BioPorto
HC Wainwright Conference

September 15, 2020

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Agenda

1 About BioPorto

2 Acute Kidney Injury

3 The NGAL Test™

4 Regulatory Studies

5 The Addressable Market

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7 Summary

About BioPorto

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 Boston, and is listed on the Nasdaq Copenhagen stock exchange [CPH:BIOPOR]. The company has 25 employees and 2019 revenue of $4M.

Actionable Biomarkers

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

Assay Development

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

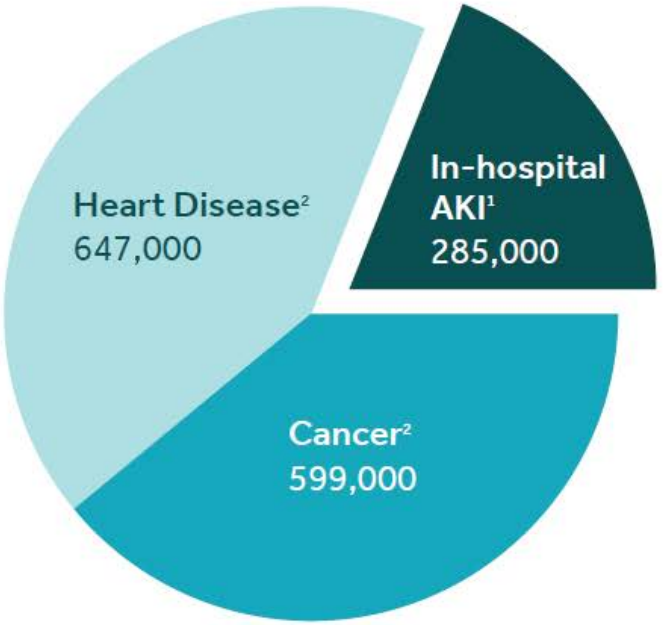
Antibody Library

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

Acute Kidney Injury (AKI)

AKI is a Major Public Health Concern

3rd Leading Cause of Death Annually



In-Hospital AKI

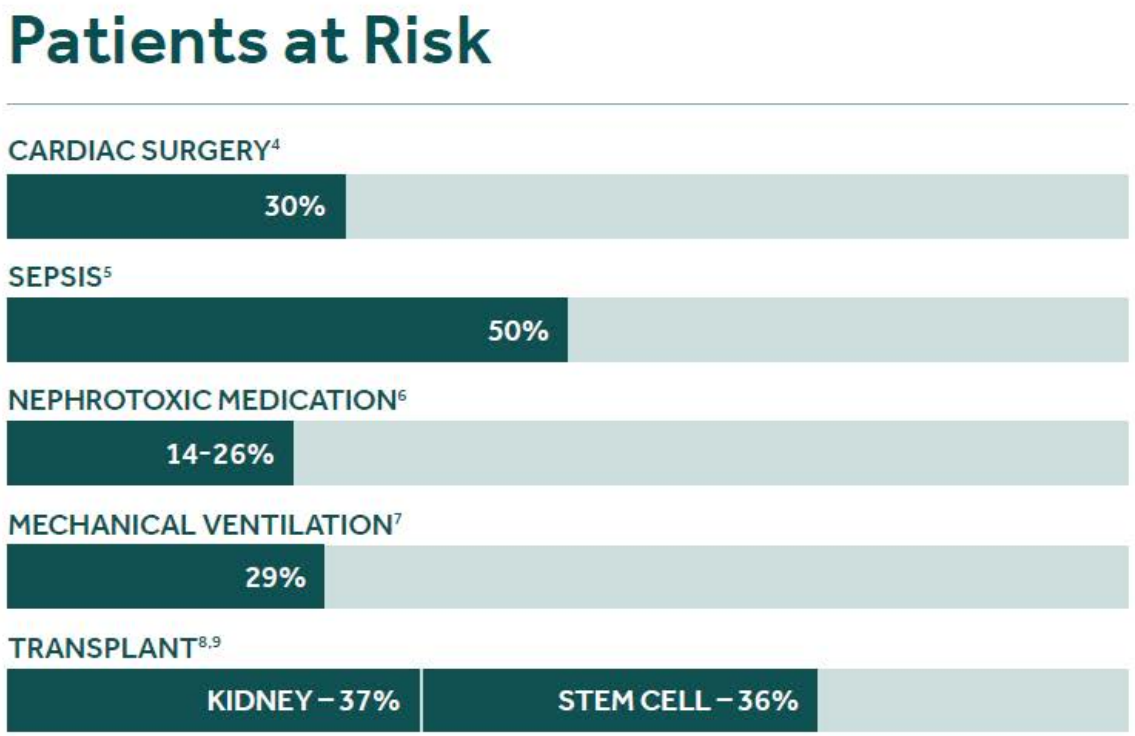
230%

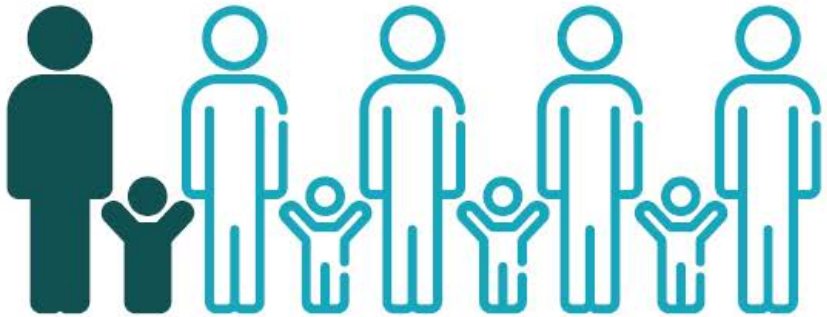
INCREASE

in AKI hospitalizations in the US (2000-2014)[3]

1) *Brown JR, BioMed Research International. 2016;ID4278579. (2) CDC, FastStats: Deaths and Mortality. 2017. (3) Pavkov ME. MMWR Morb Mortal Wkly Rep. 2018;67.*

Many Patients at Risk





1 in 5 ADULTS[10]
& 1 in 4 CHILDREN[11]
is affected with AKI during hospitalization

4) O'Neal JB, Crit Care. 2016;20(1). 5) Alobaidi R, Semin Nephrol. 2015;35(1). 6) Perazella MA, CJASN. 2018;13. 7) Lombardi R, CJASN. 2011;6(7). 8) Alkandari O, CJASN. 2018;13(11). 9) Hingorani SR, Kidney Int. 2005 Jan;67(1). 10) Susantitaphong P, CJASN. 2014;9(6). 11) Kaddourah A, N Engl J Med. 2017;376.

Clinical Burden Inside & Outside the Hospital

IN-HOSPITAL

Increased Length of Stay[12]

7-23 days

Increased need for Dialysis[13]

12%

of critically ill adults

Increased overall Mortality Rate[13]

25%

3 YEARS POST-DISCHARGE

- 30% readmission rate[14]
- 38% increase in a major cardiac event[15]
- 59% of AKI survivors have 1 or more kidney abnormalities: *microalbuminuria, hyperfiltration, decreased GFR, hypertension*[16]
- Up to 25% progress to CKD[17]

12) Sutherland SM, *CJASN*. 2013;8(10). 13) Hoste EA, *Intensive Care Med*. 2015;41(8). 14) Hessey E, *CJASN*. 2018;13(5). 15) Odutayo A, *JASN*. 2016;28. 16) Askenazi DJ, *Kidney Int*. 2006;69(1). 17) Horne KL, *BMJ Open*. 2017;7(3).

Costs of AKI

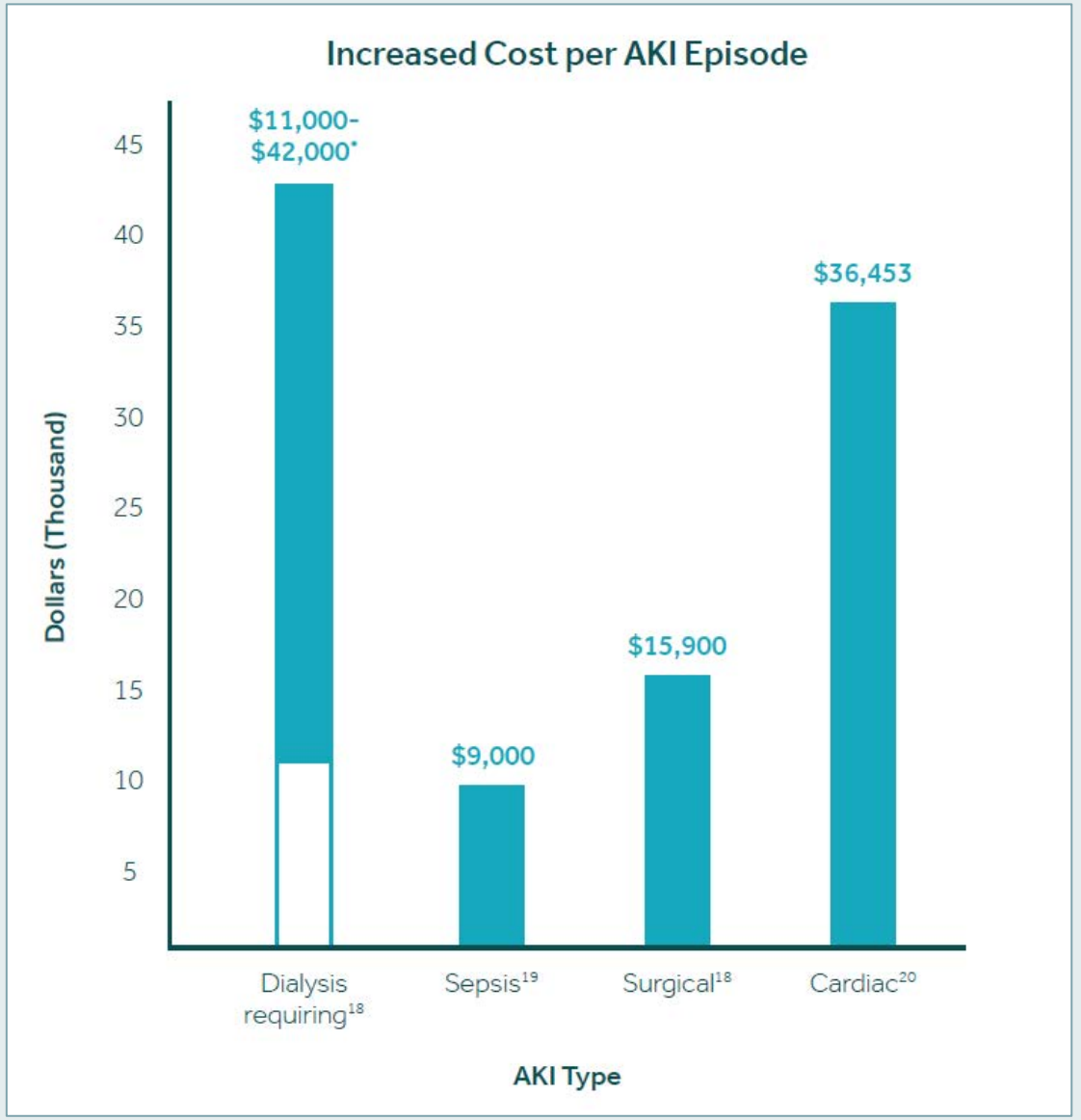
Economic Burden

AKI is hard to identify, when recognized late, it requires more intensive and costly interventions.

- Using KDIGO criteria, AKI was associated with a **$7,000 increase** in costs per episode.

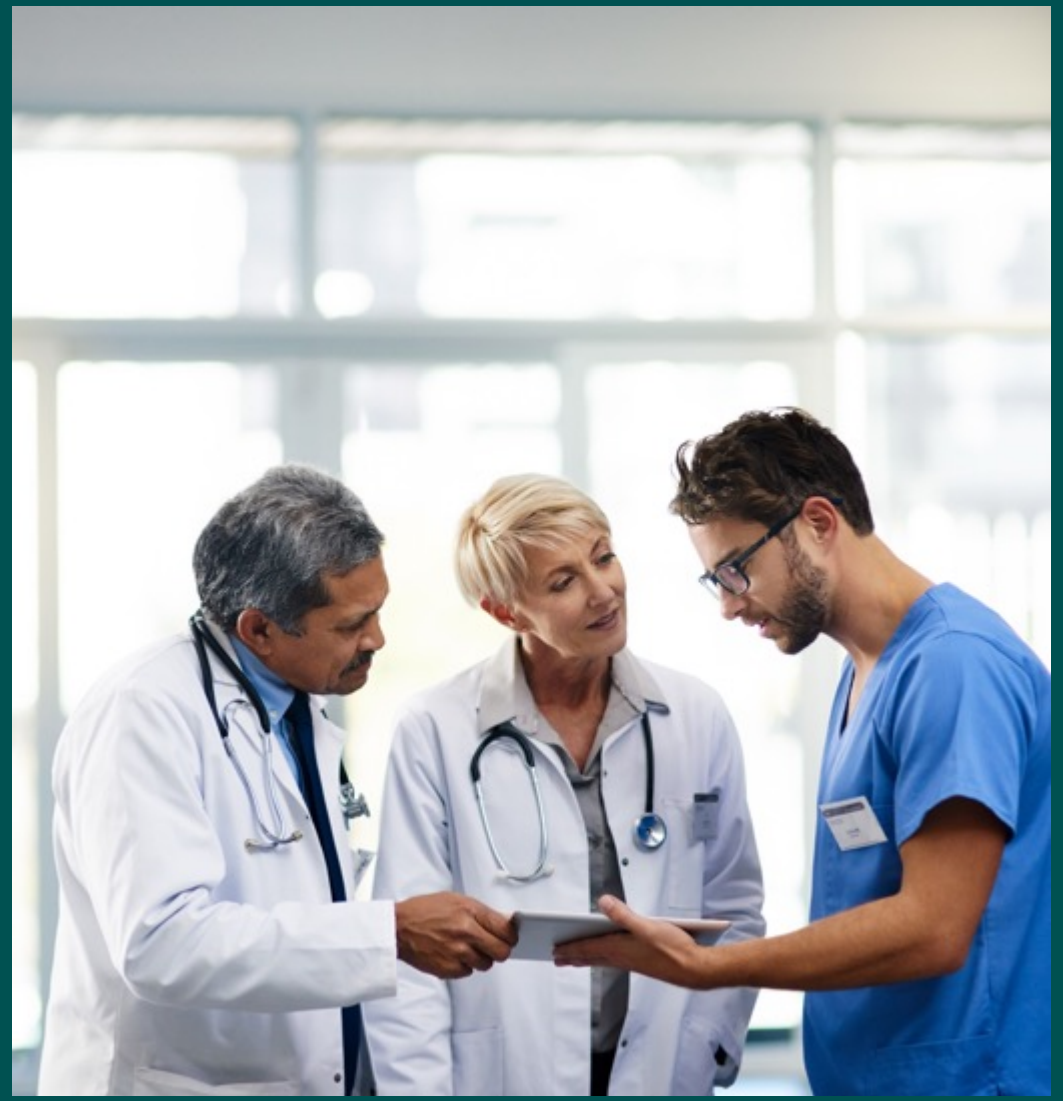
AKI costs the US healthcare system
$5.4 - $24.0 billion* annually

** Range for adjusted vs. unadjusted costs. (Adjusted for demographic factors, hospital differences, comorbidities and procedures.)*



18) Silver SA, Nephron. 2017;137. 19) Alobaidi R, Semin Nephrol. 2015;35(1).
20) Alshaikh HN, Ann Thorac Surg. 2018;105.

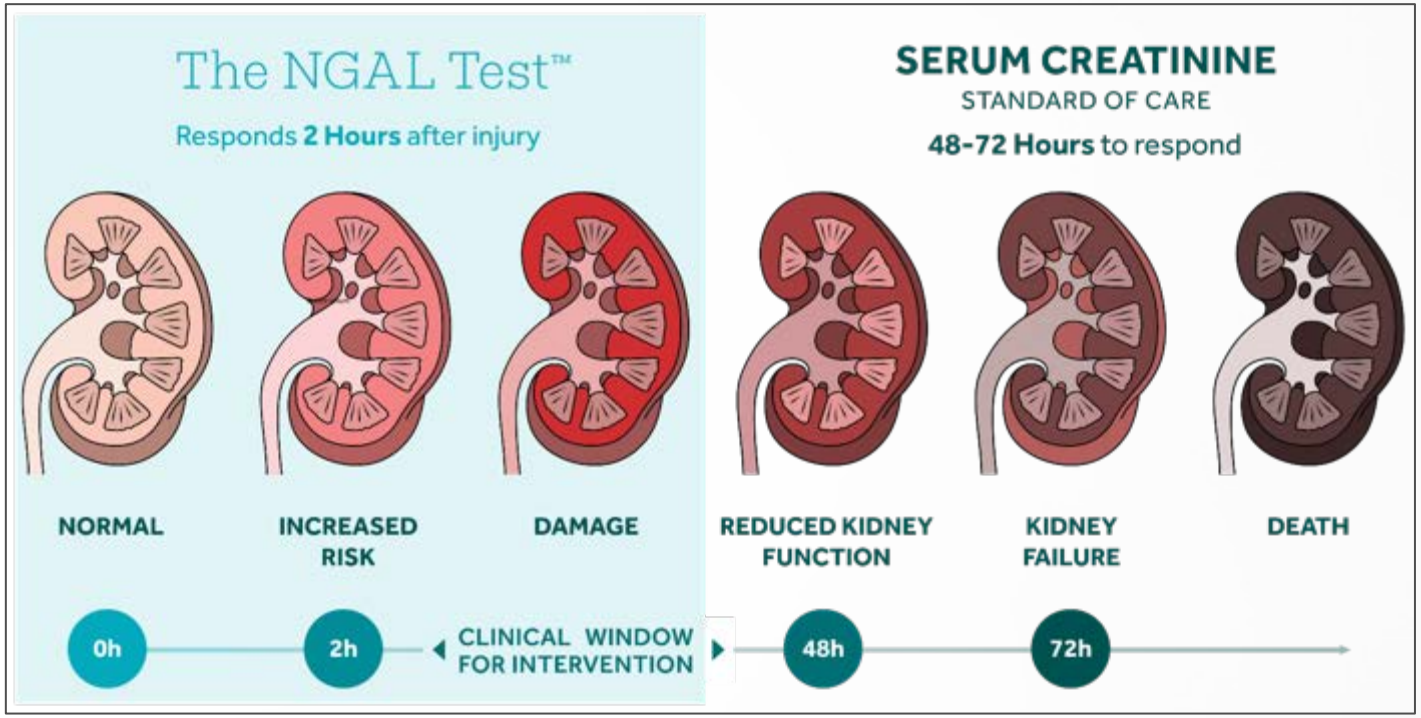
The NGAL Test



Standard of Care is Slow and Non-Specific

The NGAL Test is a tool to aid in the risk assessment of AKI.

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.



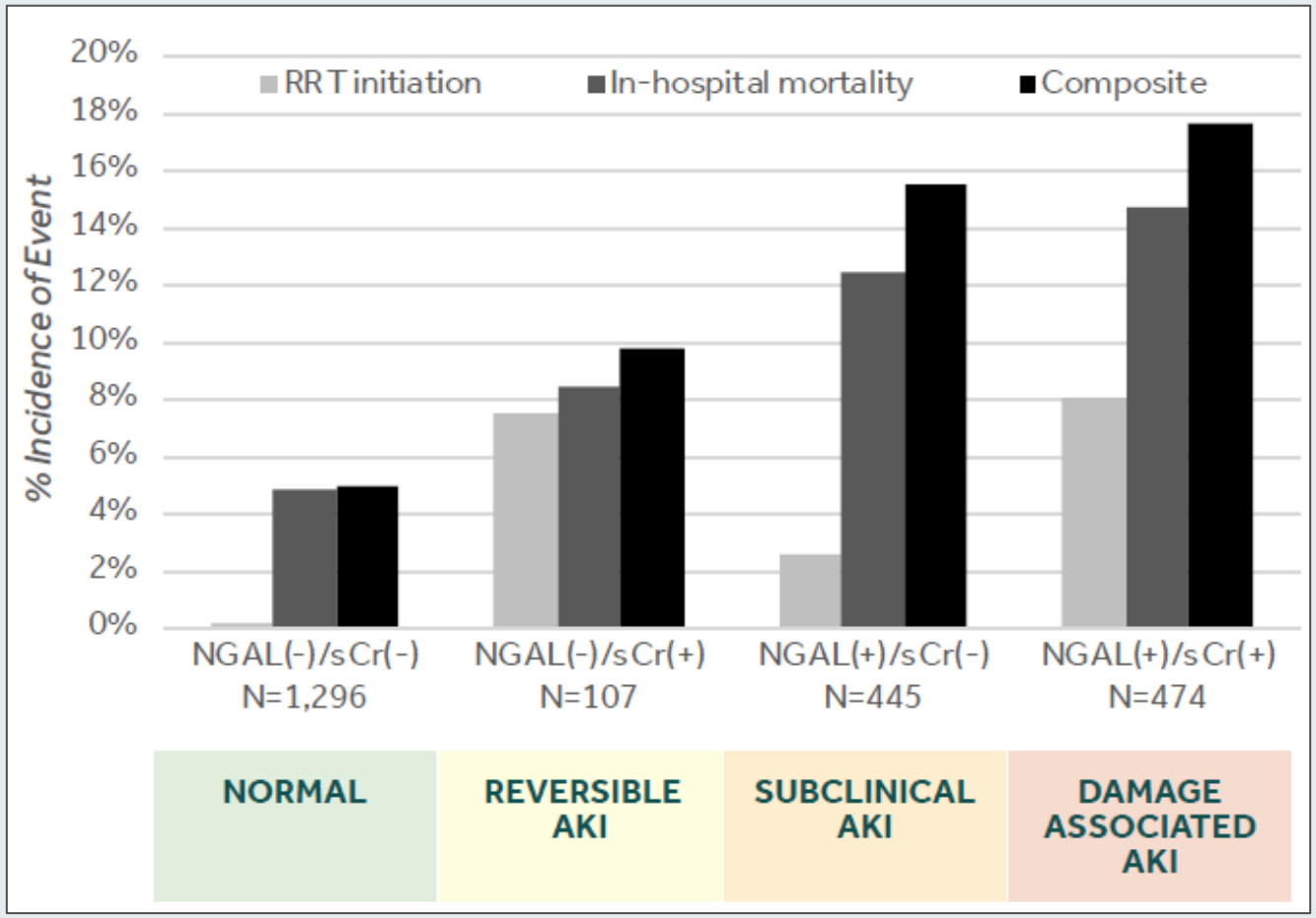
The NGAL Test is CE marked and available for IVD use in the European Union, Canada, Korea and Israel. For research use only in all other territories.

NGAL integrated with sCr

NGAL+ Identifies Poorer Outcomes

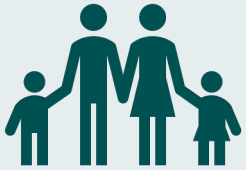
This 2011 multicenter pooled analysis of prospective studies evaluated data from 2,322 critically ill patients from 10 prospective observational studies of NGAL showed:

"In the absence of diagnostic increases in serum creatinine, NGAL detects patients with likely subclinical AKI who have an increased risk of adverse outcomes."



Adapted from 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.

Potential 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

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Regulatory Strategy

Regulatory Strategy for NGAL

Pediatrics

1 in 4 affected with AKI[2] during hospitalization

Predict AKI Risk in Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

De novo application being developed, expected submission 2020

Adults

1 in 5 adults affected with AKI during a hospital episode of care[1]

Predict AKI Risk in Intensive Care Setting

- Plasma sample
- Predict Stage 2/3 AKI

Study planning underway, expected submission to follow pediatric clearance

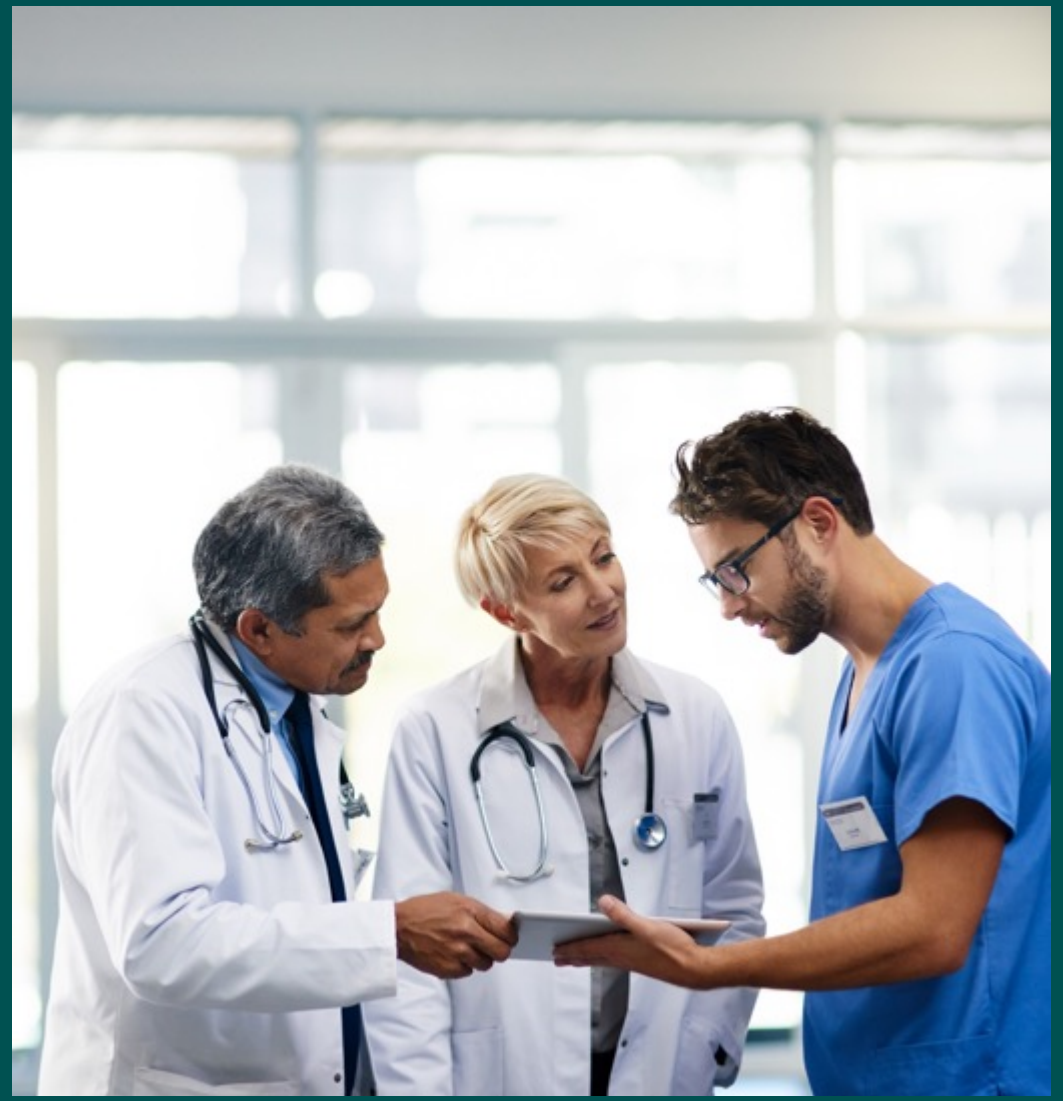
Additional Indications

- Nephrotoxicity
  - Oncology
  - Cardiology
  - Diabetes
  - Transplant
  - Autoimmune
- Therapeutic monitoring
- Diagnosis of AKI
- Point-of-care applications

Initiate following potential FDA clearance of initial AKI risk assessment indications

1) Susantitaphong, P et al. *Clin J Am Soc Nephrol*. 2013 Sep;8(9):1482-93. 2) Kaddourah A, et al. *N Engl J Med*. 2017; 376(1):11-20.

The Addressable Market



Addressing a Significant Unmet Need

Initial Focus
Global Opportunity: ~100 M tests; $2 Bn

Long Term
Global Oppt'y: ~150M tests; $3Bn

Research Use Only
(Currently ~30 AMCs)

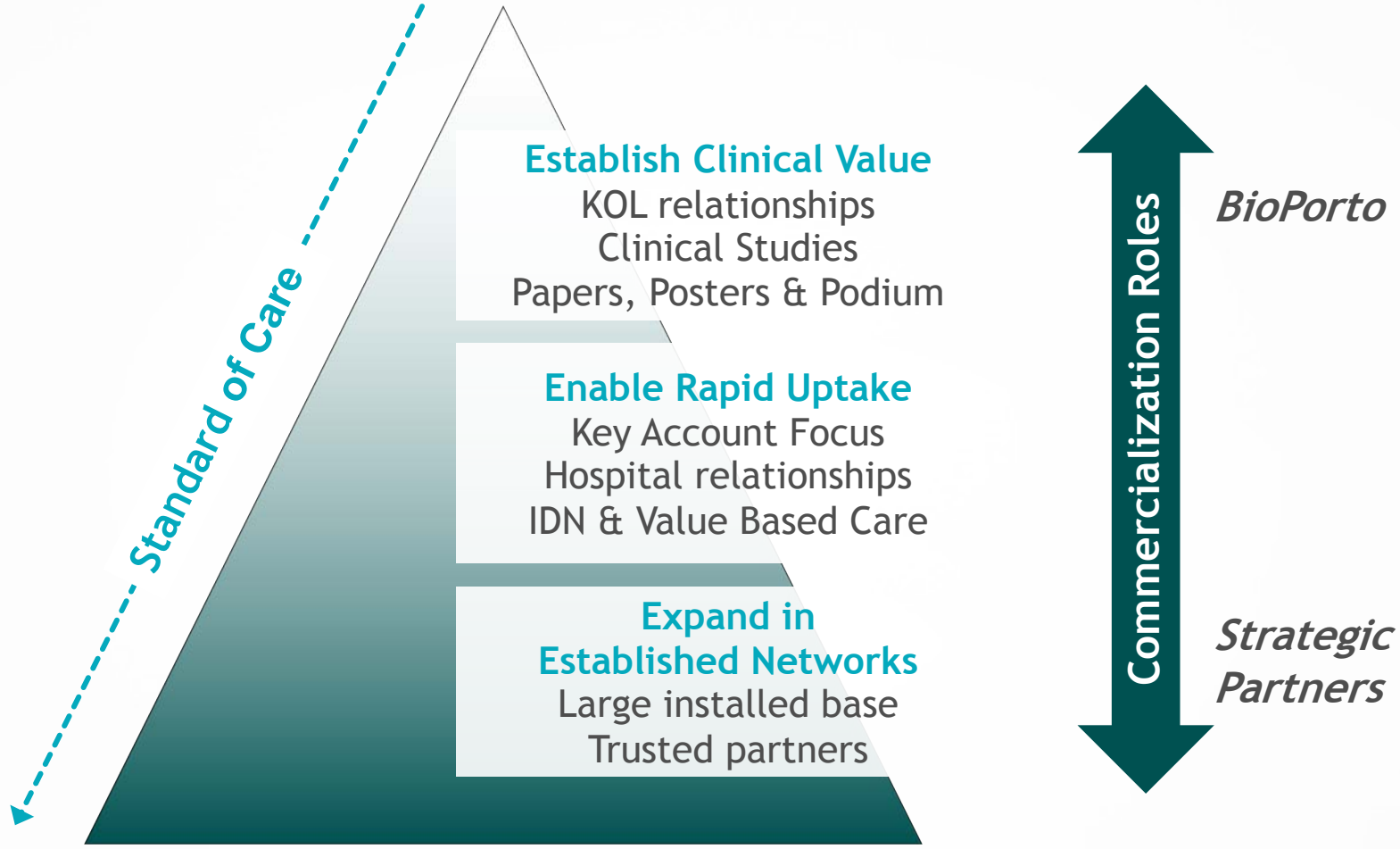
Pediatric Risk Assessment (ICU)
Breakthrough Designation; submit 2020)

Adult Risk Assessment (ICU)
(Submit following pediatric clearance)

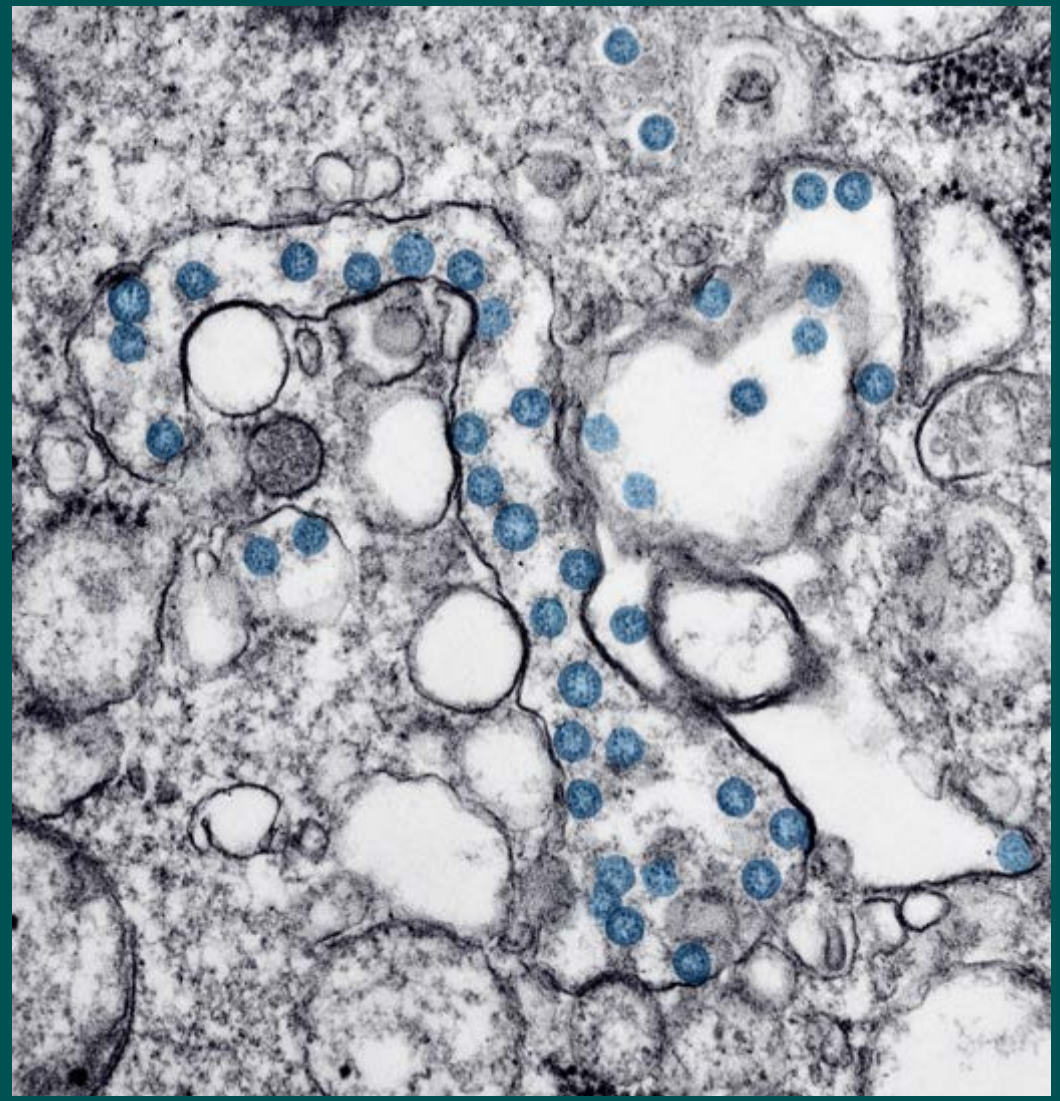
New indications
- *Exclusion in the ED*
- *Monitoring*
- *Toxicity*
- *Trauma*

Planned evolution of commercial activities

Driving Commercialization Through Partnerships



NGAL & COVID-19

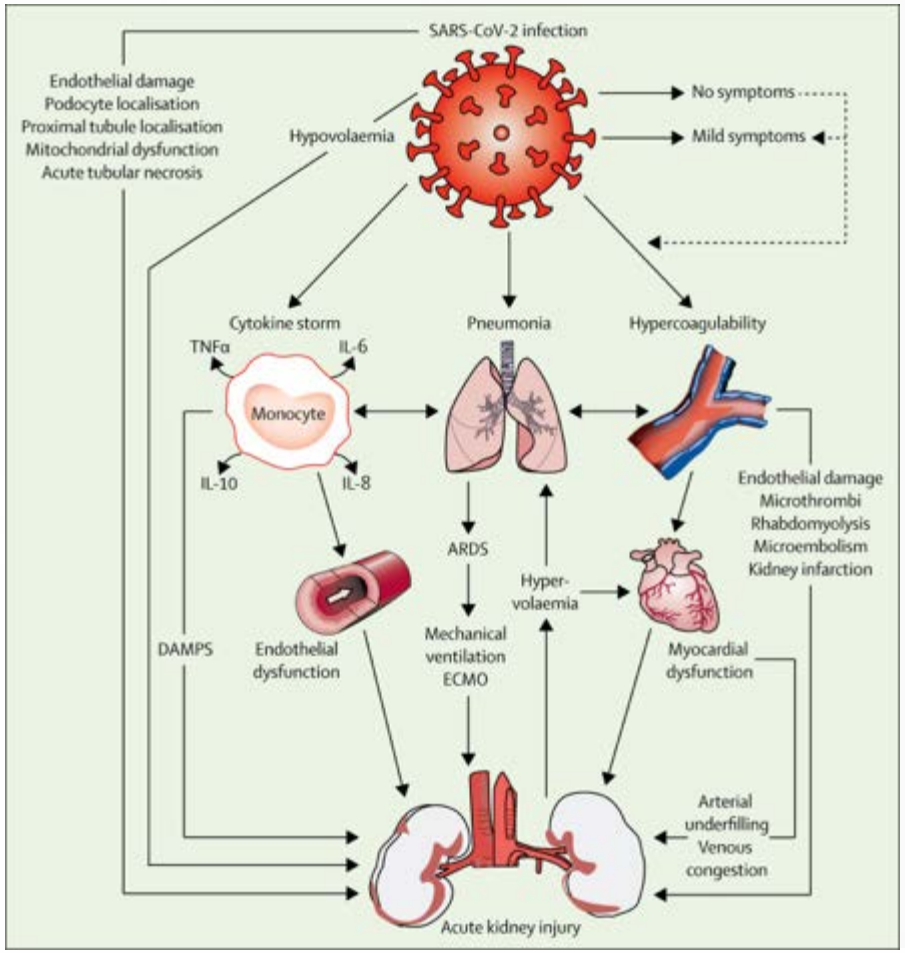


Multifactorial Causes of Kidney Dysfunction

- Kidney involvement in hospitalized patients is frequent, ranging from mild dysfunction to progressive acute kidney injury (AKI)
- Multiple dependent pathways in the setting of COVID-19 increase the risk of acute kidney injury
- Systemic inflammation precedes cytokine storms where NGAL production is also observed and could potentially be used to triage care
- At right: the possible hemodynamic, proinflammatory and proapoptotic consequences of lung inflammation, cytokine release syndrome, and hypercoagulability on renal function, and potential organ support options
- NGAL may also indicate broader distress caused by inflammation:

"The parallel is that serum/urine NGAL is reflective of IL-6 expression and IL-6 is a mediator of significant early inflammation."

-Dr. Raj Basu, Children's Hospital of Atlanta



Ronco, C. Management of acute kidney injury in patients with COVID-19; May 14, 2020; DOI:https://doi.org/10.1016/S2213-2600(20)30229-0

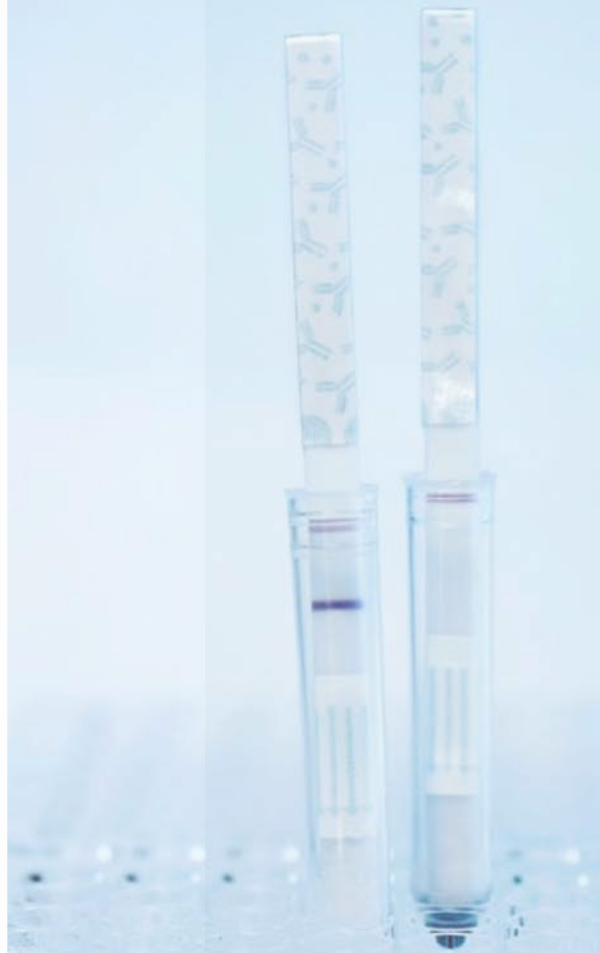
Generic Rapid Assay Device (gRAD)

bioporto

BioPorto's patented lateral flow development system

Proprietary Platform: gRAD

- **BioPorto's patented Generic Rapid Assay Device (gRAD) was developed in 2016 to enable rapid development of lateral flow devices**
- **gRAD has been used in the development of 3 novel lateral flow tests, including** NGALds, Horse NGALds, and SHINEds
- **Features of gRAD include:**
  - Optimized with two printed lines: a **test line** for biotinylated antibody (or biotinylated protein), and a **control line** designed to capture any mouse, rabbit or goat antibody
  - Biological recognition between the specific capture antibody, the antigen in the sample and the detection antibody occurs in solution – no specific antibodies are immobilized on the strip
  - Assay incubation time is short, typically 10-15 minutes
- **Cost effective, flexible design**



See how gRAD works

Benefits of BioPorto's gRAD Solution

Fast

Short incubation time <15 minutes

Versatile

Flexible design allows different sample types

Easy

No instruments, fewer than 5 steps, room temp stable

Low Cost

Simple format with few components

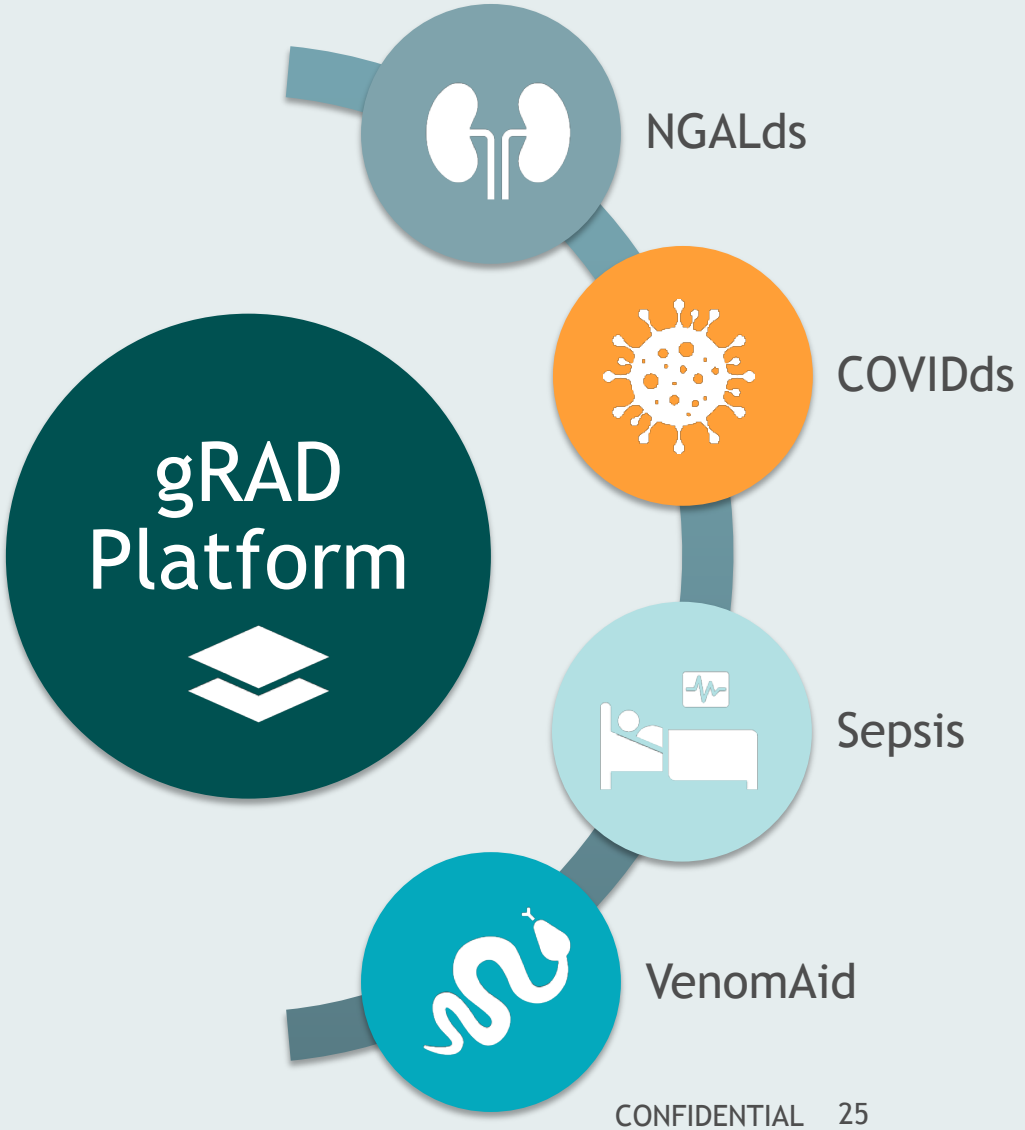
Scalable

Design allows rapid iteration (days not weeks) and scale up

Platform for Product Development & Growth

Leveraging the gRAD platform, BioPorto is developing tests for NGAL as well as three emerging applications:

1. **NGALds:** for outpatient assessment of kidney injury
2. **Two COVID-19 assays**: a viral diagnostic test and a serology-based test for immunity assessment
3. **Sepsis**: a blood test using antibodies to thrombomodulin, a marker of endothelial injury, for the early identification of septic shock
4. **Stratification of snakebites**: Rapid tests to allow for earlier intervention, with the possibility to treat using specific, rather than broad-spectrum, antivenoms



2020 Milestones

Targeted 2020 Milestones

- Finalize collection of data for the FDA application of The NGAL Test for pediatrics and submit application in the second half of 2020
- Collect supplementary data to support submission of an application for The NGAL Test in adults
- Co-development of COVID-19 tests for early and rapid detection of SARS-CoV-2 with SDU
- Review new opportunities for NGAL and BioPorto's antibody library
- Grow total revenue by 10%
- Financial projections: Revenue of DKK 30m and an EBIT loss of DKK 73m

Experienced International Management Team

Peter Mørch Eriksen
CEO

Ole Larsen
CFO

Jan Kuhlmann
COO

Amy Winslow
President,
BioPorto Diagnostics Inc.

Christopher Bird
CMO, BioPorto Inc.

Thank you !