

*BioPorto presentation  
@ HC Andersen Capital/Nordea  
Small Cap Seminar*

December 15, 2020





# Forward-Looking Statements

References herein to this presentation shall mean and include this document, any oral presentation accompanying this document provided by BioPorto A/S (the “Company”) and any further information that may be made available in connection with the subject matter contained herein. By viewing or receiving or reading this presentation or attending any meeting where this presentation is made, you agree to be bound by the limitations, qualifications and restrictions set out below:

This presentation contains forward-looking statements. Words such as “believe”, “expect”, “may”, “plan”, “strategy”, “estimate”, “target” and similar expressions identify such forward-looking statements. Statements other than historical facts included in this presentation concerning our plans, objectives, goals, future events and performance are forward-looking statements. They involve risks, uncertainties and other factors, which may cause actual results, performance and achievements to differ materially from the results discussed in the forward-looking statements. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date of this presentation.

This presentation is confidential, is intended for the recipient only and thus may not be forwarded, reproduced, redistributed or passed to any other person or published in whole or in part for any purpose. If this document has been received in error, it must be returned immediately to the Company. By receiving this presentation, you become bound by the above-referred confidentiality obligation. Failure to comply with such confidentiality obligation may result in civil, administrative or criminal liabilities.

This presentation contains inside information with regard to the Company and/or its securities. Recipients of this presentation should not deal or encourage any other person to deal in the securities of the Company until the transaction described in this Presentation is either announced or abandoned by the Company. Dealing in securities of the Company when in possession of inside information would result in liability for breach of insider dealing restrictions under applicable law, including United States and Danish law.

This presentation is not directed to, or intended for distribution to or use by, any person or entity that is a citizen or resident or located in any locality, state, country or other jurisdiction where such distribution, transmission, publication, availability or use would be contrary to law or regulation or which would require any registration or licensing within such jurisdiction. No communication or information relating to the transaction described herein may be distributed to the public in any jurisdiction in which registration or approval would be required prior to such distribution.

No securities of the Company have been or will be registered under the Securities Act of 1933, as amended (the “Securities Act”), or under any state securities laws, and the securities of the Company may not be offered or sold in the United States (or to, or for the account or benefit of U.S. Persons) except pursuant to an exemption from, or a transaction not subject to, the registration requirements of the Securities Act. The Company does not intend to register in the United States any portion of its securities or to conduct a public offering of any of its securities in the United States. Any offer or sale of the securities of the Company in the United States is limited to “accredited investors” as defined in Rule 501(a), both under the Securities Act. Any securities issued will be “restricted securities” as defined in Rule 144 of the Securities Act.



# Agenda

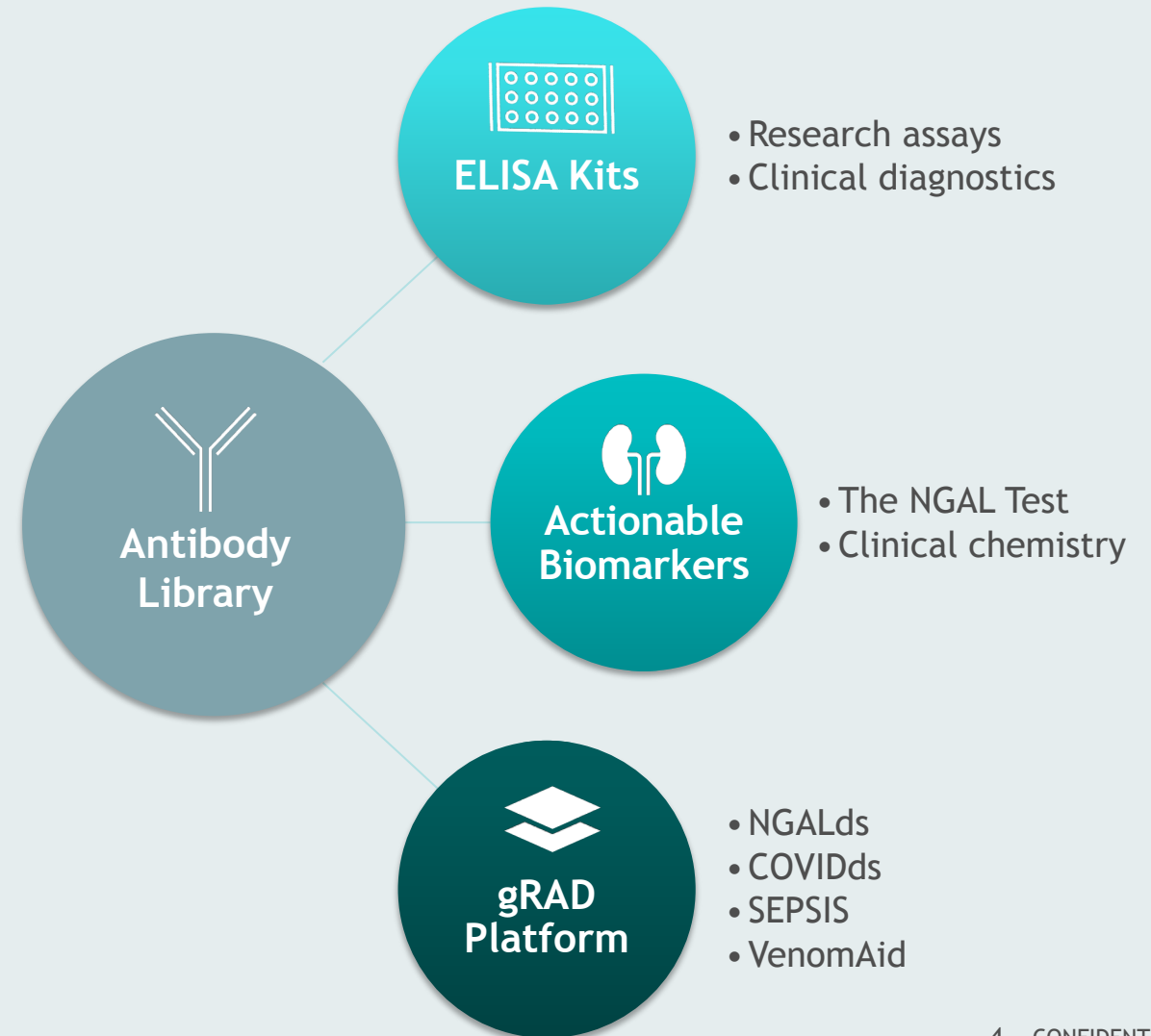
- 1 About BioPorto
- 2 Acute Kidney Injury
- 3 A Novel Solution: The NGAL Test
- 4 The Addressable Market
- 5 NGAL Regulatory Strategy
- 6 A Development Platform - gRAD
- 7 Summary



# 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 be one of the world's leading companies in diagnostics for kidney health.



## Establish commercial capabilities to drive growth

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



## Expand product pipeline and clinical knowledge

We expand our pipeline through development of new indications for NGAL and by leveraging the gRAD platform to develop new rapid assays for emerging conditions.



## Strengthen infrastructure to ensure quality and drive profitability

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



*BioPorto's leadership*

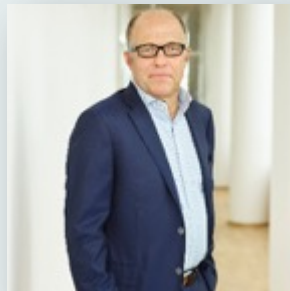
# Experienced International Management Team

---



**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



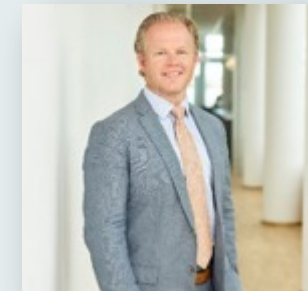
**Peter Mørch Eriksen**  
CEO

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

---

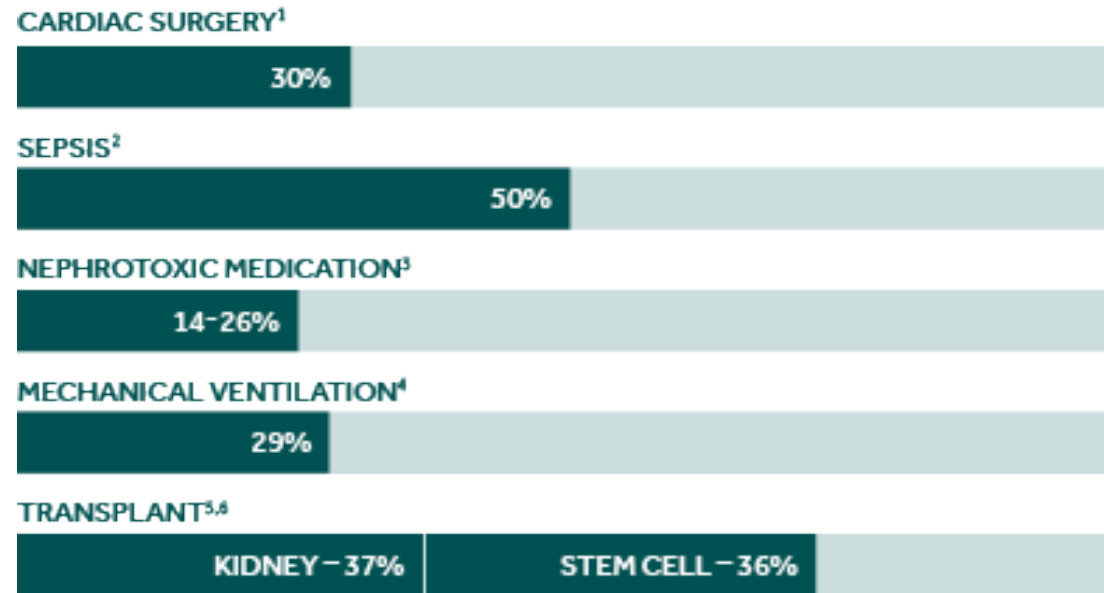




Why is Acute Kidney Injury (AKI) important ?

# 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.



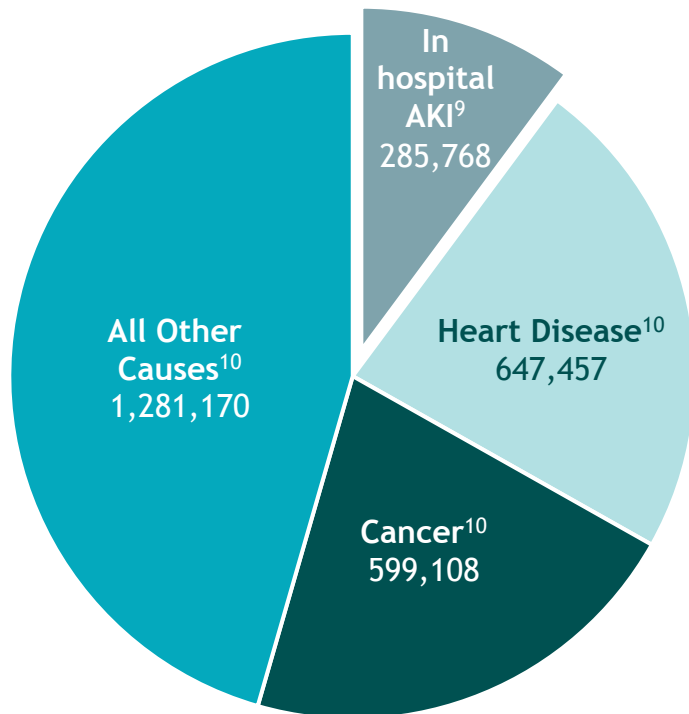


*The unsolved problem*

# AKI is a Major Public Health Concern

## Third Leading Cause of Death

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



## 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%*

9) Company estimate, based on recent studies, including: Brown JR, BioMed Research International. 2016;1D4278579.

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*



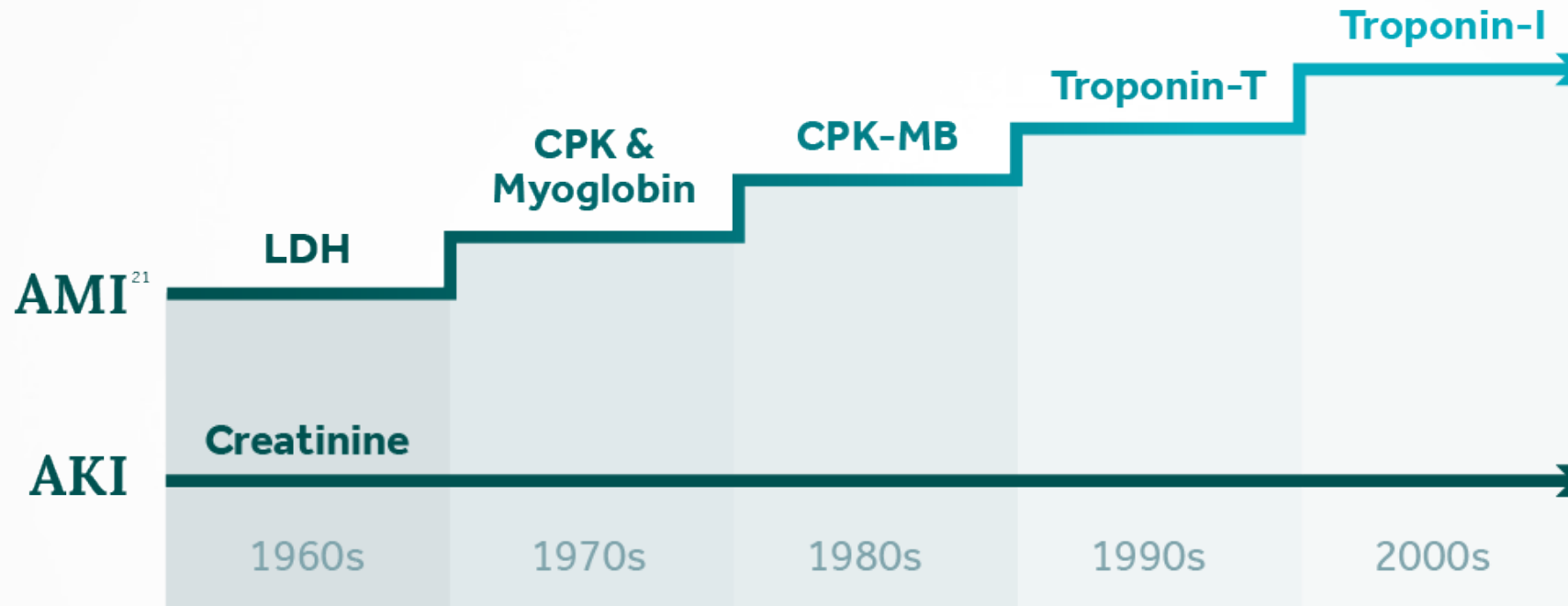
Increased Overall  
Mortality Rate<sup>13</sup>  
**25%**

- 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) Odotayo A, *JASN*. 2016;28. 16) Askenazi DJ, *Kidney Int*. 2006;69(1). 17) Horne KL, *BMJ Open*. 2017;7(3).



# Cardiac Markers Highlight Innovation Needed in AKI



AMI: Acute Myocardial Infarction, AKI: Acute Kidney Injury

**40%** Patients with probable AKI missed by consensus criteria<sup>22</sup>

*A similar proportion to that identified by troponin in subjects with myocardial injury missed by conventional cardiac biomarkers.<sup>23</sup>*

21) Mythili S, Malathi N. *Biomed Rep.* 2015 Nov;3(6):743-748.  
22) Pickering JW, Endre ZH. *J Renal Inj Prev.* 2013 Nov 30;3(1):21-5.  
23) Ronco C, et al. *J Am Coll Cardiol.* 2008 Nov 4; 52(19):1527-39.

*A Novel Solution*

# The NGAL Test

---



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.



# 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



NORMAL

INCREASED RISK

DAMAGE

0h

2h

CLINICAL WINDOW FOR INTERVENTION

## SERUM CREATININE

STANDARD OF CARE

48-72 Hours to respond



REDUCED KIDNEY FUNCTION

KIDNEY FAILURE

DEATH

48h

72h

## 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.



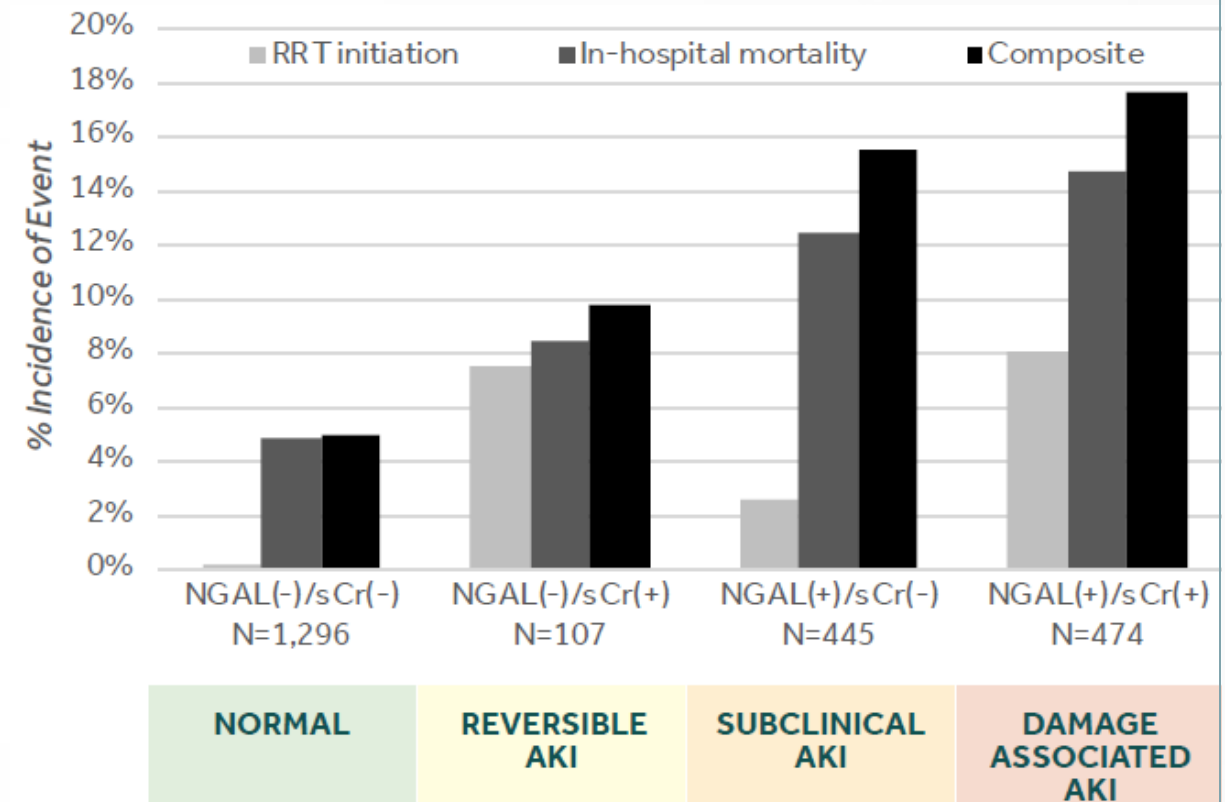
Utility of integrating NGAL with sCr reveals four phenotypes

# 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.

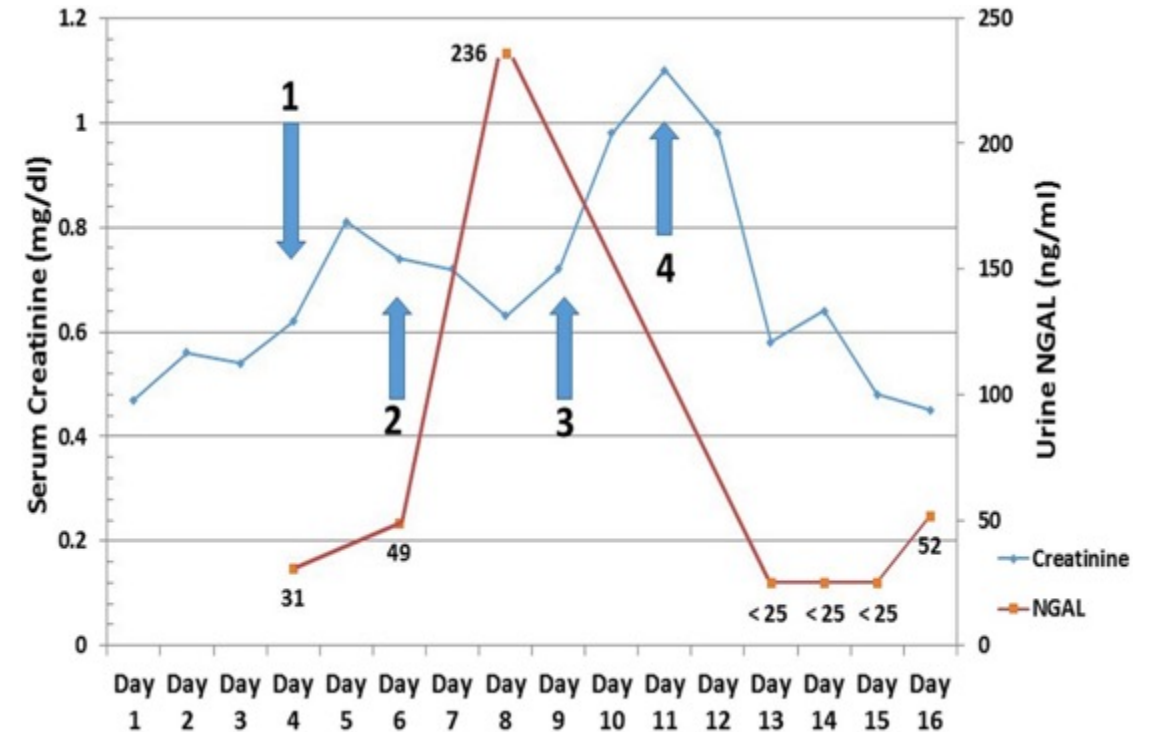


# NGAL Predicting Tubular Injury

## 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.





*The NGAL Test\**

# 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<sup>†</sup>)



## 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.

<sup>†</sup>Management estimate of US sales price following expected FDA clearance.



# The Addressable Market

---





# 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*

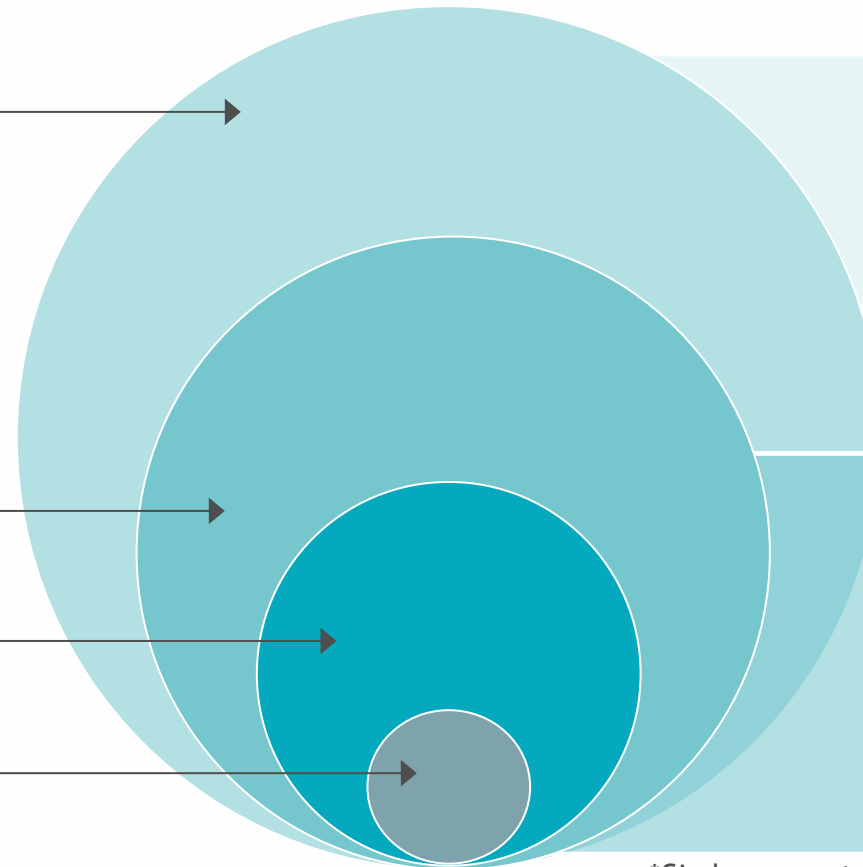
## Global Opportunity

### Long Term Expansion

*~150M tests; \$3Bn*

### Initial Focus Indications

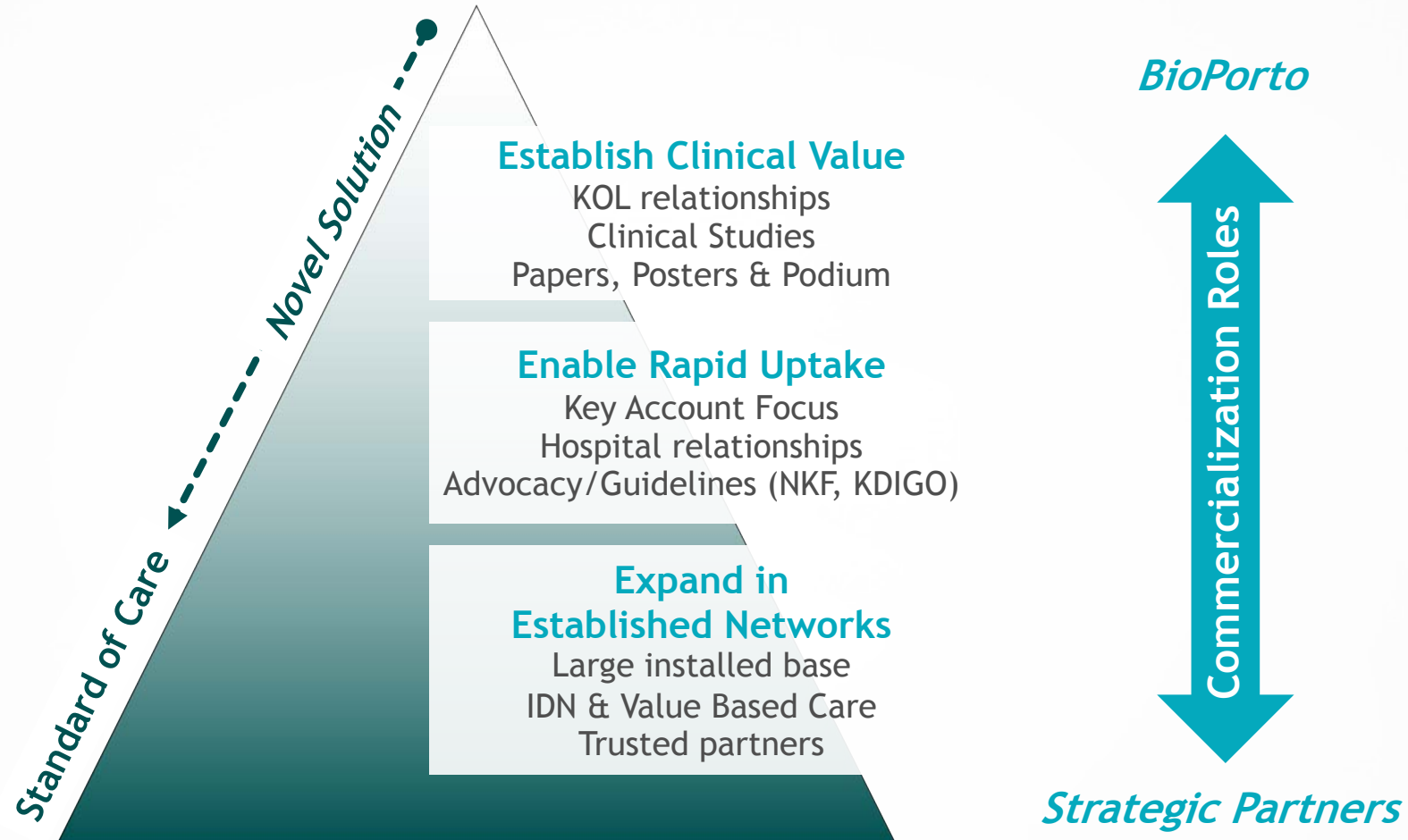
*~100M tests; \$2Bn*





*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.

# Regulatory Strategy

---





# Regulatory Strategy for NGAL

## Pediatrics



1 in 4 affected with AKI during hospitalization (ICU)<sup>31</sup>

Predict AKI Risk in Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

De Novo application being developed, expected submission Q1 2021

## Adults



1 in 5 adults affected with AKI during a hospital episode of care<sup>32</sup>

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;

*BioPorto's gRAD*

# A Development Platform

---





*BioPorto's patented lateral flow development system*

# Highlights gRAD

---

[See how gRAD works](#)



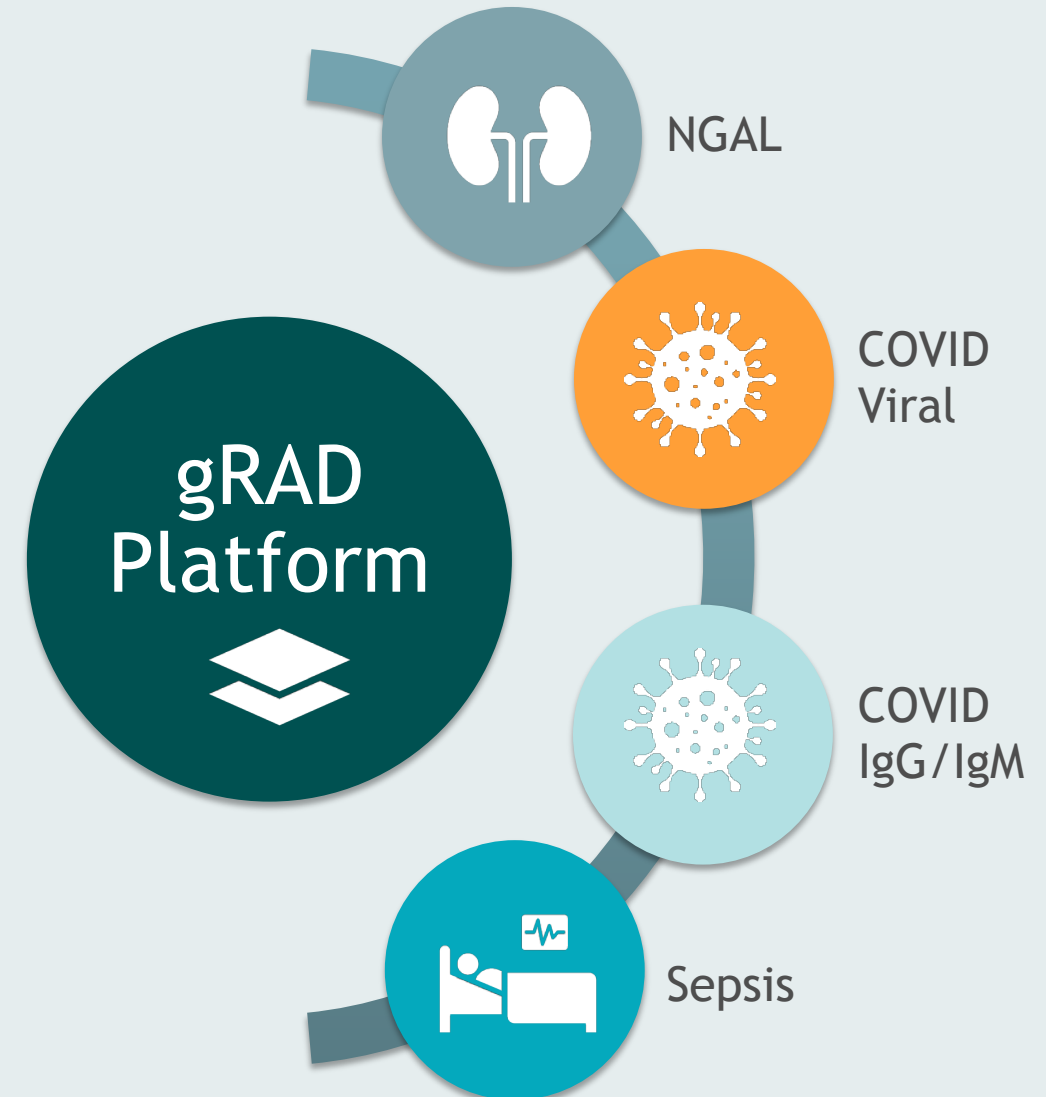
- Rapid development of lateral flow tests
- High accuracy - same level as the ELISA test
- Multi sample types - plasma, urine, saliva etc.
- Semi-quantitative test result
- Fast test - from sample to result ~10 minutes
- Simple manufacturing process
- Potential use - laboratories, hospitals, out patients
- Low cost



# Platform for Product Development & Growth

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

1. **NGAL:** for near-patient assessment of kidney injury
2. **COVID-19:** a viral diagnostic test
3. **COVID-19:** a serology-based test for immunity assessment (IgG/IgM)
4. **Sepsis:** a blood test using antibodies to thrombomodulin, a marker of endothelial injury, for the early identification of septic shock
5. More to come







# NGALds for Near-Patient Testing

---

- 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



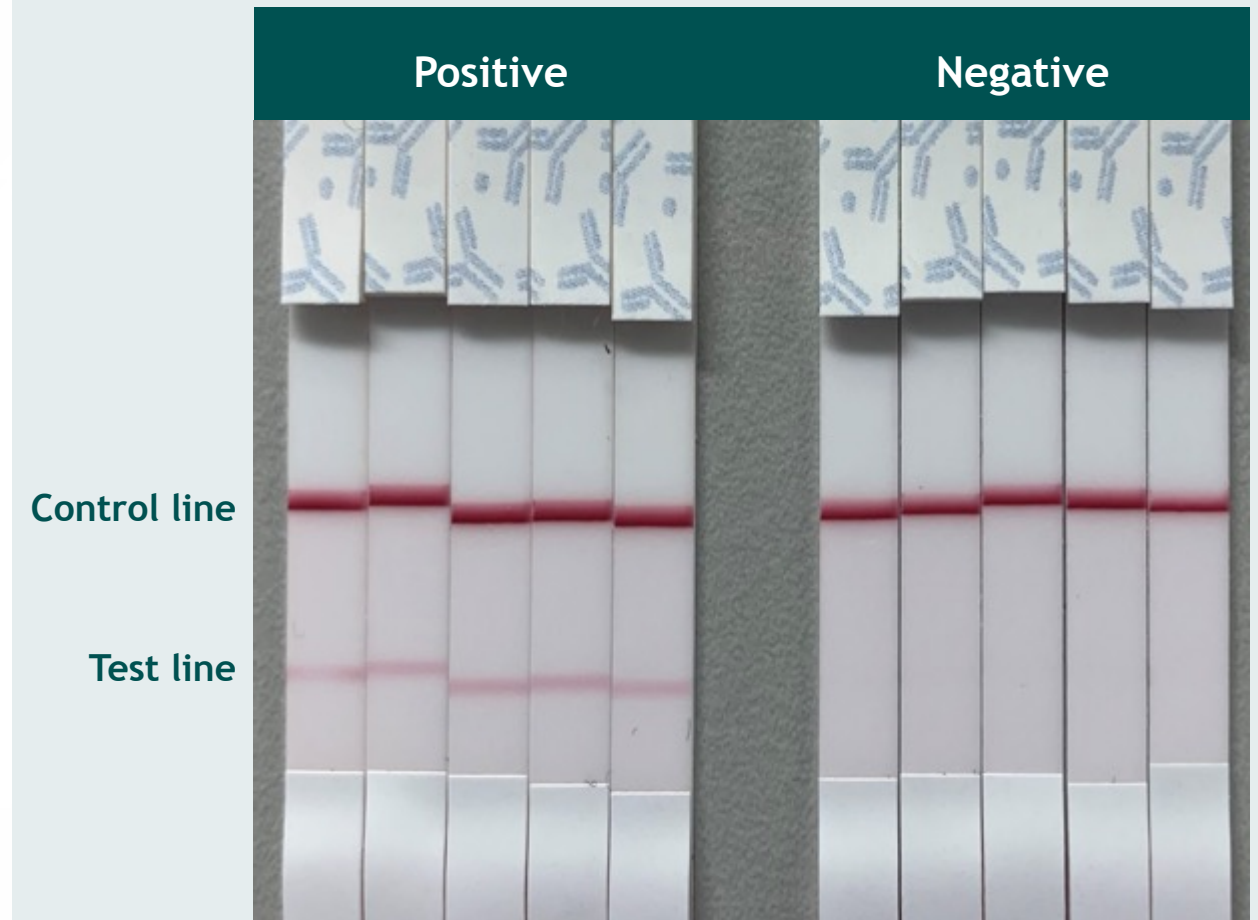


# Generic Rapid Assay Device (gRAD) platform

*BioPorto's patented Generic Rapid Assay Device (gRAD) technology is a lateral flow test development platform with no analyte-specific reagents on the strip.*

*Instead, labelled capture antibodies and gold nanoparticle conjugated detection antibodies form detectable complexes with the analyte in a simple preanalytical mixing step (off-strip).*

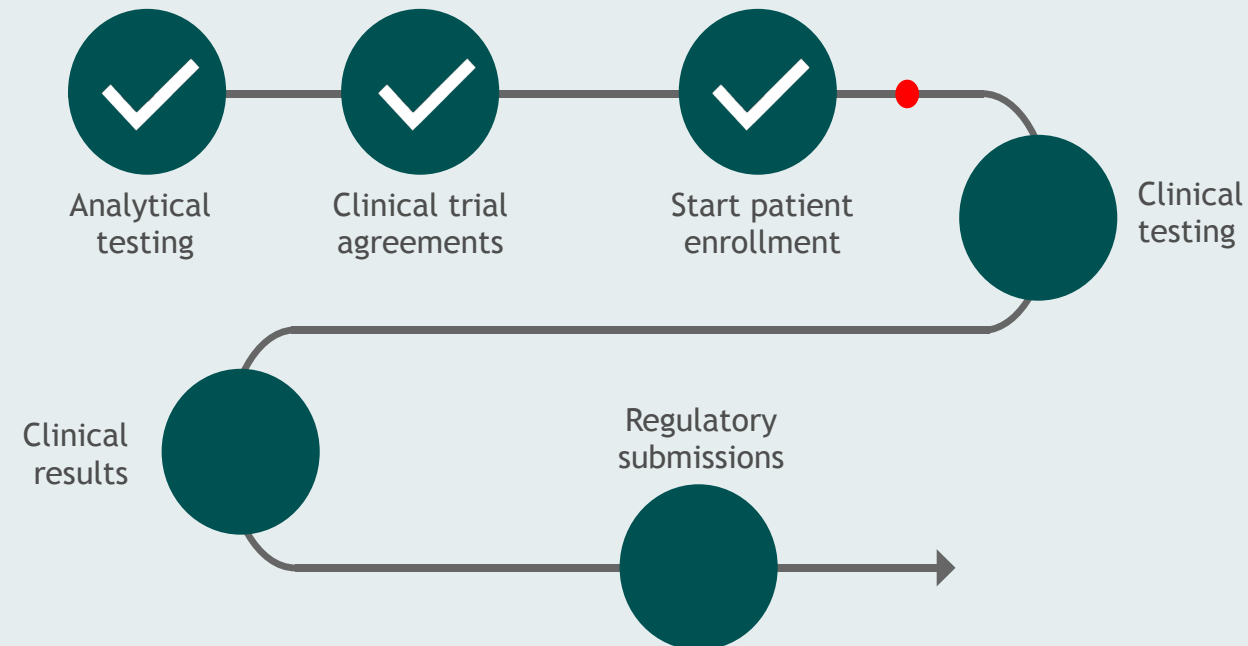
*Complexes are detected by the dipstick and can be evaluated both qualitatively and quantitatively with superior performance characteristics, compared to standard lateral flow assays.*





# COVID-19 viral test development process

## Assay Development Timeline



# 2020 Milestones

---





*Clinical, regulatory and commercial*

# 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, gRAD, and BioPorto's antibody library
- Financial Guidance: Revenue of approx. DKK 30 million and an EBIT loss of approx. DKK 73 million

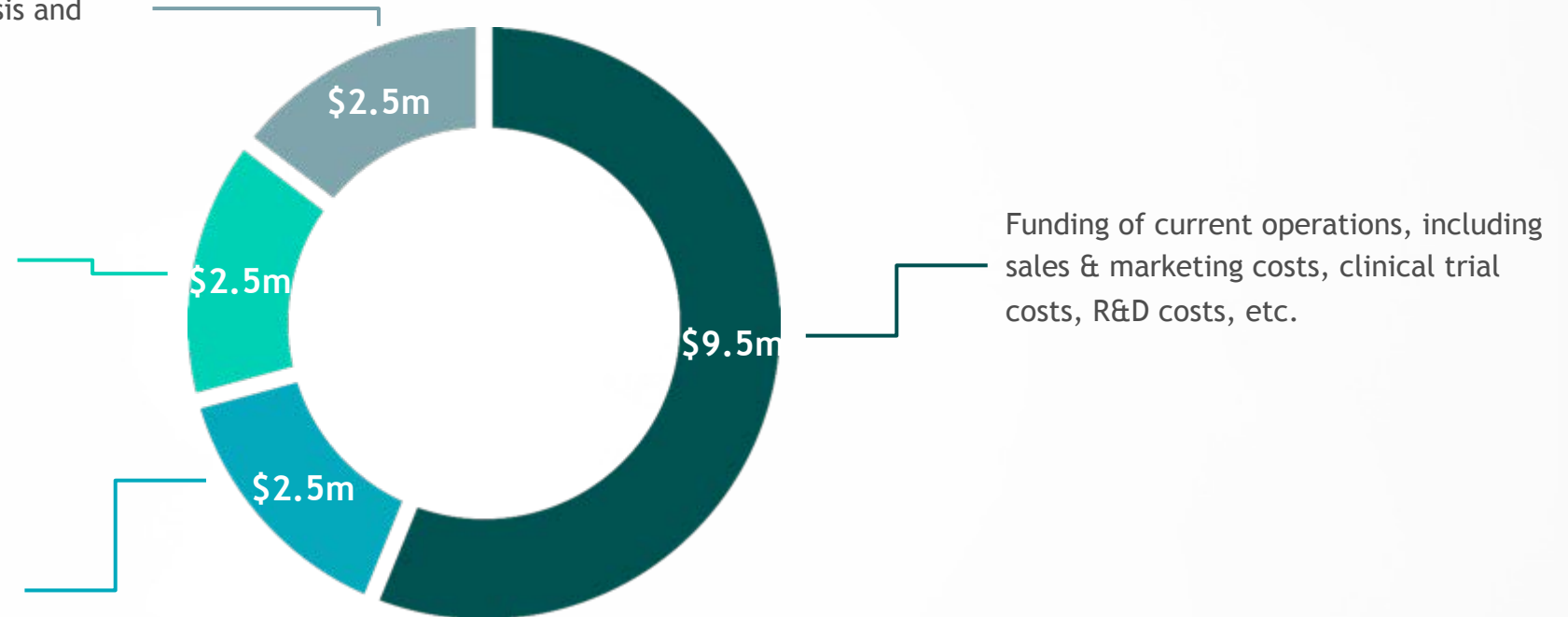


# ~\$17m Financing Finalized in October

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





# Financial Calendar 2021

March 17, 2021

April 29, 2021

May 12, 2021

August 18, 2021

November 17, 2021

Annual report 2020

Annual General Meeting

Q1 2021 Results

Q2 2021 Results

Q3 2021 Results

Contact:

Ole Larsen (CFO)

[ol@bioporto.com](mailto:ol@bioporto.com)

