

# *Investor Presentation* **BioPorto**

October 2020



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# Agenda

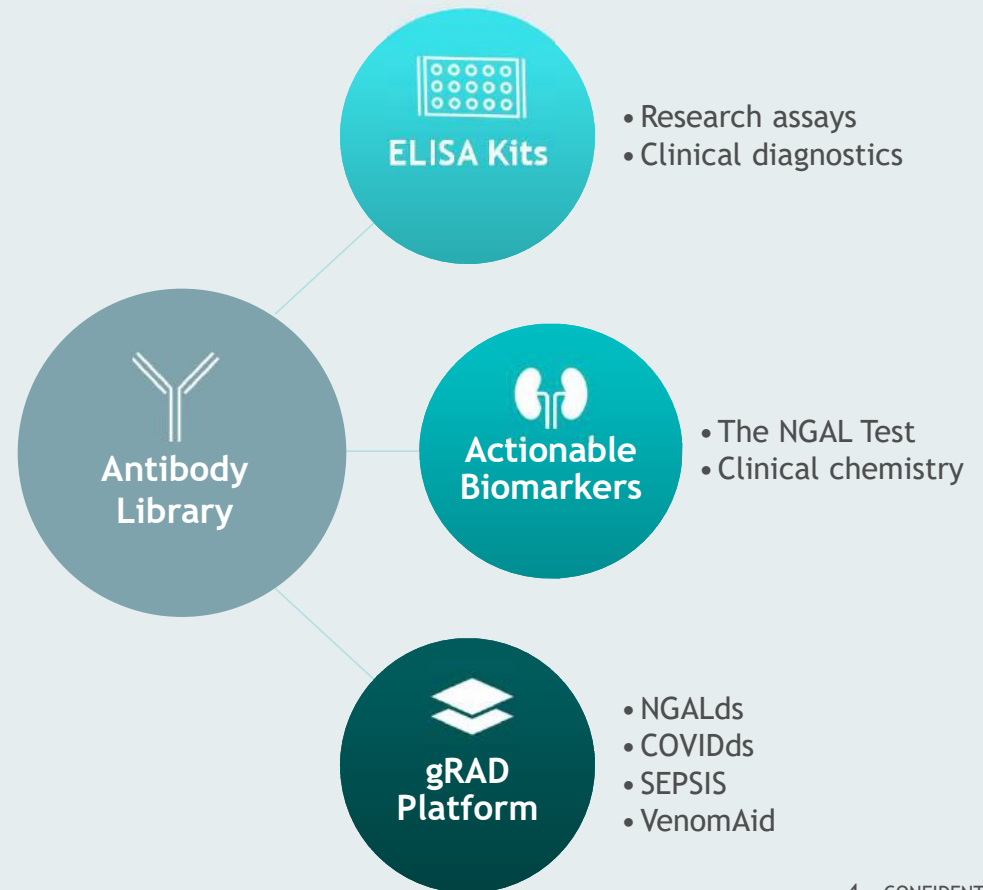
- 1 About BioPorto
- 2 Acute Kidney Injury
- 3 A Novel Solution: The NGAL Test
- 4 The Addressable Market
- 5 NGAL Regulatory Strategy
- 6 A Development Platform - gRAD
- 7 Summary

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# 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 outside of Boston, and is listed on the Nasdaq Copenhagen stock exchange [CPH:BIOPOR]. The company has 27 employees and 2019 revenue of DKK 27 million.*





# Mission, Vision and Strategy

BioPorto helps healthcare providers improve patient management and outcomes with products that provide early and specific insights into significant clinical conditions.

By 2025, we aspire to become one of the world's leading companies in diagnostics that improve kidney health.



## Establish commercial capabilities to drive growth

Through our own commercial team, and through partnerships, we seek to introduce and expand use of novel assays by communicating the clinical and economic value of our products in a clear, efficient and compelling manner.



## Expand product pipeline and clinical knowledge

We focus on expanding our pipeline vertically through development of new indications for The NGAL Test, as well as horizontally by leveraging the gRAD platform to develop new rapid assays for emerging conditions, such as COVID-19.



## Strengthen infrastructure to ensure quality and drive profitability

We seek to secure strong suppliers to support our chemistry assays and will also build in-house expertise in product logistics and supply chain in both Denmark and the US.



# Experienced International Management Team

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**Ole Larsen**  
CFO

CFO of BioPorto since June 2018. 20+ years CFO experience including 12 years at Bavarian Nordic



**Jan Kuhlmann**  
COO

COO of BioPorto since August 2016. 25+ years in the life sciences with FMC, Cambrex, Fisher Scientific, and Chr. Hansen A/S



**Peter Mørch Eriksen**  
CEO

CEO of BioPorto since July 2013  
20+ years in medtech/life sciences, including CEO of Sense A/S and VP/GM of Medtronic



**Amy Winslow**  
President,  
BioPorto Diagnostics Inc.

Joined in April 2019. 25+ years in the medtech industry, most recently as President and CEO of Magellan Diagnostics



**Christopher Bird**  
CMO

CMO of BioPorto since August 2019. 20+ years in the life science industry primarily at Roche Diagnostics

*Significant Unmet Need*  
**Acute Kidney Injury**

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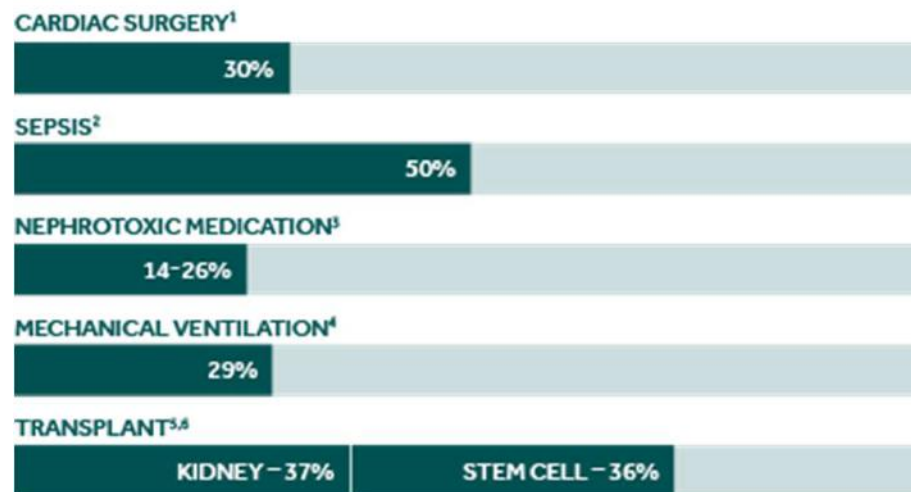




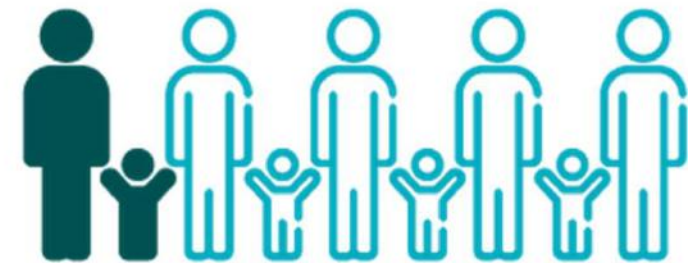
Why is Acute Kidney Injury (AKI) important ?

# Many Patients at Risk

## Patients at Risk



\*Kidney transplant rate is in children; Stem cell is rate in children/adults



**1 in 5 ADULTS<sup>7</sup>**  
**& 1 in 4 CHILDREN<sup>8</sup>**

Is affected with AKI during hospitalization,  
and during admission to the ICU, respectively

1) O'Neal JB, Crit Care. 2016;20(1). 2) Alobaidi R, Semin Nephrol. 2015;35(1). 3) Perazella MA, CJASN. 2018;13. 4) Lombardi R, CJASN. 2011;6(7). 5) Alkandari O, CJASN. 2018;13(11). 6) Hingorani SR, Kidney Int. 2005 Jan;67(1). 7) Susantitaphong P, CJASN. 2014;9(6). 8) Kaddourah A, N Engl J Med. 2017;376.



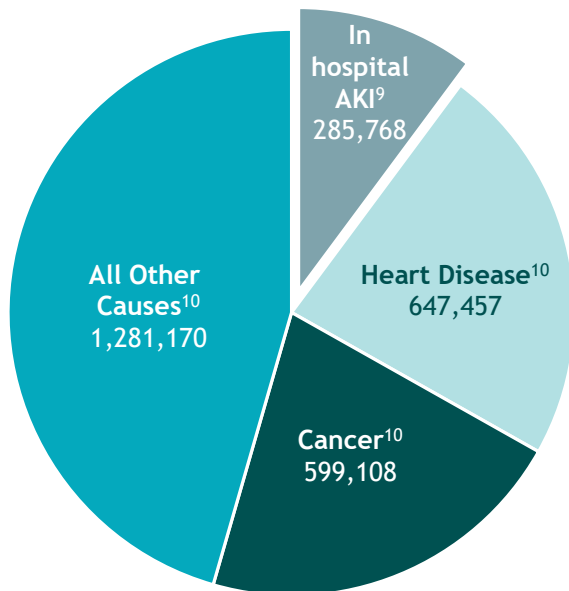


*The unsolved problem*

# AKI is a Major Public Health Concern

## Third Leading Cause of Death

Annual US deaths: 2,813,503<sup>10</sup>



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## AKI-associated In-hospital Mortality

# 230%

**INCREASE**  
in AKI hospitalizations  
in the US (2000-2014)<sup>11</sup>

*Rate among non-diabetic adults; among diabetics the increase was 139%*

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9) Company estimate, based on recent studies, including: Brown JR, BioMed Research International. 2016;ID4278579.

10) CDC, FastStats: Deaths and Mortality. 2017.

11) Pavkov ME. MMWR Morb Mortal Wkly Rep. 2018;67.



# Clinical Burden Inside & Outside the Hospital

## IN-HOSPITAL

## 3 YEARS POST-DISCHARGE



Increased  
Length of Stay<sup>12</sup>  
**7-29 days**



Increased Use  
of Dialysis  
(renal replacement therapy)<sup>13</sup>  
**12%**  
of critically ill adults



Increased Overall  
Mortality Rate<sup>13</sup>  
**25%**

- 30% higher risk of hospital readmission<sup>14</sup>
- 38% more likely to have a major cardiac event<sup>15</sup>
- Up to 25% progress to Chronic Kidney Disease (CKD)<sup>17</sup>
- 59% of AKI survivors have 1 or more kidney abnormalities: *microalbuminuria, hyperfiltration, decreased GFR, hypertension*<sup>16</sup>

12) Sutherland SM, *CJASN*. 2013;8(10). 13) Hoste EA, *Intensive Care Med*. 2015;41(8). 14) Hessey E, *CJASN*. 2018;13(5). 15) Oduyayo 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

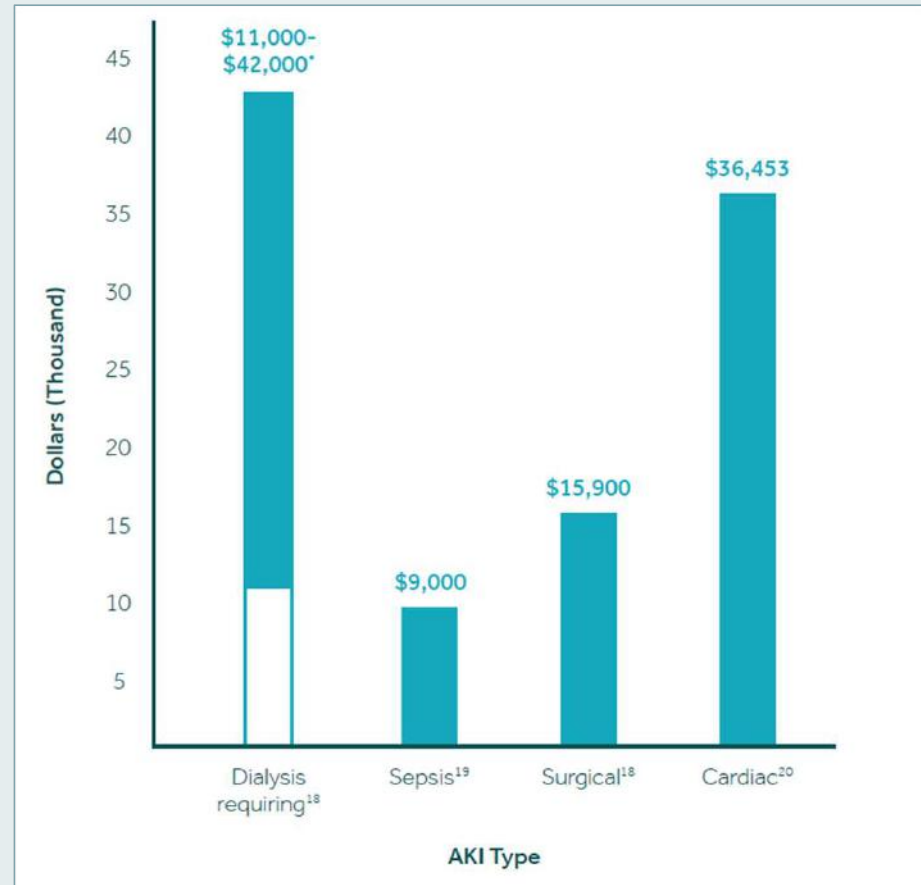
- Using KDIGO criteria, AKI was associated with a **\$1,795-\$7,933 increase** in costs per episode, in the US

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.)*



Increased Cost per AKI Episode for Selected Types of AKI

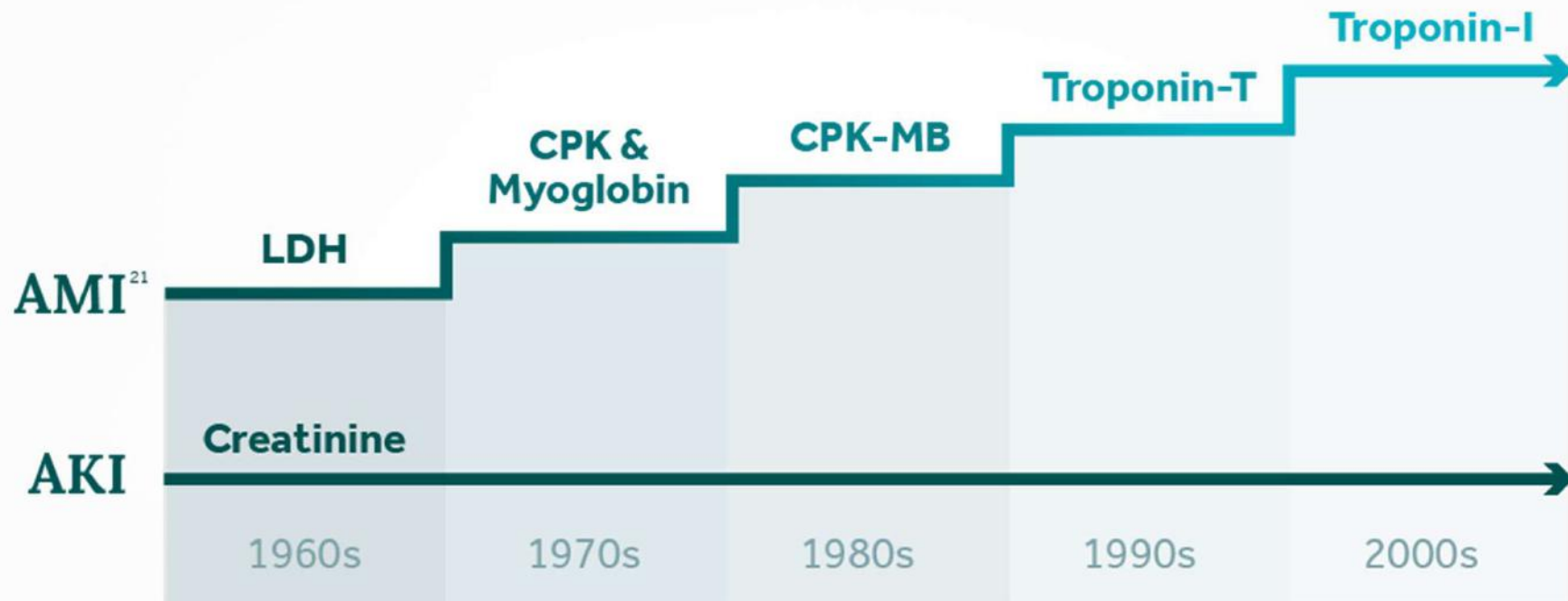


18) Silver SA, Nephron. 2017;137. 19) Alobaidi R, Semin Nephrol. 2015;35(1).

20) Alshaikh HN, Ann Thorac Surg. 2018;105.



# Cardiac Markers Highlight Innovation Needed in AKI



AMI: Acute Myocardial Infarction, AKI: Acute Kidney Injury

*A Novel Solution*

# The NGAL Test

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



AKI assessment tools: NGAL vs. Standard of Care

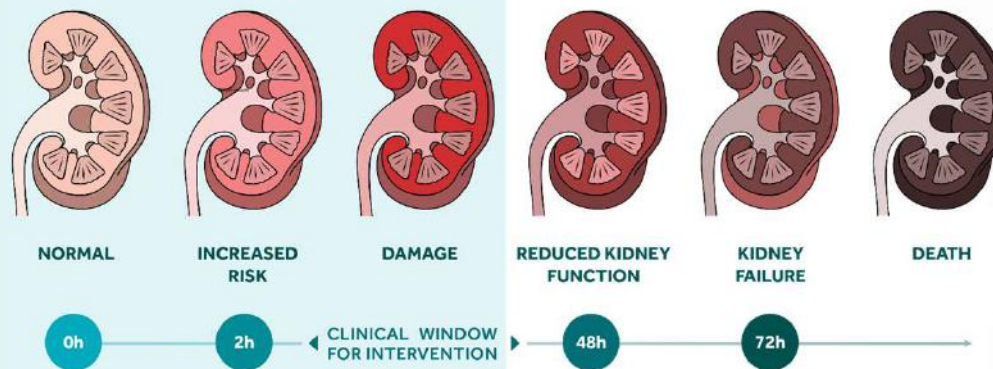
# An Early Warning System for Kidney Injury

## Neutrophil Gelatinase Associated Lipocalin (NGAL)

- Small protein expressed in neutrophils & certain epithelia, including the renal tubules
- Produced rapidly in response to injury, rises within 2 hours<sup>24</sup>
- Responds in a “dose dependent” manner<sup>25</sup>
- Not dialyzed, not affected by fluids<sup>26</sup>

### The NGAL Test™

Responds 2 Hours after injury



## Serum Creatinine (sCr)

- A non-specific marker of kidney function<sup>27</sup>
- Delayed: peaks 48-72 hours after injury<sup>27</sup>
- Insensitive: patients may have kidney damage without a sCr increase<sup>27</sup>
- Results affected by fluid overload<sup>27</sup>
- Also influenced by age, muscle mass, gender, nutrition<sup>27</sup>

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

24) Mishra J, et al. *Lancet*. 2005;365(9466):1231-1238; 25) Haase-Fielitz A, Haase M, Devarajan P. *Ann Clin Biochem*. 2014;51(Pt 3):335-351. 26) Varnell CD Jr, Goldstein SL, Devarajan P, Basu RK. *Kidney Int Rep*. 2017;2(6):1243-1249. 27) Desanti De Oliveira, et al. *Nat Rev Nephrol*. 2019 Oct; 15(10): 599-612.



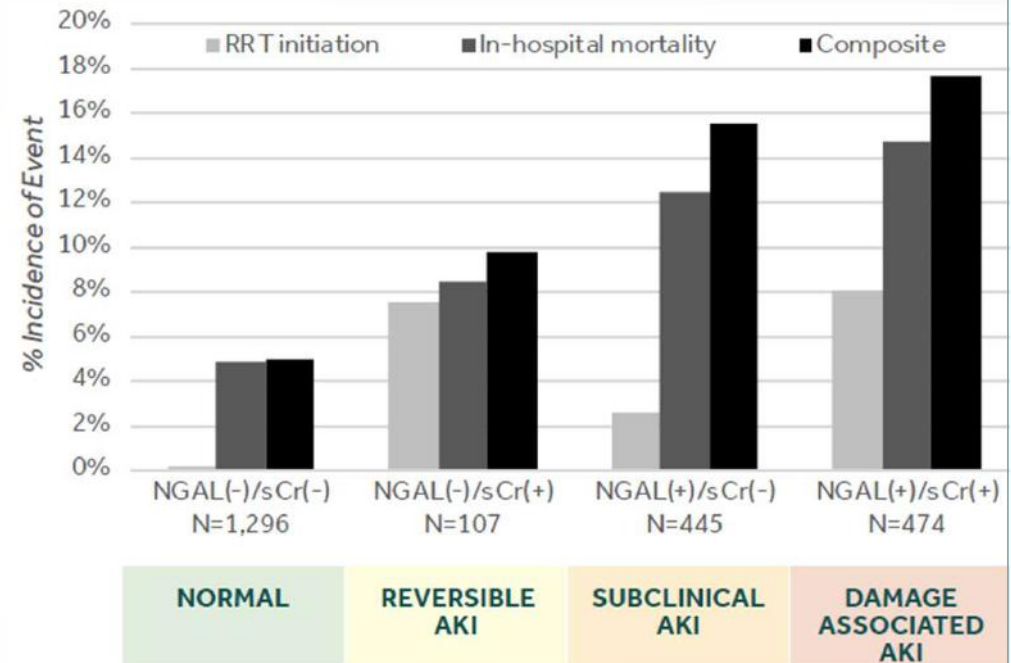
Utility of integrating NGAL with sCr reveals four phenotypes

## NGAL(+) Identifies Poorer Outcomes

Multicenter pooled analysis (2011) evaluated 10 prospective observational studies including 2,322 critically ill patients

Utility of integrating NGAL with sCr revealed four phenotypes:

- Both negative:**  
Patients with most favorable outcomes
- NGAL(-), sCr(+)**  
Reversible AKI (pre-renal azotemia), shows functional loss without injury, often caused by hypovolemia
- NGAL(+), sCr(-)**  
Subclinical AKI, indicates kidney injury before functional changes arise
- Both positive:**  
Damage associated AKI shows injury with functional loss, had poorest outcomes



Adapted from 28) Haase M et al. *J Am Coll Cardiol.* 2011;57(17):1752-1761.

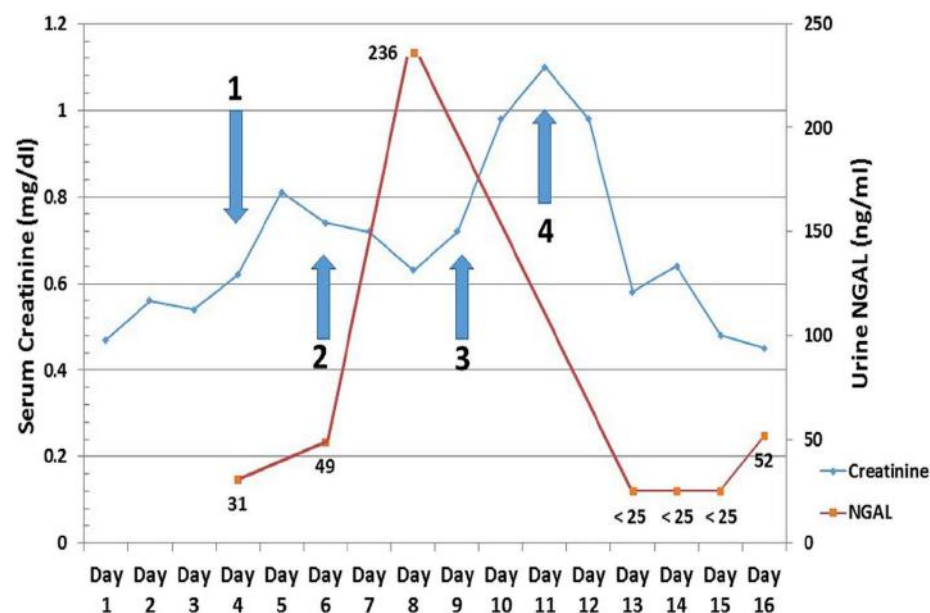


# NGAL Predicting Tubular Injury

## Case Highlights Corresponding to Numbered Arrows<sup>29</sup>

1. After 4 days in the CICU, nephrology was consulted due to rising creatinine levels with fluid overload. Initial uNGAL test is not elevated, suggesting no significant tubular damage
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



29) Varnell CD Jr, Goldstein SL, Devarajan P, Basu RK. *Kidney Int Rep.* 2017;2(6):1243-1249.





# 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



## Core Lab

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



## Hospitals

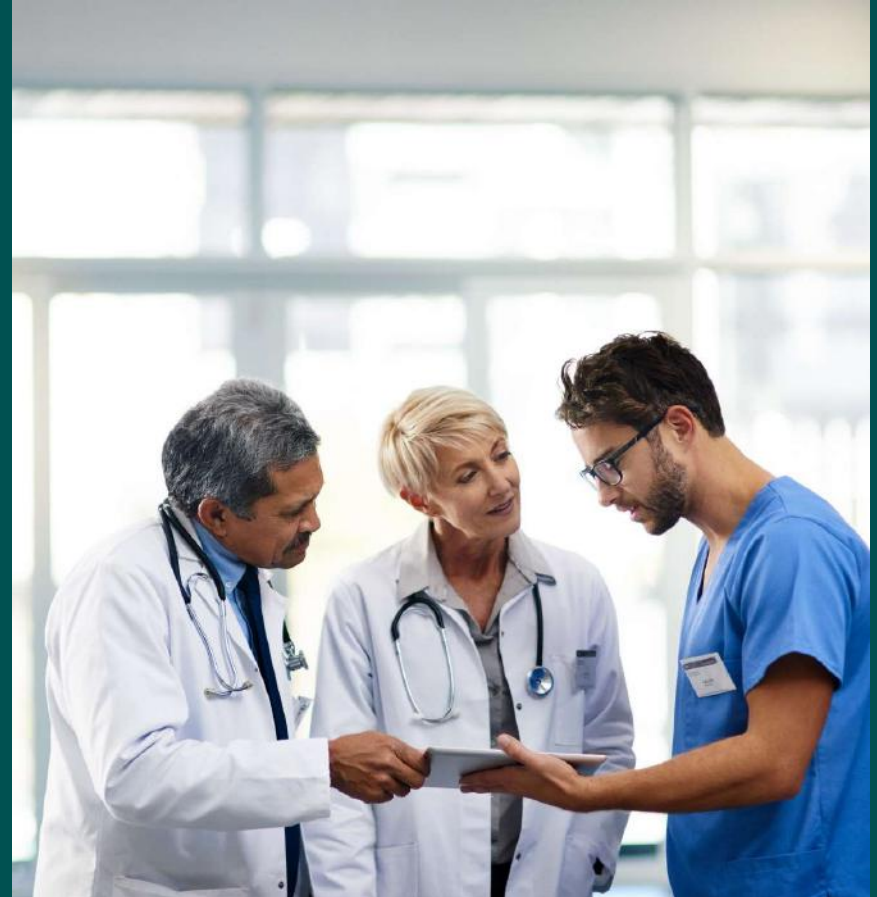
Reduce morbidity and mortality  
Fewer patients needing RRT  
Shorter lengths of stay  
Reduced cost per patient

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

†Management estimate of US sales price following expected FDA clearance.

# The Addressable Market

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Market Opportunity for The NGAL Test

# Addressing a Significant Unmet Need

## Markets & Indications

### Expanded Indications

- Exclusion in the ED
- Monitoring
- Drug Toxicity
- Trauma/Triage

### Adult ICU Risk Assessment

*Submit following pediatric clearance*

### Pediatric ICU Risk Assessment

*Breakthrough Designation; Submit 2020*

### Research Use Only

*Currently ~30 Academic Medical Centers*

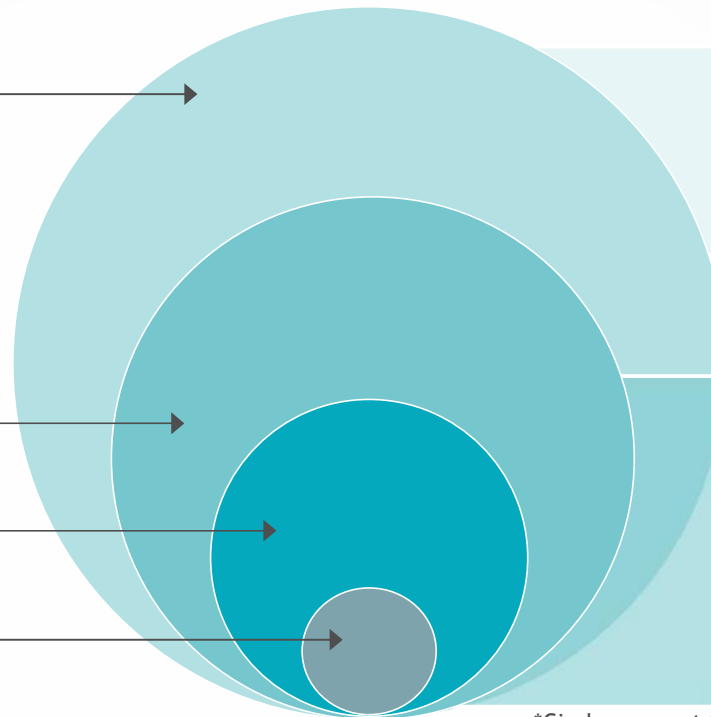
## Global Opportunity

### Long Term Expansion

**~150M tests; \$3Bn**

### Initial Focus Indications

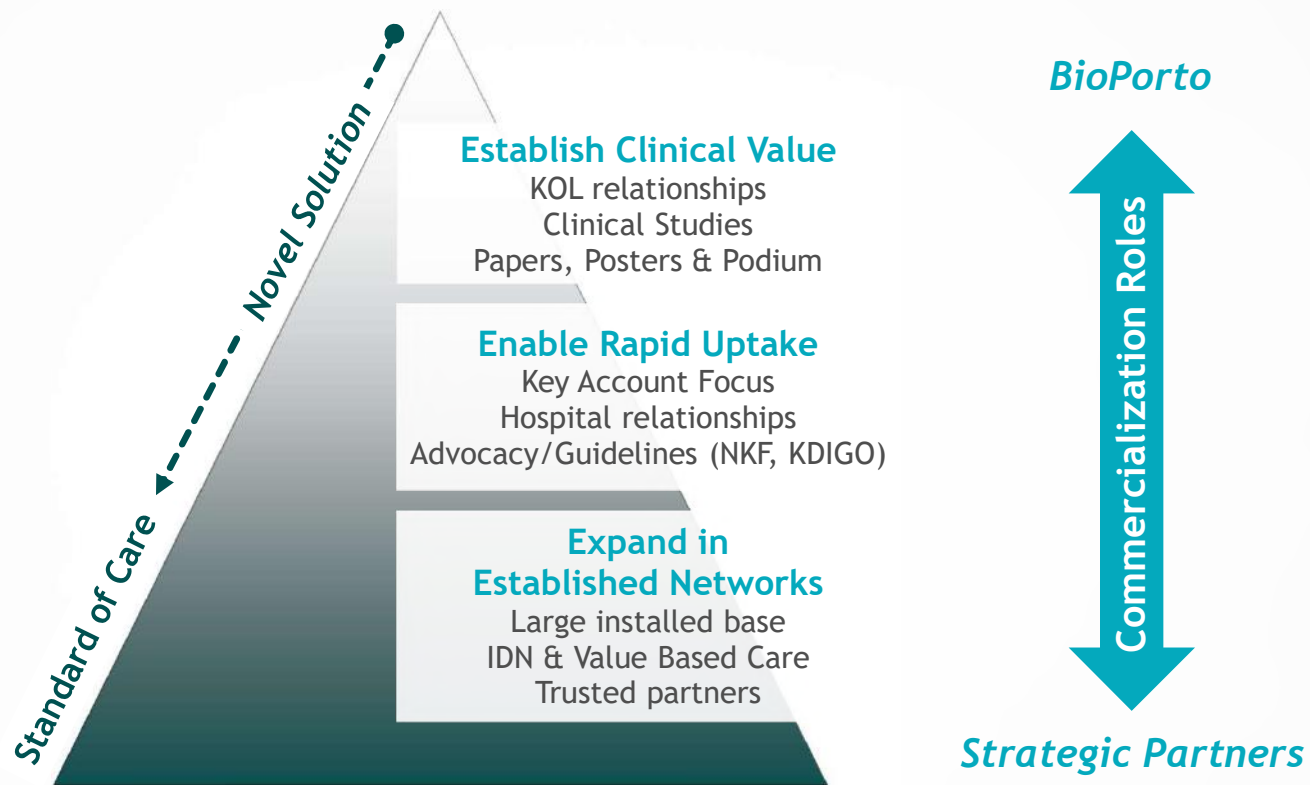
**~100M tests; \$2Bn**





*Planned evolution of commercial activities for The NGAL Test\**

# Driving Commercialization Through Partnerships



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



# Supply Chain

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- **The NGAL Test**
  - Antibodies are sourced from a subcontractor, then supplied to a third-party to complete manufacturing
  - Manufactured product is assembled, labeled, packaged and shipped from Company headquarters in Hellerup, Denmark
- **Antibodies**
  - Antibodies for direct sale and for use in gRAD products are developed by and sourced from established antibody producers, according to Company specifications
  - Manufacturing of the gRAD “blank” test strip is outsourced, with final assembly occurring in Hellerup
- **ELISA Kits**
  - All ELISA kits are manufactured and distributed from Hellerup
- **Strategic Vision**
  - To secure additional suppliers and build in-house expertise in product logistics and supply chain in both Denmark and the U.S.



# Regulatory Strategy

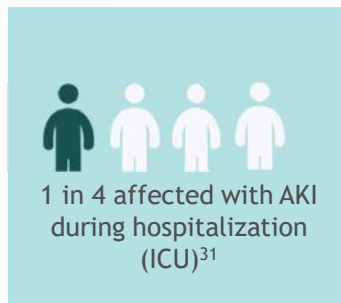
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# Regulatory Strategy for NGAL

## Pediatrics

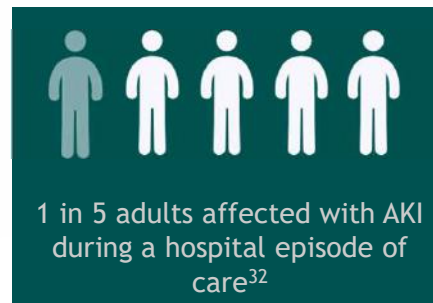


Predict AKI Risk in Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

De Novo application being developed, expected submission Q4 2020

## Adults



Predict AKI Risk in Intensive Care Setting

- Urine or plasma samples
- Predict Stage 2/3 AKI

Study planning underway, expected submission to follow pediatric clearance

## Additional Indications

- Nephrotoxicity
  - Oncology
  - Cardiology
  - Diabetes
  - Transplant
  - Autoimmune
- COVID-19 patient management
- Therapeutic monitoring
- Diagnosis of AKI
- Point-of-care applications

Initiate following potential FDA clearance of initial AKI risk assessment indications

31) Kaddourah A, et al. *N Engl J Med*. 2017; 376(1):11-20. 32) Susantitaphong, P et al. *Clin J Am Soc Nephrol*. 2013 Sep;8(9):1482-93;



*Study overview*

# NGAL 2020 Pediatric Study

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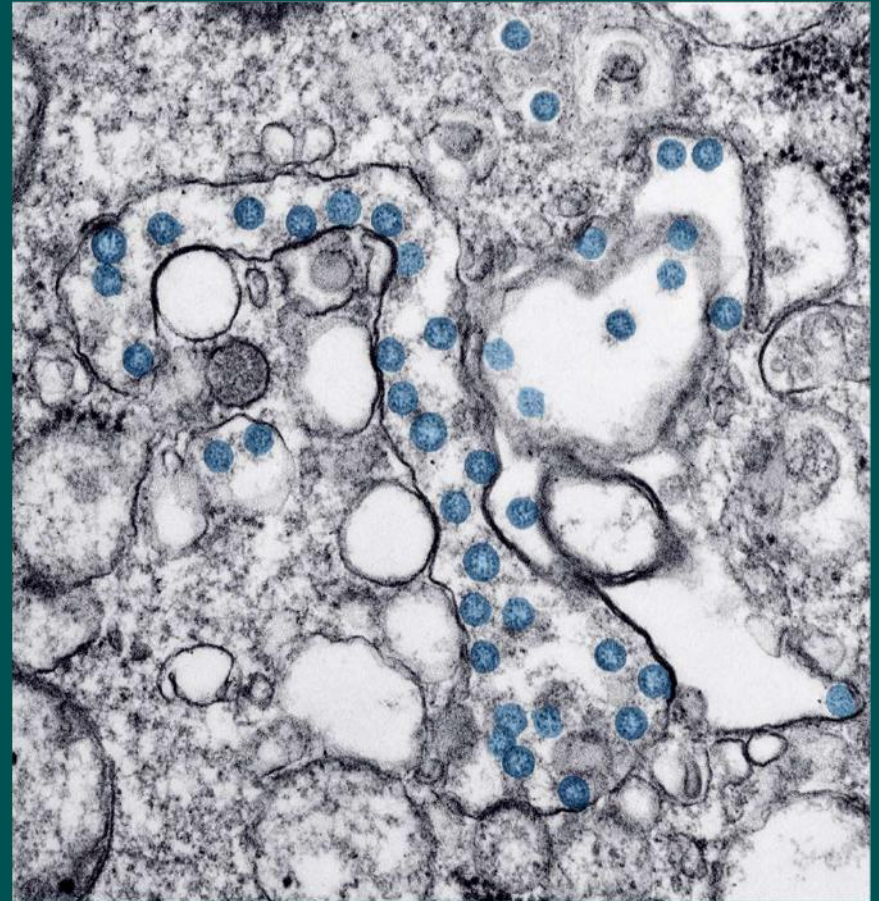
- Prospective trial to establish and validate the performance of The NGAL Test
- Pediatric population ( $\geq 3$  months to  $< 22$  years old), urine samples
- Patients admitted to the ICU
- Predict risk of developing moderate to severe AKI (stages 2/3)
  - Test within the first 12 hours after admission to predict the development of Stage 2/3 AKI in the next 48-72 hours
- Consortium of top US Children's Hospitals participating, led by Cincinnati Children's Hospital
- De Novo application planned to submit Q4 2020





*Recent Developments*  
**NGAL & COVID-19**

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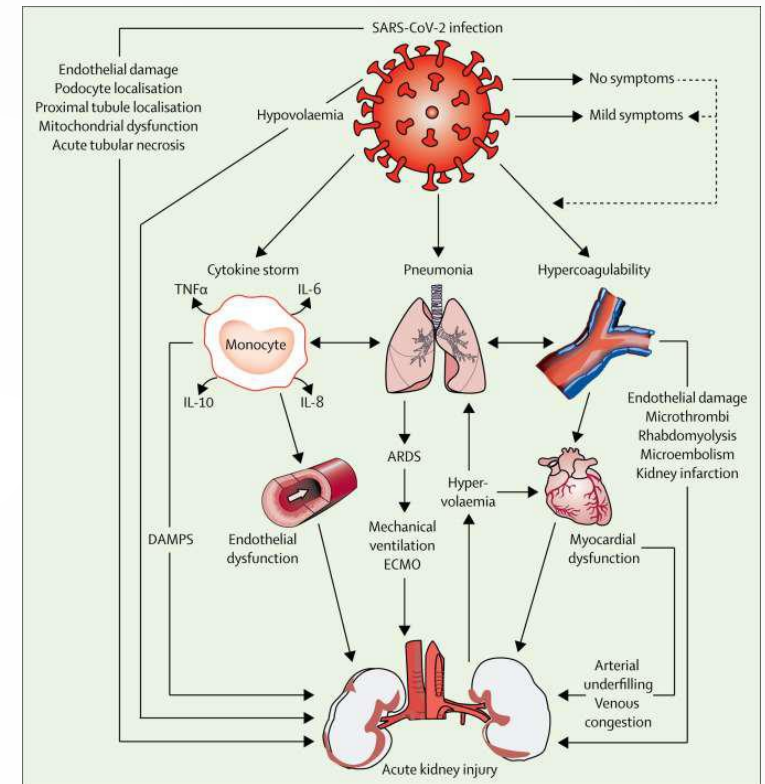


# Multifactorial Causes of Kidney Dysfunction

- Kidney involvement in hospitalized patients is frequent, ranging from mild dysfunction to progressive acute kidney injury (AKI)<sup>33</sup>
- Multiple dependent pathways in the setting of COVID-19 increase the risk of acute kidney injury<sup>33</sup>
- Systemic inflammation precedes cytokine storms where NGAL production is also observed and could potentially be used to triage care<sup>33</sup>
- 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<sup>33</sup>
- 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.”

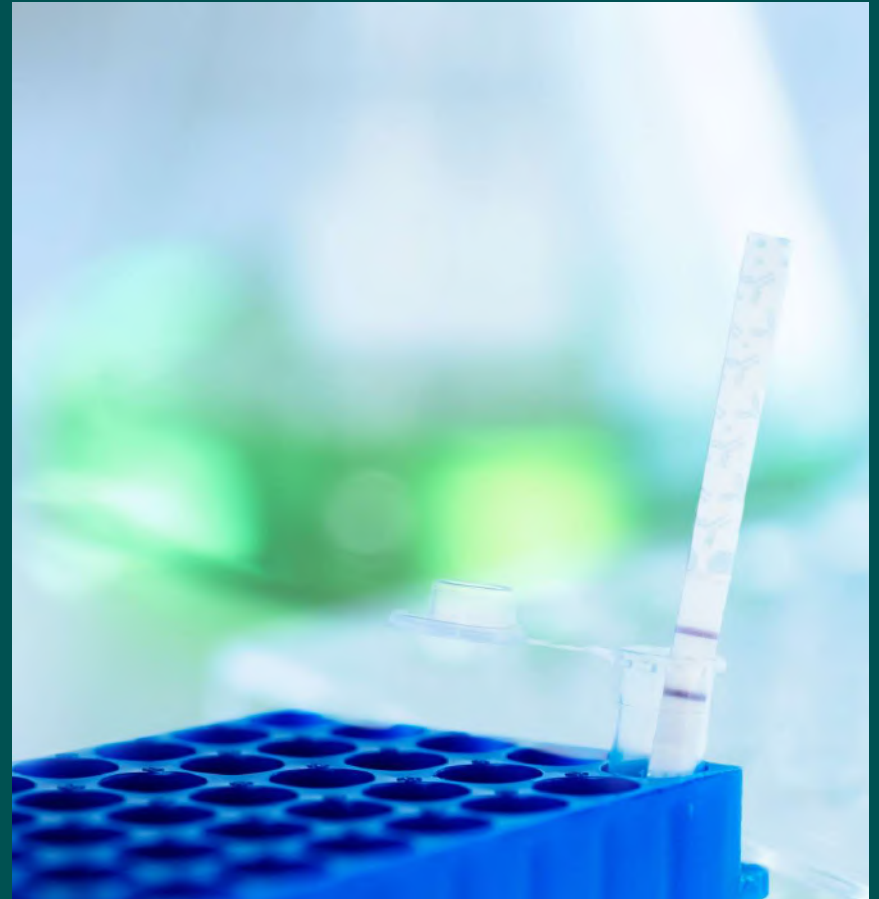
-Dr. Raj Basu, Children's Hospital of Atlanta



33) Ronco, C. The Lancet Respiratory Medicine Volume 8, Issue 7, July 2020, Pages 738-742

*BioPorto's gRAD*  
**A Development  
Platform**

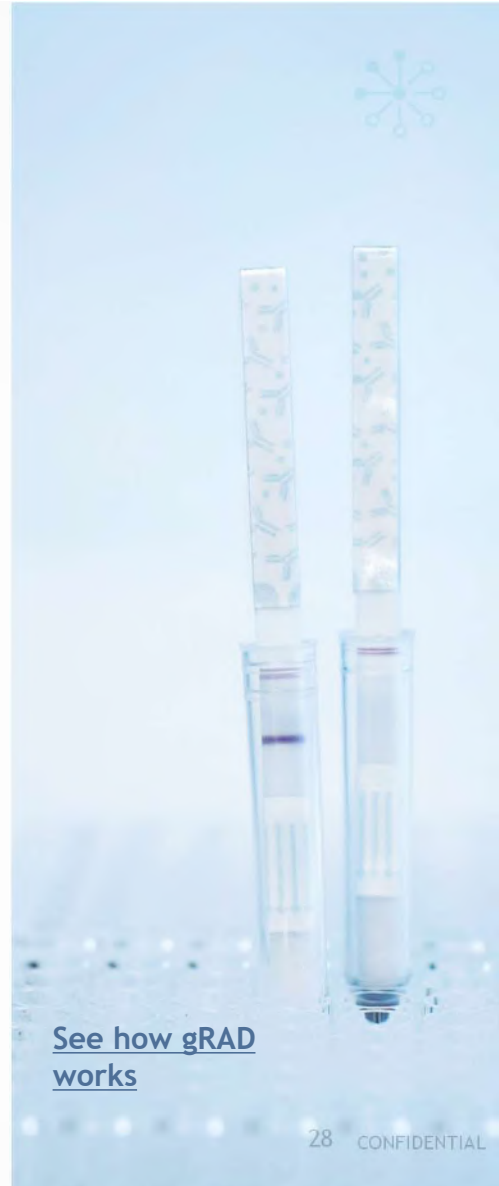
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*BioPorto's patented lateral flow development system*

## Proprietary Platform: gRAD

- BioPorto's patented Generic Rapid Assay Device (gRAD) was developed in 2016 to enable rapid development of lateral flow tests
- Features of gRAD include:
  - Optimized with two printed lines: a test line for biotinylated antibody/protein and a control line 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
- Shortens development time compared to standard ELISA development
- Manufacturing process can leverage standard, automated equipment capable of high-volume production





# Benefits of BioPorto's gRAD Solution

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## 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

## Rapid Iteration



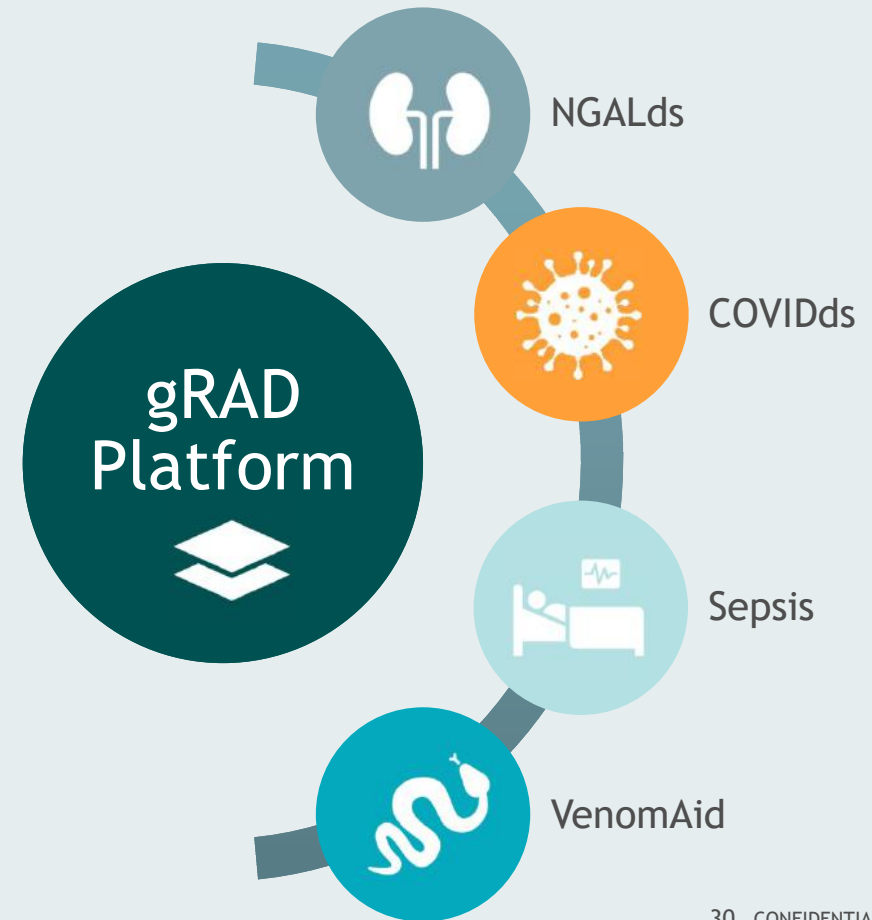
Design allows rapid  
iteration  
(days not weeks)

*gRAD*

# Platform for Product Development & Growth

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

1. **NGALds:** for near-patient 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







# NGALds for Near-Patient Testing

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- NGALds is the first assay developed on the gRAD platform
- CE Mark expected in Q4 2020
- A rapid lateral flow test to offer semi-quantitative urine NGAL results without complexity or instrumentation - idea for outpatient or low-resource settings
- A sandwich lateral flow immunoassay specific to NGAL, the kit consists of:
  - Lateral flow strips
  - Vials containing lyophilized NGAL antibody
  - Sample dilution buffer
  - Pipette tips





*Unique opportunity to use gRAD technology*

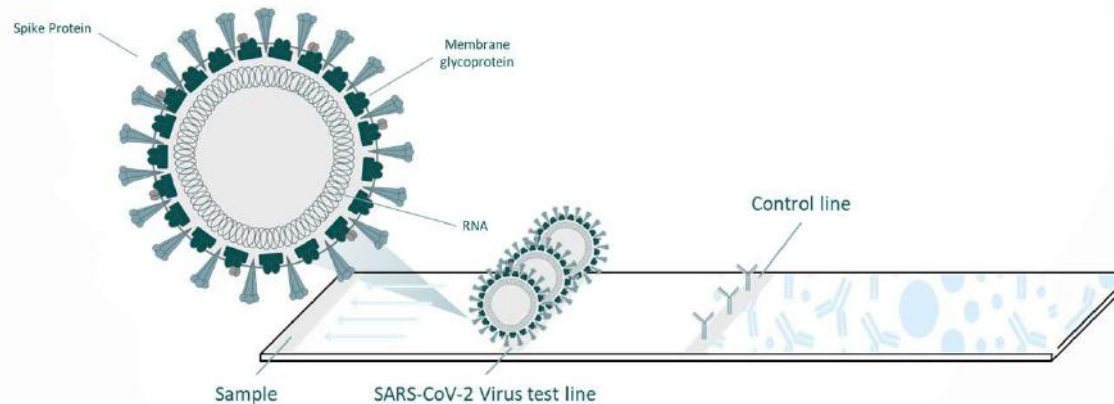
# Viral COVIDds

## Product Format

- Indication: Screen patients suspected of COVID-19 infection for active virus
- Semi-quantitative, rapid immunoassay detection of SARS-CoV-2 viral particles
- Minimally invasive sample types

## Update & Next Steps

- Antibody development & testing - **ongoing**
- Antibody selection & optimization - **ongoing**
- Prototype development
- Prototype testing & technical evaluations
- EUA submission





# 2020 Milestones

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*Clinical, regulatory and commercial*

# Targeted 2020 Milestones

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- 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, gRAD, and BioPorto's antibody library
- Grow total revenue by 10%
- Financial Guidance: Revenue of approx. DKK 30 million and an EBIT loss of approx. DKK 73 million

# Rights Issue

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# Offering Structure and Transaction Overview

Transaction and Terms	<ul style="list-style-type: none"><li>Fully-guaranteed rights issue with offering of up to 66,645,476 new shares, gross proceeds of up to DKK 106.6 million and net proceeds of up to DKK 93.6 million</li><li>Subscription price of DKK 1.60 per share with a subscription ratio of 1:3, implying that:<ul style="list-style-type: none"><li>Existing shareholders in BioPorto receive one subscription right for each share held as of the record date</li><li>Three subscription rights entitles the holder to subscribe for one new share in the rights issue</li></ul></li></ul>
Subscription Commitments	<ul style="list-style-type: none"><li>The full issue has been secured by existing shareholders and external guarantors, which subscription undertakings and guarantees are subject to certain terms and conditions</li><li>Existing shareholders and existing guarantors include Formue Nord Markedsneutral A/S, Aktieselskabet Arbejdernes Landsbank, Media-Invest Danmark A/S and a number of other institutional and Qualified Investors</li></ul>
Key Dates	<ul style="list-style-type: none"><li>Record day: 29 September 2020 at 17:59 CEST</li><li>Rights trading period: 28 September 2020 to 9 October 2020</li><li>Subscription period: 30 September 2020 to 13 October 2020</li><li>Expected date of announcement of outcome: 15 October 2020</li></ul>
Use of Proceeds	<ul style="list-style-type: none"><li>The Company expects to apply net proceeds of DKK 60 million to finance the Company's operations until October 2021, which includes costs of employees, clinical trial costs, sales &amp; marketing costs, production costs, R&amp;D costs not related to employees or clinical trials, as well as other operational costs</li><li>Net proceeds from DKK 60 million to DKK 90 million will be applied to finance NGAL development, which includes developing the U.S. organization to prepare for an FDA clearance and commercialization of The NGAL Test, and supporting NGAL development</li><li>Net proceeds above DKK 90 million, including BioPorto's current cash position, will be applied to develop the gRAD platform</li></ul>
Other	<ul style="list-style-type: none"><li>Upon completion of the offering BioPorto is subject to a 180-day lock-up agreement</li><li>The CEO, CFO and board of directors have undertaken a 180-day lock-up agreement</li><li>The offering is a public offering in Denmark to existing shareholders and Qualified Investors. Any offering in the U.S. will only be made pursuant to an exception from the registration requirements of the US Securities Act to QIBs, as defined in Rule 144A. Please see the prospectus for further details on restrictions for the Offering</li><li>Nordea is acting as Global Coordinator</li></ul>

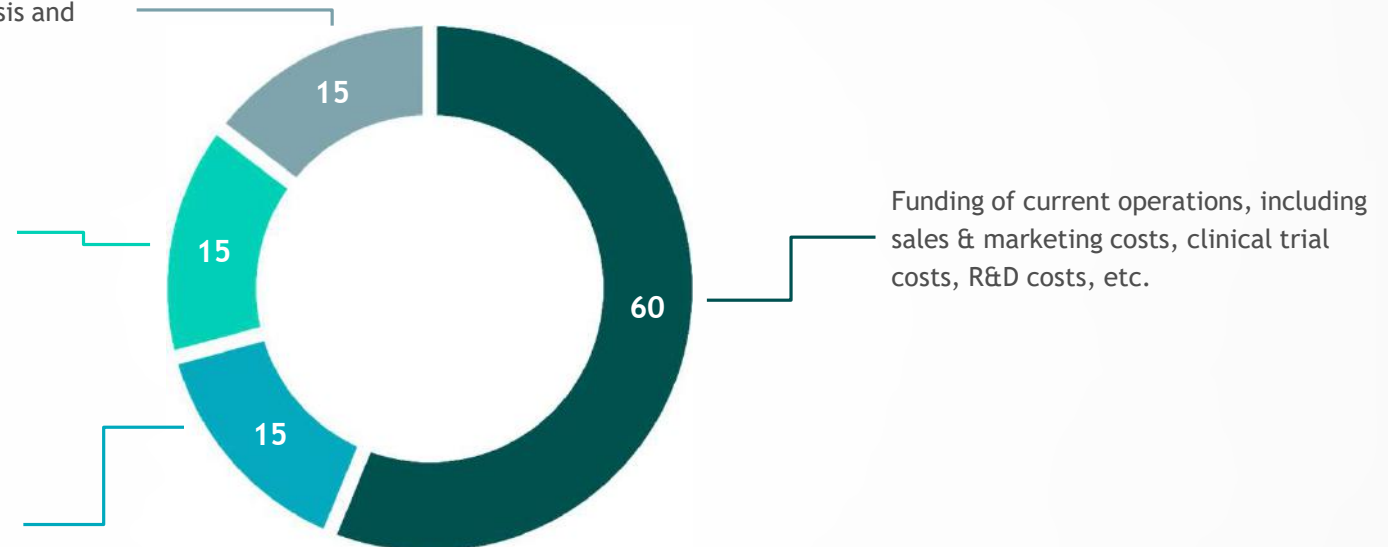


# Use of Proceeds Allocated to The NGAL Test Related Activities and Development of gRAD

Developing new indications using the gRAD platform, expectedly within the areas of COVID-19, Sepsis and Inflammation

Developing the Company's U.S. organization to prepare for an FDA clearance and commercialization of The NGAL Test for pediatric patients

Supporting the NGAL development, including costs for a clinical trial and the submission to FDA related to NGAL for adults as well as research projects to expand the label or usage of NGAL





# Key Elements of Pre-Emptive Rights Issue

- Offering of 66,645,476 new shares at a subscription price of DKK 1.60 per share (fully guaranteed)
- Holders of existing shares will receive one (1) pre-emptive right for each share held
- Three (3) pre-emptive rights allow for subscription of one (1) new share against payment of subscription price

*Example of pre-emptive rights issue*





# Important Dates for the Rights Issue

25 Sept. 2020	Announcement of Prospectus
25 Sept. 2020	Last day of trading in Existing Shares including Pre-emptive Rights
28 Sept. 2020	First day of trading in Existing Shares ex Pre-emptive Rights
28 Sept. 2020	First day of Rights Trading Period
29 Sept. 2020	Allocation Time of Pre-emptive Rights
30 Sept. 2020	First day of Subscription Period
9 Oct. 2020	Last day of Rights Trading Period
13 Oct. 2020	Last day of Subscription Period
15 Oct. 2020	Allocation of Remaining Shares
15 Oct. 2020	Expected date of publication of the results of the Offering
21 Oct. 2020	Expected registration of the New Shares with the Danish Business Authority
22 Oct. 2020	Expected date of admission of the New Shares to trading and official listing under the ISIN code of the Existing Shares
23 Oct. 2020	Expected merger of ISIN codes



# Risk Factors

## Risks related to the Company's business

- The Company's Products and Future (NGAL) Products may fail to achieve the degree of market acceptance by physicians, laboratory management, healthcare payors and others in the medical community necessary for commercial success and market penetration may be lengthy and difficult
- The Company may face competition from companies with considerably more resources and experience and/or more novel technology than the Company, which may result in others discovering, developing, receiving clearance for or commercializing products before or more successfully than the Company
- The Company is dependent on third-party partners to sell the Company's Products globally
- The pricing of the Company's Products and Future (NGAL) Products will depend in part on the clinical value of the product and delivery technology used in such products
- The Company's growth could suffer if the markets in which the Company sells its Products and intends to sell its Future (NGAL) Products decline or do not grow as anticipated
- Global economic uncertainty and other global economic or political and regulatory developments could have a material adverse effect on the Company's business, results of operations, cash flows, financial condition, and/or prospects
- Serious adverse safety events involving the Company's Products and Future (NGAL) Products can negatively affect the Company's business. This could also adversely impact the Company's business, future financial position, results of operations and future growth prospects
- The Company relies on third parties to conduct its clinical trials and perform data collection and analysis
- Timing of clinical trials depend on many factors outside of the Company's control
- The Company may not be able to successfully implement its strategies

## Risks related to the Company's Products and Future (NGAL) Products

### The NGAL Test for risk assessment of AKI

- A failure to obtain FDA clearance of The NGAL Test for risk assessment of AKI would have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects
- A failure to successfully commercialize The NGAL Test for pediatric and adult AKI uses would have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects

### Planned expansion of The NGAL Test for use on Third Party Systems and the use of The NGAL Test for new indications ("Future NGAL Products")

- A failure to successfully complete development, obtain regulatory clearance for IVD use of and commercialize Future NGAL Products would have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects

### NGAL gRAD Dipstick ("The NGALds")

- A failure to obtain regulatory clearance for and commercialize The NGALds would have a material adverse effect on the Company's future financial position, results of operations and future growth prospects

### COVID-19 gRAD Dipstick Products ("COVID-19ds")

- A failure to successfully develop, obtain regulatory clearance for and commercialize the COVID-19ds would have a material adverse effect on the Company's future financial position, results of operations and future growth prospects

### Development of New Diagnostic Products (on gRAD or other platforms) ("Future Products")

- A failure to successfully develop, obtain regulatory clearance for and commercialize Future Products would have a material adverse effect on the Company's future financial position, results of operations and future growth prospects

## Risks related to the Company's operations

- Public health epidemics, pandemics or outbreaks, such as COVID-19 could adversely impact the Company's business, future financial position, timeline, results of operations and future growth prospects
- The Company's future success depends in part on its ability to attract and retain its management team and key employees
- The Company's Products and Future (NGAL) Products are complex to manufacture, and the Company may encounter difficulties in manufacturing that could have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects
- The manufacture of the Company's Products is dependent on the supply of raw materials and key components from suppliers, some of which are single source suppliers for the Company
- The Company is dependent on third-party vendors to provide certain products and services and its business and operations, including clinical trials, could be disrupted by any problems with its significant third-party vendors
- Any interruption in the operations of manufacturing facilities may impair the Company's ability to deliver products and maintain the Company's market positions
- A breakdown of or an attack on the Company's or its critical suppliers' or partners' IT systems including cyber security breaches may result in a material disruption of the Company's or its critical suppliers' or partners' manufacturing, control measures, commercialization, and delivery of the Company's Products and Future (NGAL) Products
- The Company may be exposed to risks associated with product liability, warranties or guarantees, recall demands or other lawsuits or claims
- The Company may not be able to obtain or maintain adequate protection against potential liabilities at acceptable cost by maintaining insurance coverage, and existing, or any future insurance policies or the Company's own resources may not adequately cover claims for damages that may be received in the future
- To manage its growth the Company must continually improve existing reporting systems and procedures
- The Company's employees and collaborators may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm the Company's business
- The Company's operations involve hazardous materials and the Company and third parties with whom the Company contracts must comply with environmental laws and regulations, which can be expensive and restrict how the Company does business

## Risks related to the Company's intellectual property

- The Company's ability to compete may decline if the Company does not adequately protect its proprietary rights and confidential information
- The Company's ability to retain key licenses could affect its ability to manufacture and sell Products and Future (NGAL) Products
- The Company may be unable to protect or effectively enforce its intellectual property rights and such rights may be found invalid or unenforceable
- Third parties may assert ownership or commercial rights to inventions the Company develops
- Third parties may claim that the Company infringes their intellectual property rights
- Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and the Company's patent protection could be reduced or eliminated for non-compliance with these requirements
- Third parties may assert that the Company's employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets

## Risks related to legal and regulatory matters

- The Company operates in a highly regulated industry, and changes in regulations or the implementation or enforcement of existing regulations could have a material adverse effect
- The Company's sale of its Products and Future (NGAL) Products depends on third-party payors coverage
- The Company's Products and Future (NGAL) Products, for which the Company has or obtains regulatory clearance, are subject to post-marketing requirements or withdrawal from the market and failure to comply thereof may make the Company subject to substantial penalties
- The Company is and may in the future become involved in litigation, arbitration and governmental proceedings
- The Company faces risks related to data privacy concerns and failure to comply with privacy regulations and security requirements relating to data
- The misuse or off-label use of the Company's Products and Future (NGAL) Products may harm the Company's reputation in the marketplace or result in costly investigations, fines or sanctions by regulatory bodies if the Company is deemed to have engaged in the promotion of these uses
- In the U.S., the Affordable Care Act or changes to the act may adversely affect the Company's business and results of operations

## Risks related to the Company's financials

- The Company's capital structure may be insufficient to support its business operations and the Company may need to raise additional funding, which may not be available on acceptable terms, or at all, and failure to obtain such funding when needed may force the Company to delay, limit or terminate its product development efforts or other operations
- The Company has incurred net losses and may continue to do so
- The Company's business requires significant levels of capital investments, which the Company may be unable to fund
- The Company is facing risks related to sales and production contracts being denominated in currencies other than DKK
- Risks relating to trade receivables

## Risks related to the Offering and the Shares

- The market price of the Company's Shares and Pre-emptive Rights may be highly volatile
- If the market price of the Shares declines significantly, the Pre-emptive Rights may lose their value and the market for the Pre-emptive Rights may offer only limited liquidity, and even if a market develops, the Pre-emptive Rights may not be effectively priced against the price of the Shares
- Shareholders in jurisdictions outside Denmark may be unable to exercise Pre-emptive Rights
- Shareholders outside Denmark are subject to exchange rate risk
- Failure to exercise Pre-emptive Rights by the end of the Subscription Period (13 October 2020 at 5:00 p.m. CEST) will result in the lapse of the holder's Pre-emptive Rights
- The sale of Pre-emptive Rights on behalf of shareholders who do not take up their Pre-emptive Rights may result in a decline in the market price of the Pre-emptive Rights and the Shares and increased volatility in the Shares
- If an Existing Shareholder does not exercise any or all of the Pre-emptive Rights, their ownership interest will become diluted, and such dilution may be material
- The Company expects to retain any available funds and future earnings to fund the development of its business and to ensure an adequate capital structure, and as such, a shareholder's ability to achieve a return on investment will depend on an appreciation in the price of the shares
- It may be difficult or impossible for the Company's shareholders and investors outside Denmark to enforce judgments from their home jurisdictions against the Company
- The Offering may be withdrawn, and shareholders and investors having exercised and/or purchased Pre-emptive Rights or New Shares may incur a loss if the Offering is not completed
- Following the Offering, certain Existing Shareholders may increase their shareholdings and may be able to influence important actions the Company take
- The Subscription Commitments might not be honored

*The above is a summary of all risk factors listed in the prospectus.  
Please see the prospectus for a complete description of risk factors.*



# Financial Calendar 2020

November 18, 2020

Q3 2020 Results

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