Investor
Presentation
BioPorto A/S

Hellerup, February 22, 2024





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# Highlights and Strategic Objectives



## Highlights from 2023

Submission of application and pediatric and young adult FDA 510(k) clearance of ProNephro AKI (NGAL) in December 2023 - the first AKI biomarker test cleared for pediatric and young adult use in the US!

Process for implementing and offering test on Roche cobas c 501 analyzer initiated.

Dialog initiated with KDIGO for ProNephro AKI to be included in Guidelines for AKI and CKD for the first time.

Solid growth in revenue from sales of The NGAL Test (+25% over prior year period).

Preliminary result for financial year 2023 on par with latest guidance (November 1, 2024)



#### TOTAL REVENUE

#### **DKK 31 million**

a 7% increase over same period the prior year

ADJUSTED EBITDA

DKK (56) million

CASH POSITION

DKK 66 million

FULL ANNUAL REPORT 2023 TO BE PUBLISHED APRIL 4, 2024.

# ProNephro AKI for adults and pediatrics will boost revenue to USD +100 million by 2029



- Successful FDA clearance process for ProNephro AKI driven by strong team and close dialog with FDA.
- Accelerated strategy to focus on 1) securing commercial traction in the US for clinical testing of pediatric and young adult patients using ProNephro AKI (NGAL), 2) increasing sales of The NGAL Test for adult use in CE-marketed countries, 3) initiating and submitting an US FDA application for clearance of ProNephro AKI (NGAL) for adult use.
- Search for new CEO/CFO to drive this strategy initiated interim management with strong knowledge of product, market and organization in place.

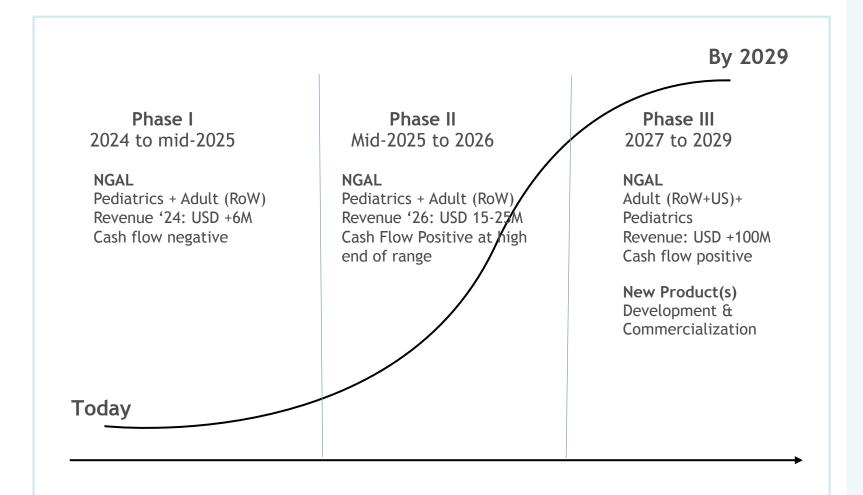
Prom

Diagnostic Innovator with potential game-changing NGAL biomarker for AKI

Attractive, profitable Diagnostic company with successful inmarket biomarker(s)

# From Diagnostic Innovator to attractive, profitable Dx company by 2029 with USD +100m topline

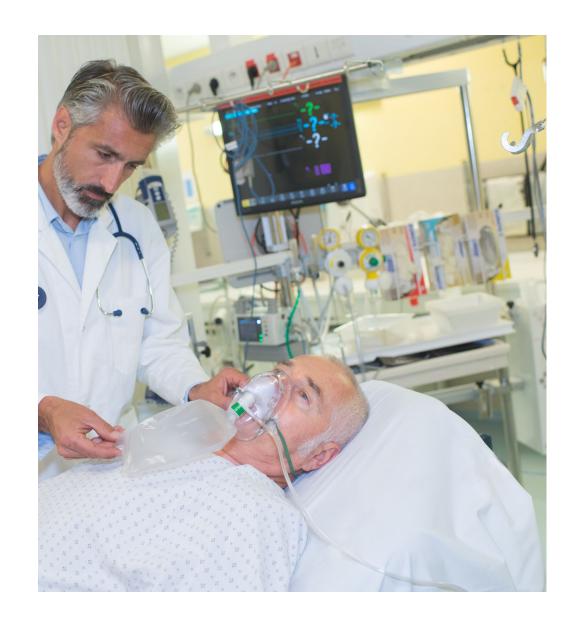




- Revenue expected to increase to USD 15-25 million by 2026 as BioPorto expands its serviceable market by +50% via expansion of instrument use of ProNephro AKI.
- USD 20 million in new capital to drive submission of FDA clearance for ProNephro AKI Adult in 2026.
- ProNephro AKI for adults and pediatrics will boost revenue to USD +100 million by 2029.



## About Acute Kidney Injury



## Acute Kidney Injury (AKI) - A major Unmet Clinical Need





# 1 in 5 ADULTS & 1 in 4 CHILDREN

is affected with AKI during hospitalization

- An abrupt loss of kidney function that develops rapidly over a few hours or days.
- Symptoms may include decreased urinary output, swelling due to fluid retention, nausea, fatigue, and shortness of breath. Often painless without symptoms.
- Difficult to diagnose.
- AKI can progress to CKD, a lifetime of dialysis, and death.

## AKI is common and costly



## Hospital Patients at Risk of AKI<sup>3</sup>:

- Cardiac Surgery
- Mechanical Ventilation
- Sepsis
- Organ or Bone Marrow Transplant
- Nephrotoxic Agents/Drugs



Increased Length of Stay

7 – 23 DAYS<sup>6</sup>



Increased need for Dialysis

12% OF CRITICALLY ILL ADULTS<sup>5</sup>



Overall Mortality Rate

**21**%<sup>6</sup>



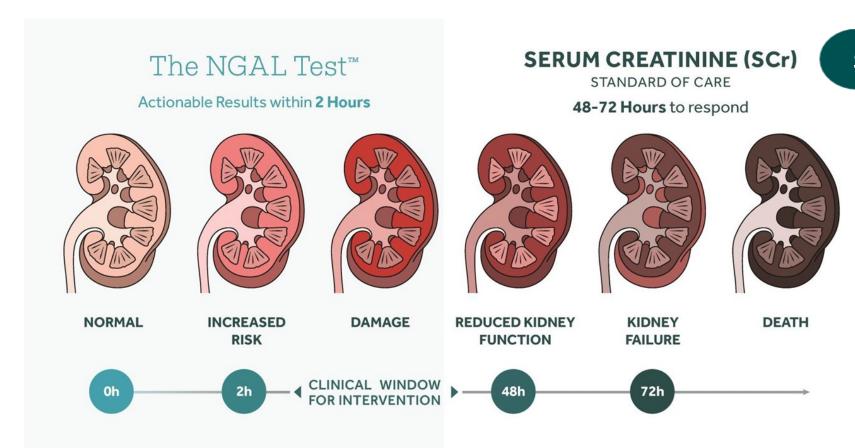
\$7,000 increase per episode<sup>7</sup>



\$5-20 billion annual cost<sup>7</sup>

## ProNephro improves the Standard of Care





#### Serum Creatinine is Inadequate

#### Hospital Patients at Risk of AKI<sup>3</sup>:

- 2-23 days delayed<sup>1</sup>.
- 43% of patients missed using SCr alone<sup>2</sup>.
- 66% of AKI is misclassified<sup>3</sup>.
- 70% of clinicians believe they are missing AKI<sup>4</sup>.



# ...and enables clinicians to deliver personalized, differentiated treatment based on AKI phenotypes

#### **Serum Creatinine is Inadequate**

|                         | No Injury                                     |  | Structural Injury                             |  |
|-------------------------|---|--|---|--|
| No Functional<br>Change | <ul><li>NGAL</li><li>Creatinine</li></ul>     | NORMAL   | <ul><li>→ NGAL</li><li>→ Creatinine</li></ul> | SUBCLINICAL AKI  VALUE OF NGAL ⊕  Identifying risk of AKI early increases vigilance, may enable more rapid interventions, such as fluid management and Rx decisions. |
| Functional<br>Change    | <ul><li>○ NGAL</li><li>⊕ Creatinine</li></ul> | 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. | <ul><li>→ NGAL</li><li>→ Creatinine</li></ul> | DAMAGE ASSOCIATED AKI  VALUE OF NGAL ⊕  NGAL provides early risk assessment of Stage 2/3 AKI. These patients may have increased odds of needing RRT.                 |

Adapted from: Murray PT, Mehta RL, Shaw A, et al. Kidney Int. 2014 and Stanski N, Menon S, Goldstein SL, Basu RJ. J Crit Care. 2019.



# Strategic roadmap



## USD 3 Billion market for ProNephro AKI



#### **TAM Global USD 3 Billion**

World wide, all big five instrumentations, all AKI indications











#### US

Adult USD 1.1 Bn

Pediatric/Young Adults USD 60-80 million

#### RoW

Adult USD 1.7 Bn

Pediatric/Young Adults USD 90-120 million

## New Strategic Plan



Phase I

Pediatric / Young Adult Indication approved

#### **Key Objectives:**

- ✓ Initiate usage in Pediatrics/young adults (US)
- ✓ Initiate Adult usage in RoW
- ✓ Financing Round USD 20 million
- ✓ Instrument Expansion -Pediatrics/Young Adults
- ✓ Strategy for Adult Trial and execution timeline (FDA)
- ✓ IVDR indication selection and execution timeline & Submission

Phase II

Instrument Expansion executed

#### **Key Objectives:**

- ✓ Drive usage Pediatrics/Young Adults (US)
- ✓ Consolidate Adult usage in RoW
- ✓ Adult Trial Submission to FDA For Clearance
- ✓ New Product Introduction (NPI) Strategy

Phase III

Clearance Adult indication (FDA | IVDR)

#### **Key Objectives:**

- ✓ Initiate Adult usage in US
- ✓ Fortify Adult usage in RoW
- NGAL Label expansion (FDA / IVDR)

2024 -Jun 2025

Jul 2025 - Dec 2026

2027-2029

# From 58%-104% CAGR in 2024-2026 to broader portfolio and high growth by 2029



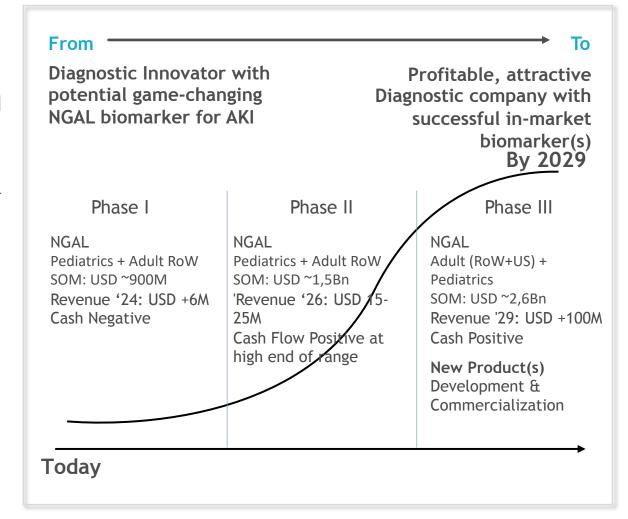
#### **Today**

BioPorto is the ProNephro AKI (NGAL) Market Maker - we need to build authentic demand

NGAL awareness is high -Education on how to use in Clinical setting is low

#### Key to success:

Performance in PED/young adults, Initiating Adult usage in Europe + US RUO\*



#### **Key initiatives**

- Win in Pediatrics/Young Adults | US & Europe
- Strategic Partnership / Instrument Expansion
- Implement ProNephro AKI
  in Adult clinical usage | US
  & Europe
- Successful funding rounds

15



# Roadmap for Pediatrics



## Commercial strategy for Pediatric/Young Adult ProNephro AKI (US)



2024 - June 2025

#### **Pediatric / Young Adult Indication approved**

July 2025 - December 2026

#### Instrument **Expansion executed**

2027-2029

**Clearance Adult indication** (FDA|IVDR)

Go-to-Market Model

Direct sales to ICU

- Distribution via partnership with Roche to pediatric ICU
- RUO\* sales in pediatrics and adult

• Direct sales to pediatric clinics and hospitals

- Indirect sales via partnership with Roche
- Distribution via new instrument partnerships
- Direct RUO\* sales

**Target** customers Target Accounts: Large ped

hospitals/centers

Target customers: Nephrologists;

Cardiologists; Intensivists; CV Surgeons;

Laboratory directors

Target Accounts: Large integrated hospital centers; Mid-size ped hospitals Target customers: Nephrologists; Cardiologists; Oncologist Intensivists; CV Surgeons; Laboratory directors

**Target Accounts:** Large integrated hospital centers; Heart centers, Oncology centers Target customers: Nephrologists; Cardiologists; Oncologist Intensivists; CV Surgeons; Laboratory directors

**US** sales organization & Partners

- Add Sales reps
- 1 distribution partnership

- Ramp up Sales Organization
- Add distribution partnerships

- Enhance Sales Organization
- Add distribution partnerships

US serviceable obtainable market

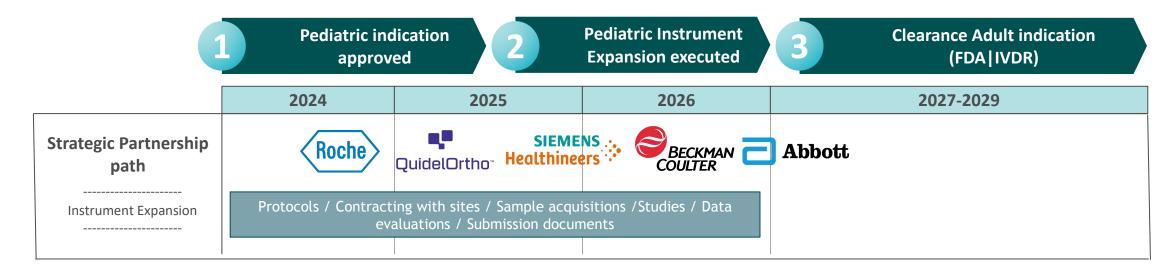
 USD ~20 million in serviceable obtainable market

 USD ~30 million in serviceable obtainable market

 USD ~50 million in serviceable obtainable market

# Strategic Partnerships to drive Instrument Expansion - extending Serviceable Obtainable Market for ProNephro AKI

- ProNephro AKI was cleared in December 2023 by FDA for marketing on Roche cobas c 501 analyzers in Pediatric
  and Young Adult indication
- BioPorto has initiated clearance processes for additional Roche Analyzers in 2024 via a family approach as defined in FDA guidelines which will require limited technical evaluations and studies (CLIA categorization).
- Furthermore, BioPorto will seek to extend use to Siemens, QuidelOrtho, Beckman and Abbott analyzers.



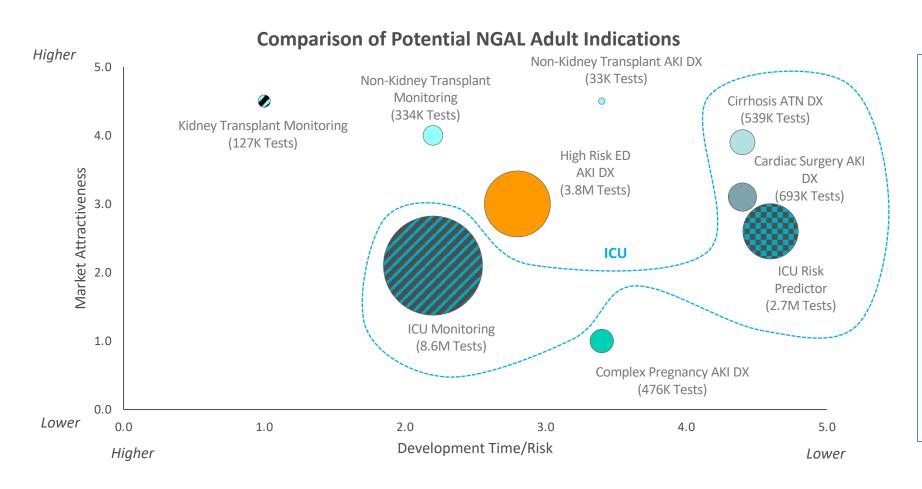


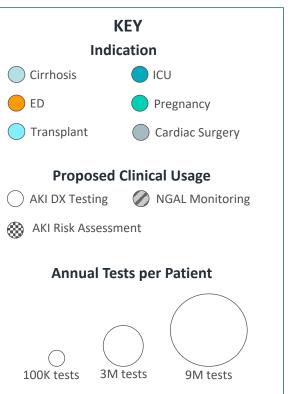
# Roadmap for Adult



## FDA Clearance strategy utilizes Basket Clinical Study



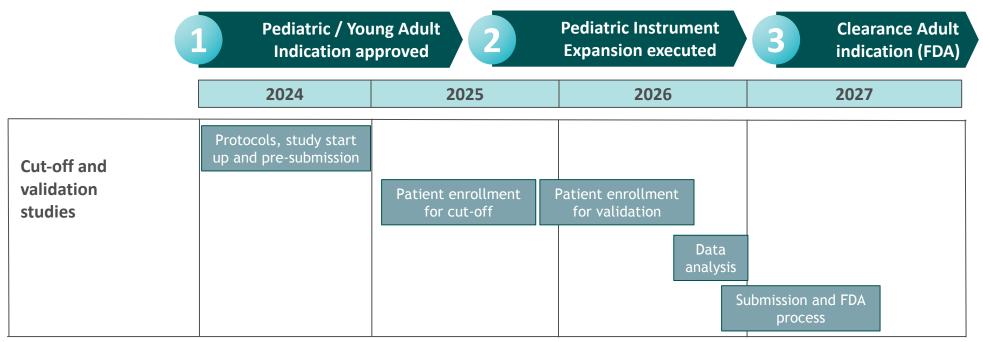




## <del>\</del>\$

# Adult ProNephro AKI indication for *General ICU Risk Assessment* expected to be submitted to FDA in 2026

- Primary Regulatory Target is FDA clearance for General ICU Risk Assessment similar to pediatric indication.
- Project initiation has begun literature review completed, KOLs have been engaged and biostatisticians are being onboarded to move into protocol draft completion.
- Estimated cost of FDA clearance process for Adult ProNephro AKI estimated to USD 15-20 million.



# Adult remains RoW primary Source of Business. Recent FDA clearance is driver for clinicians to consider NGAL's broad clinical Value

1

2024 - June 2025

Pediatric / Young Adult Indication approved

2

Instrument Expansion executed

July 2025 - December 2026

3

2027-2029

Clearance Adult indication (FDA|IVDR)

Go-to-Market Model Distributor (Primary focus)

- + local demand generation
- Primary: IT, DE, ES, KR, Secondary: Benelux, GR, IL, EU, MY, MX, IN

Sources of business

Sales

- Adult patients ICU Cardio and Pulmonary
- Pre and post surgery patients;
   Transplantation patients
- Ped ICU patients

2 Strategic partnerships

Sales reps

- Adult patients ICU Cardio and Pulmonary
- Adult ED patients Cardio and Pulmonary;
   Pre and post surgery patients;
   Transplantation patients; Sepsis patients
- Ped ICU patients
- Ramp up Sales Organization
- 5 Strategic partnerships

Serviceable obtainable market

organization & Partners

- USD ~900 million in serviceable obtainable market
- USD ~900 million in serviceable obtainable market

Distributor +

local demand generation (*Primary focus*)

- Primary: IT, DE, ES, FR, KR, GB, EU, Secondary: Benelux, GR, IL, MY, ID, MX, IN, Middle East, BR
- Adult patients ICU Cardio and Pulmonary
- Adult ED patients Cardio and Pulmonary;
   Pre and post surgery patients;
   Transplantation patients; Sepsis patients
- Ped ICU patients
- Enhance Sales Organization
- 5+ Strategic partnership

• USD ~1,500 million in serviceable obtainable market



# Financial guidance



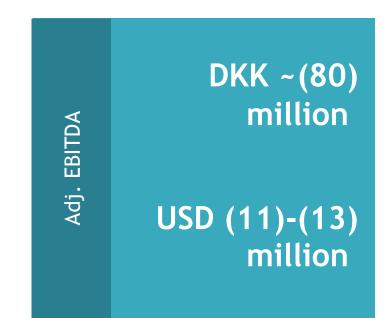
#### 2024 Financial outlook



2024

2024





#### Key revenue drivers

- Pediatric/Young Adult approval US
- Halo effect RoW
- Increased investment in demand driving activities

#### Key EBITDA driver

 EBITDA impact of FTE ramp up to scale and grow business

### Long term financial ambition



2026

2029

Revenue

USD 15-25 million

Cash Flow Positive at high end of range Revenue

USD +100 million

Cash Flow Positive, Profitable

- Grow revenues with 3-5x from 2023 level by 2026 by expanding ProNephro AKI sales in the US and ROW.
- Steep growth in 2027 and onwards, following an FDA clearance for adult ProNephro AKI

# Unlocking USD 2.8 Billion in the Adult Market with A Vital USD 20 Million Capital Infusion from Current, Strategic, and Institutional Investors



- To maximize BioPorto's growth and value creation potential, the company is investigating opportunities to bolster its financial position
- The FDA clearance of ProNephro AKI for pediatrics / young adults
  was a major milestone, allowing marketing in the world's largest
  IVD market. Now, to unlock the USD 2.8 billion adult market,
  BioPorto seeks additional funding through new share issuance to
  current, strategic, and institutional investors
- The company anticipates raising **USD 20 million in new capital** to complete the necessary clinical studies and commercialization efforts for an adult indication launch.
- The Board of Directors is assessing various strategies to secure funding and currently expects to carry out a share issuance in Q2 2024.



## Summary

BioPorto evolves from a Diagnostic Innovator to profitable, attractive Company by 2029

• 2026: USD 15-25M Top-Line

• 2029 : USD +100M Top-Line

#### Key Must-Wins

- Win in Pediatrics / Young Adults US|Europe
- Kick-start Adult RUO\* & Clinical usage
- Adult FDA submission 2026



### Financial calendar 2024



