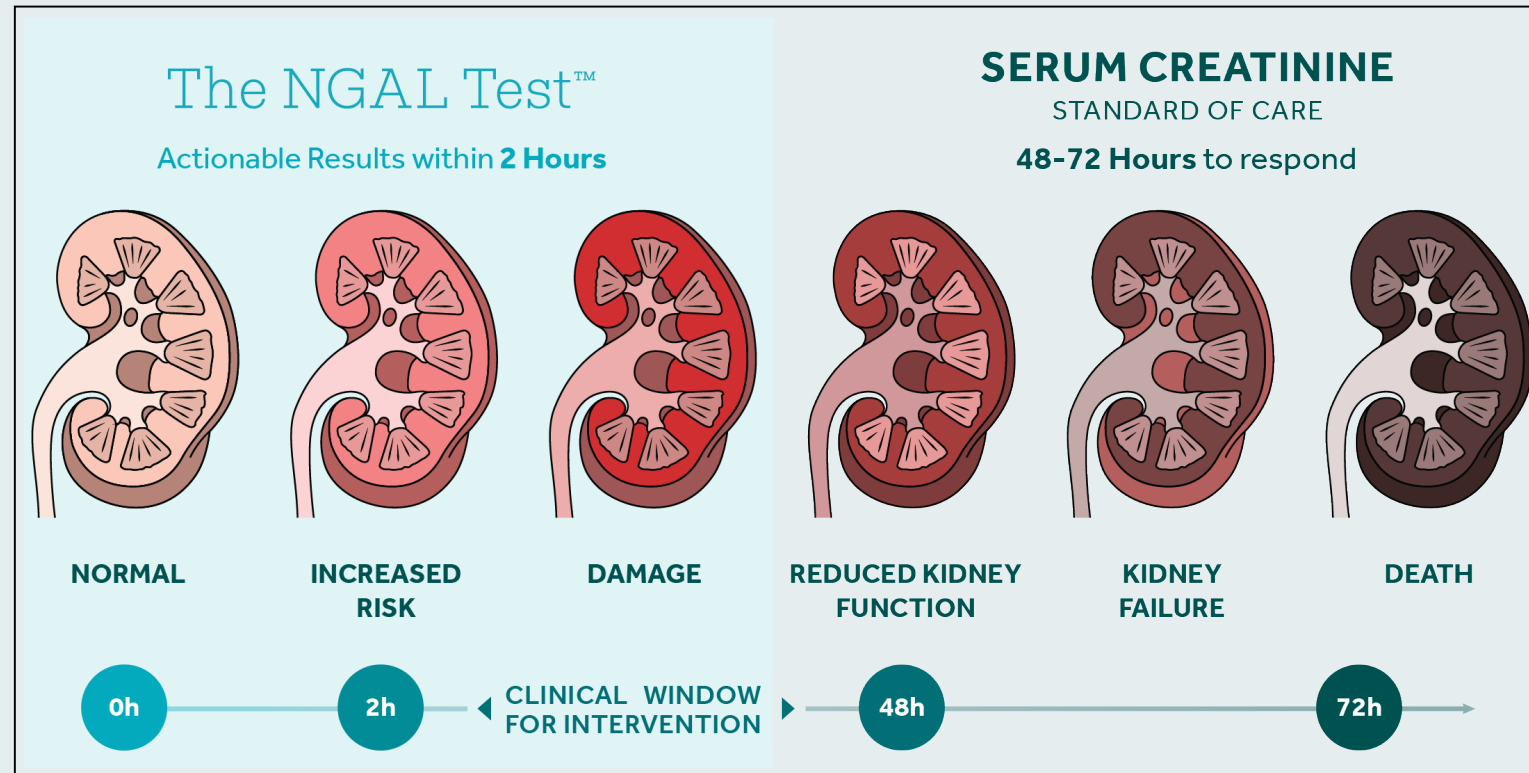


AKI assessment tools

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.



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



Early identification of AKI risk

NGAL biomarker integrated with sCr

	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>	<i>Cause: AKI due to tubular damage</i> <i>Initiate: Early patient risk stratification, consult KDIGO-based management guidelines</i>
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.



Case Study: 4 mo. old in the cardiac ICU with hypoplastic left heart syndrome, respiratory failure, mechanical ventilation

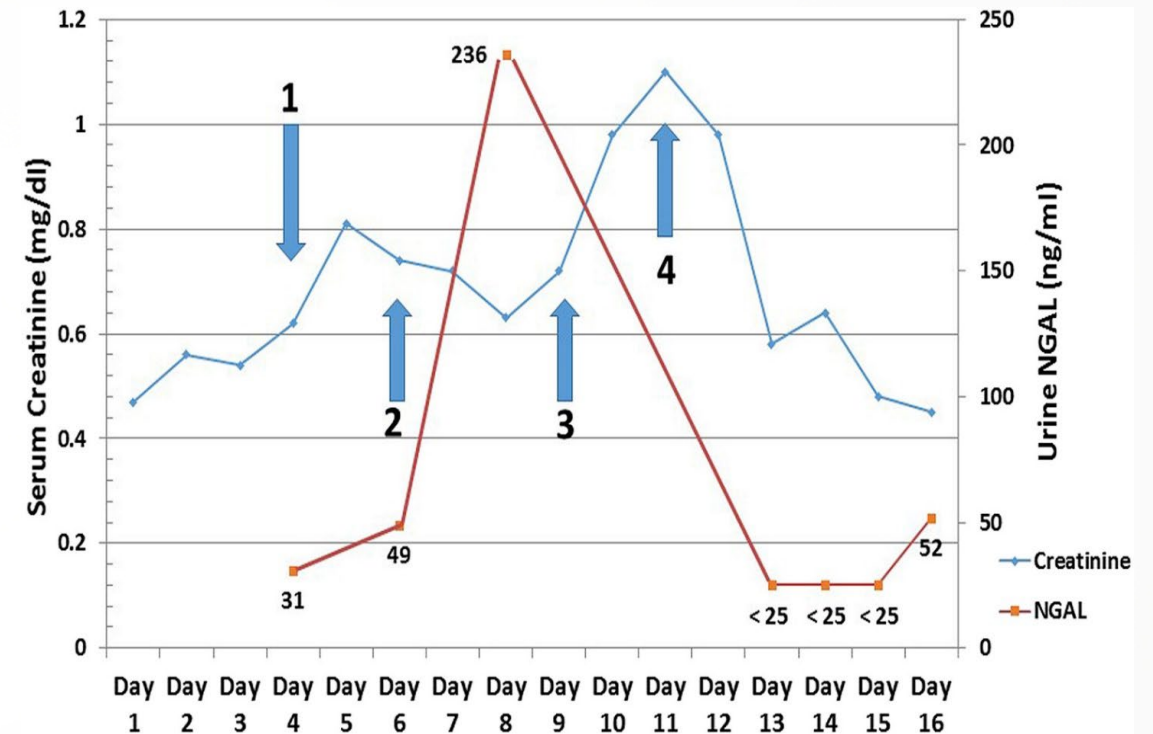
Serial NGAL Testing Improving Care

Case Highlights Corresponding to Numbered Arrows

- 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.
- Fluid overload causes placement of dialysis catheter on Day 6. Serial uNGAL measurements taken, levels spike on Day 8, concurrent creatinine levels were decreasing.
- Patient stops producing urine on Day 9
- 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

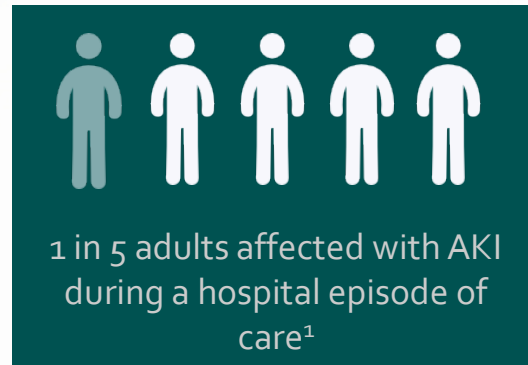


Varnell CD Jr, Goldstein SL, Devarajan P, Basu RK. Impact of Near Real-Time Urine Neutrophil Gelatinase-Associated Lipocalin Assessment on Clinical Practice. *Kidney Int Rep.* 2017;2(6):1243–1249.



Clinical Applications of The NGAL Test*

Adults



Predict AKI Risk in Intensive Care Setting

- Plasma
- Predict Stage 2 & 3 AKI

FDA application to be submitted in Q4 2019

Exclude AKI in Emergency Dept.

- Plasma
- Rule out AKI to improve triage & care

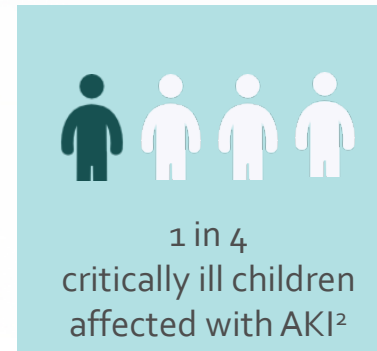
To initiate following FDA clearance of prediction

Monitoring of AKI

- Plasma
- Change in NGAL to evaluate efficacy of interventions

To initiate following FDA clearance of prediction

Pediatrics



Predict AKI Risk in Intensive Care Setting

- Urine
- Predict Stage 2/3 AKI

FDA application to be submitted in Q4 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. Research, Critical Care Medicine
Associate Prof. 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.

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.



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)



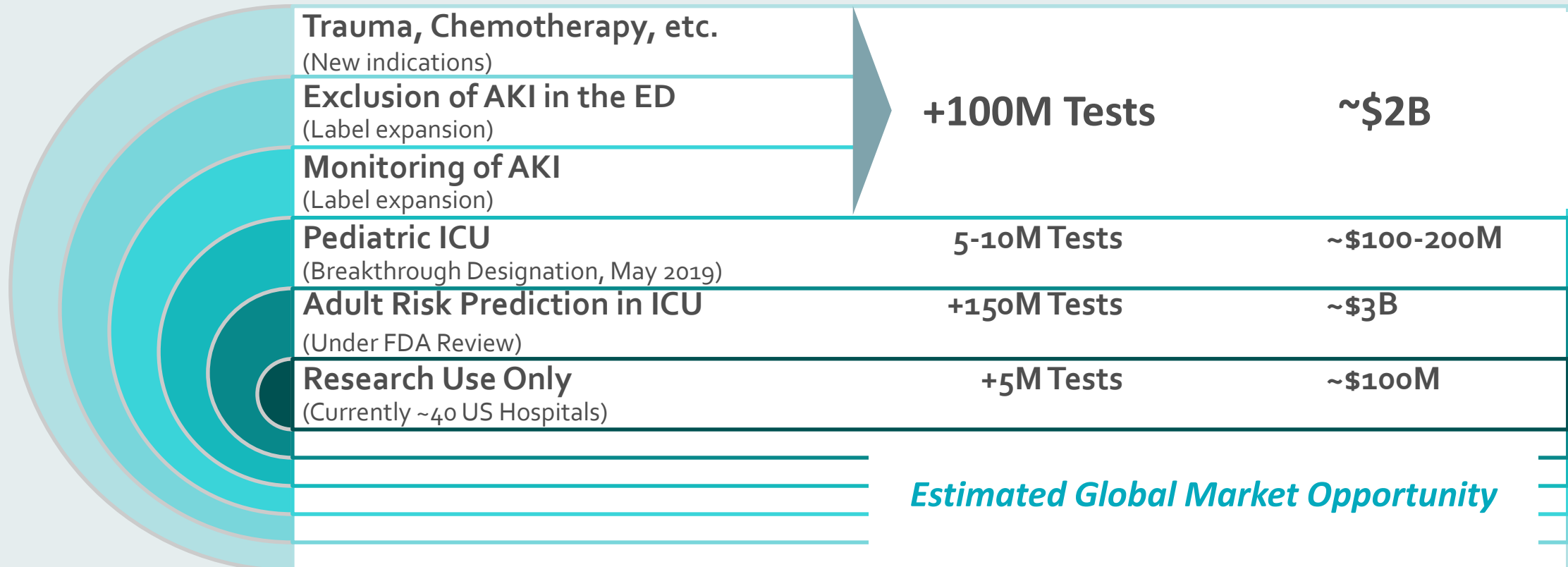
Hospitals

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



*The NGAL Test**

Addresses a Significant Unmet Need



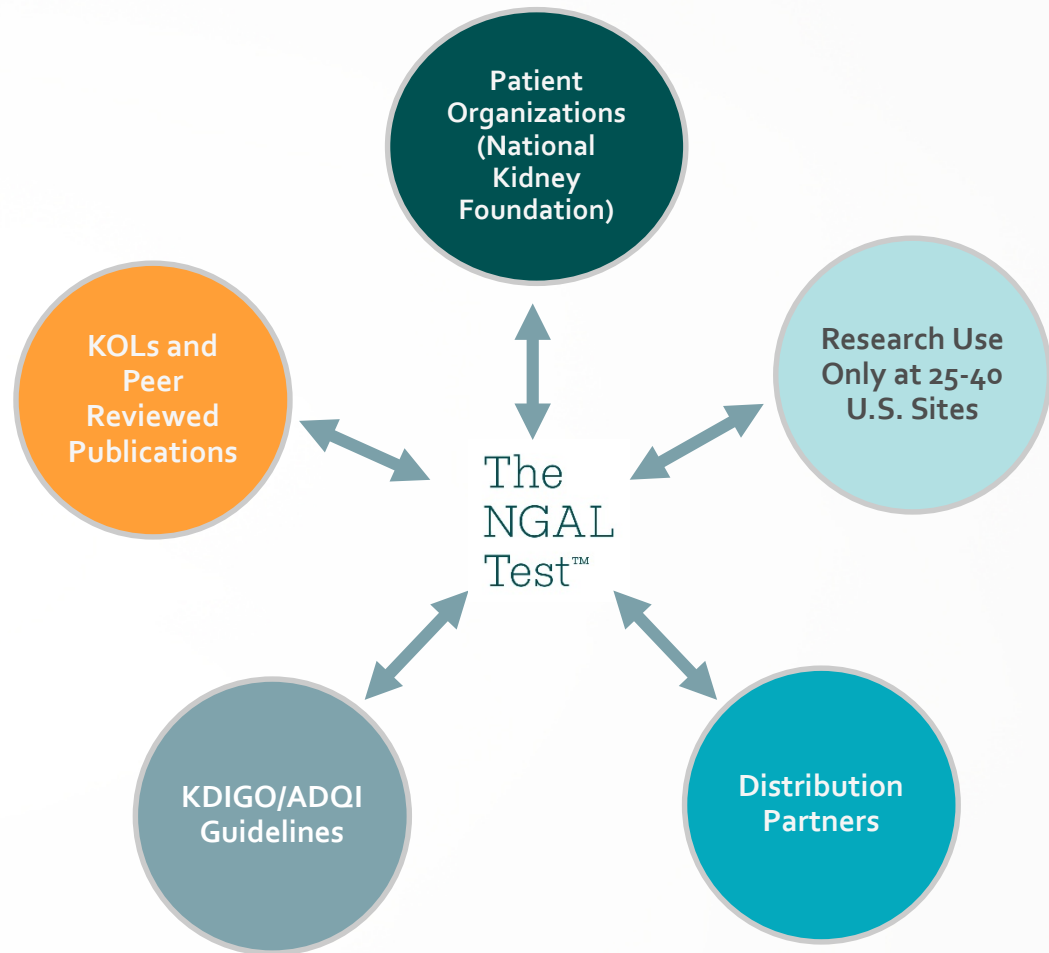
*The NGAL Test is pending US FDA 510(K) clearance.

During an average course of illness, 4-5 tests is assumed to be used to diagnose AKI
Sources: CDC, AHA, Ciccia 2017, Lameire NHet al. *Lancet* 2013; 382: (9887) 170-9



Building U.S. Market Awareness of NGAL

- Leverage BioPorto's strategic investments in establishing the clinical need for NGAL as a biomarker for AKI risk assessment
- U.S. commercial team expanded Q2 2019
- Commercial focus on engagement with KOLs and other stakeholders and on building RUO testing at research hospitals
- Number of accounts using as RUO up from 15 in 2017 to 35 end-2018, provides support for analytical performance and helps to establish hospital partnerships





Clinical, regulatory and commercial

Targeted 2019 Milestones



- Submission 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 U.S. ahead of launch
- Build U.S. organization by onboarding leadership and hiring core commercial team
- Prepare for U.S. launch of The NGAL Test to be accomplished through direct sales and partnerships



Revised Financial Projections for 2019

Revenue

DKK32m

Revenue reduced from DKK 40m due to the delay in NGAL clearance for pediatric

EBIT loss

DKK65m

Operating Loss increased due to reduced revenue, investment in U.S. organization and extra costs i.c.w. the delayed clearance

Financial calendar 2019

August 15

Q2 2019 Results

November 7

Q3 2019 Results

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