



# Interim Report Q1 2024 BioPorto A/S

Hellerup, May 8, 2024

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# Forward-Looking Statements

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# Highlights from Q1 2024



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# Highlights from Q1 2024

- 80% growth from sales of NGAL products in the US and 27% increase in revenue from NGAL globally.
- Development and implementation of revised strategy with detailed and ambitious long-term growth and earnings targets.
- First milestone for instrument expansion for ProNephro AKI NGAL secured.
- Solid momentum in process for Adult submission of ProNephro AKI NGAL to the FDA.
- New management team being established.
- Financial guidance for 2024 maintained.

## TOTAL REVENUE

**DKK 9.5 million**

a 18% increase over same period the prior year

## ADJ. EBITDA

**DKK (15.3) million**

## CASH POSITION

**DKK 45 million**

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# Strategic Roadmap



# Unlocking a USD 3bn Market for ProNephro AKI NGAL

## TAM Global USD 3 Billion

Worldwide, all big 5 instrumentations,  
all AKI indications



QuidelOrtho™



**Adult US** USD 1.1 B  
**Pediatric US** USD 60-80 M

**Adult RoW** USD 1.7 B  
**Pediatric RoW** USD 90-120 M

# Strategic initiatives and milestones towards 2029

## Phase I

2024 – Jun 2025

### Pediatric Indication Approved

#### Key Objectives:

- Initiate usage in Pediatrics (US)
- Initiate Adult usage in RoW
- Financing Round – USD 20 million
- Instrument Expansion – Pediatric
- Strategy for Adult Trial and execution timeline (FDA)
- IVDR indication selection and execution timeline & Submission

## Phase II

Jul 2025 – Dec 2026

### Pediatric Instrument Expansion Executed

#### Key Objectives:

- Drive usage Pediatrics (US)
- Consolidate Adult usage in RoW
- Adult Trial Submission to FDA For Clearance
- New Product Introduction (NPI) Strategy (M&A | In-License | Develop)

## Phase III

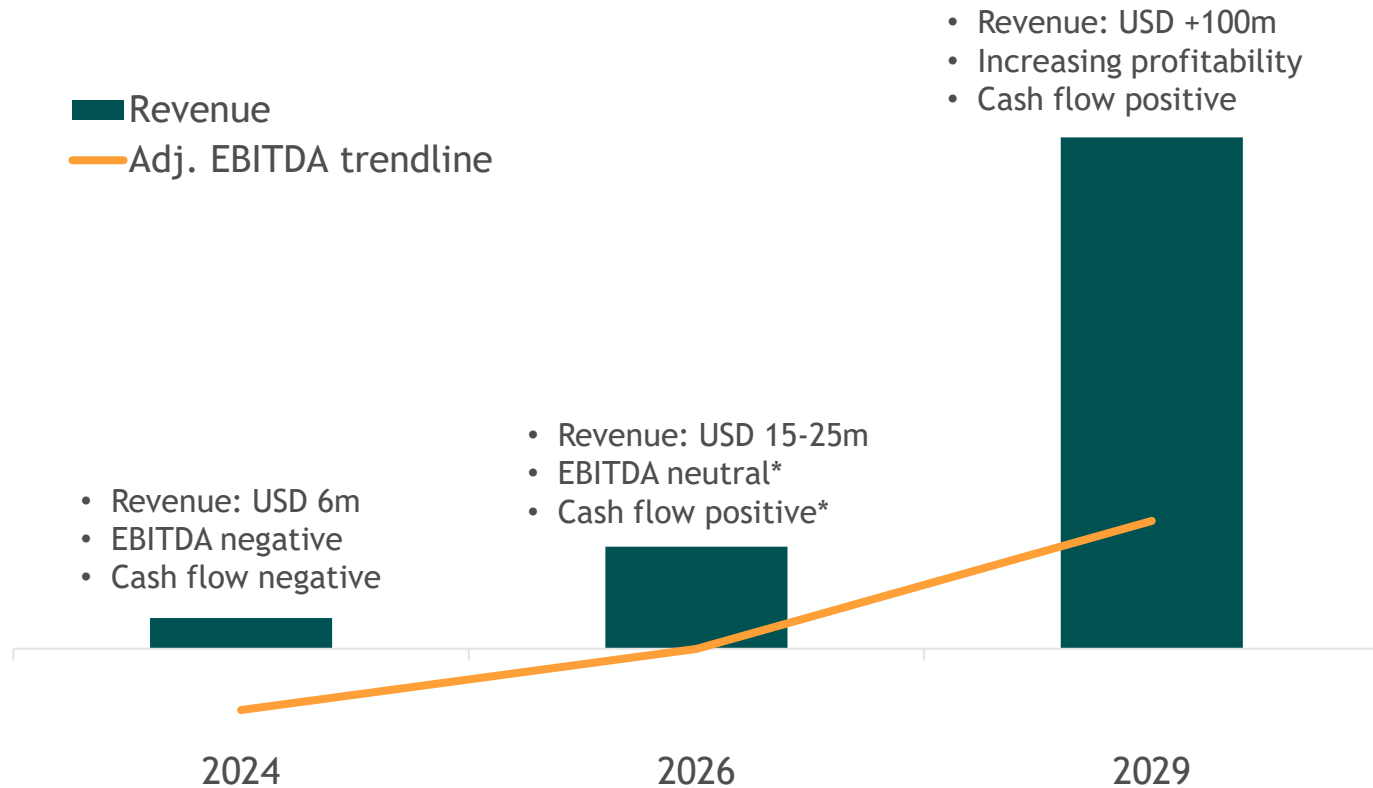
2027- 2029

### Clearance Adult Indication (FDA|IVDR)

#### Key Objectives:

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

# Targeting USD +100 million revenue in 2029 and profitability by 2026



## STRATEGIC & FINANCIAL OBJECTIVES

**Until 2026** - 4x 2024 revenue and build cash flow positive & EBITDA neutral operations by expanding ProNephro AKI NGAL sales in the US and ROW.

**Toward 2029** - 4x 2026 revenue and attractive profitability by securing FDA clearance for adult ProNephro AKI NGAL in 2027 to unlock massive world market potential.

\* At top-end of revenue range



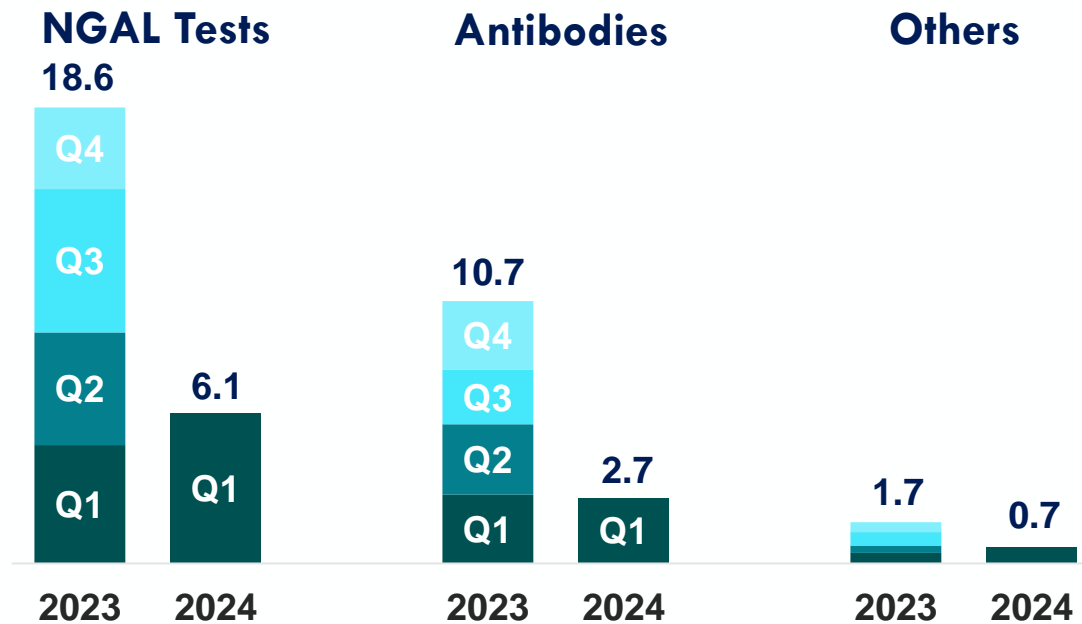
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# Financial results in Q1 2024

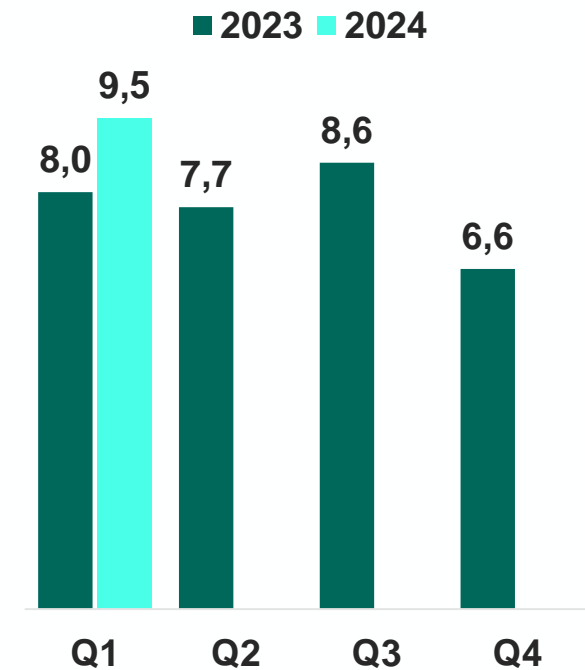


# Total revenue increase by 18% in Q1 2024 (YoY) driven by strong performance in NGAL tests

## Annual Revenue by Product Group\*

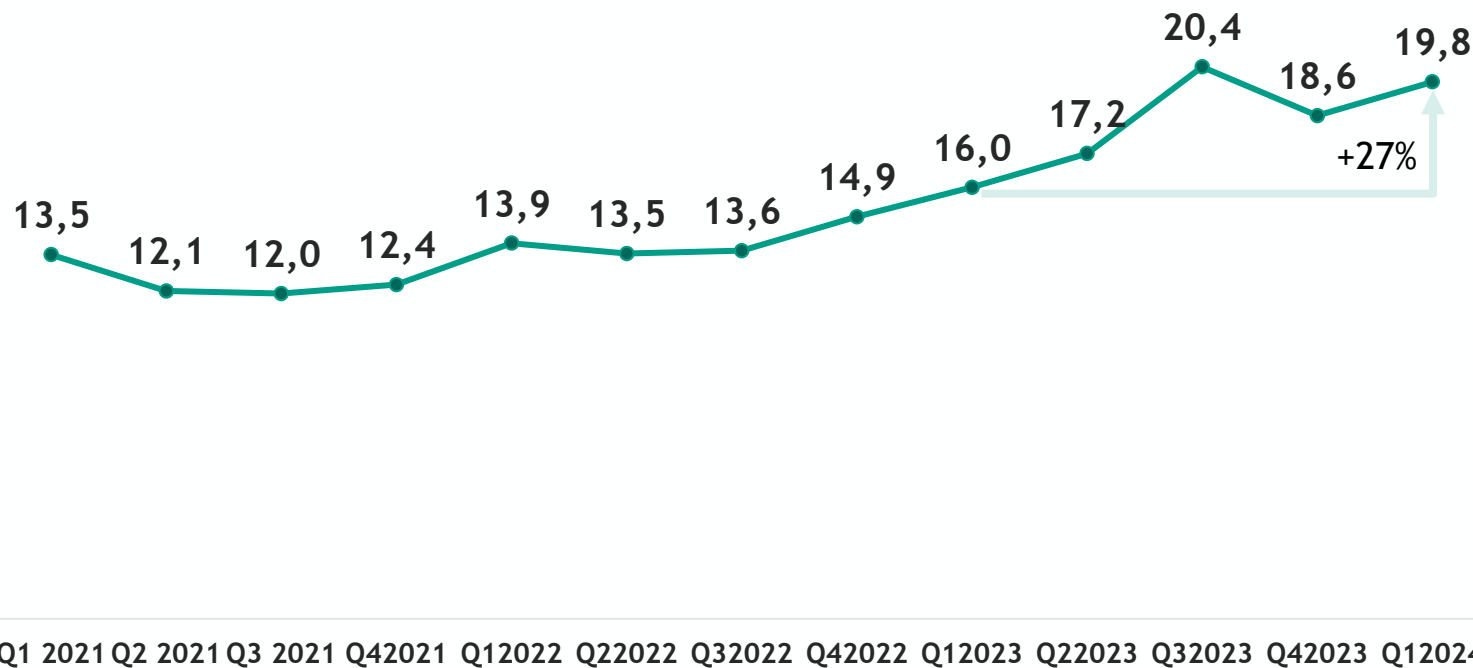


## Revenue by Quarter\*



# NGAL Test sales in the US up 80% and 27% globally YoY

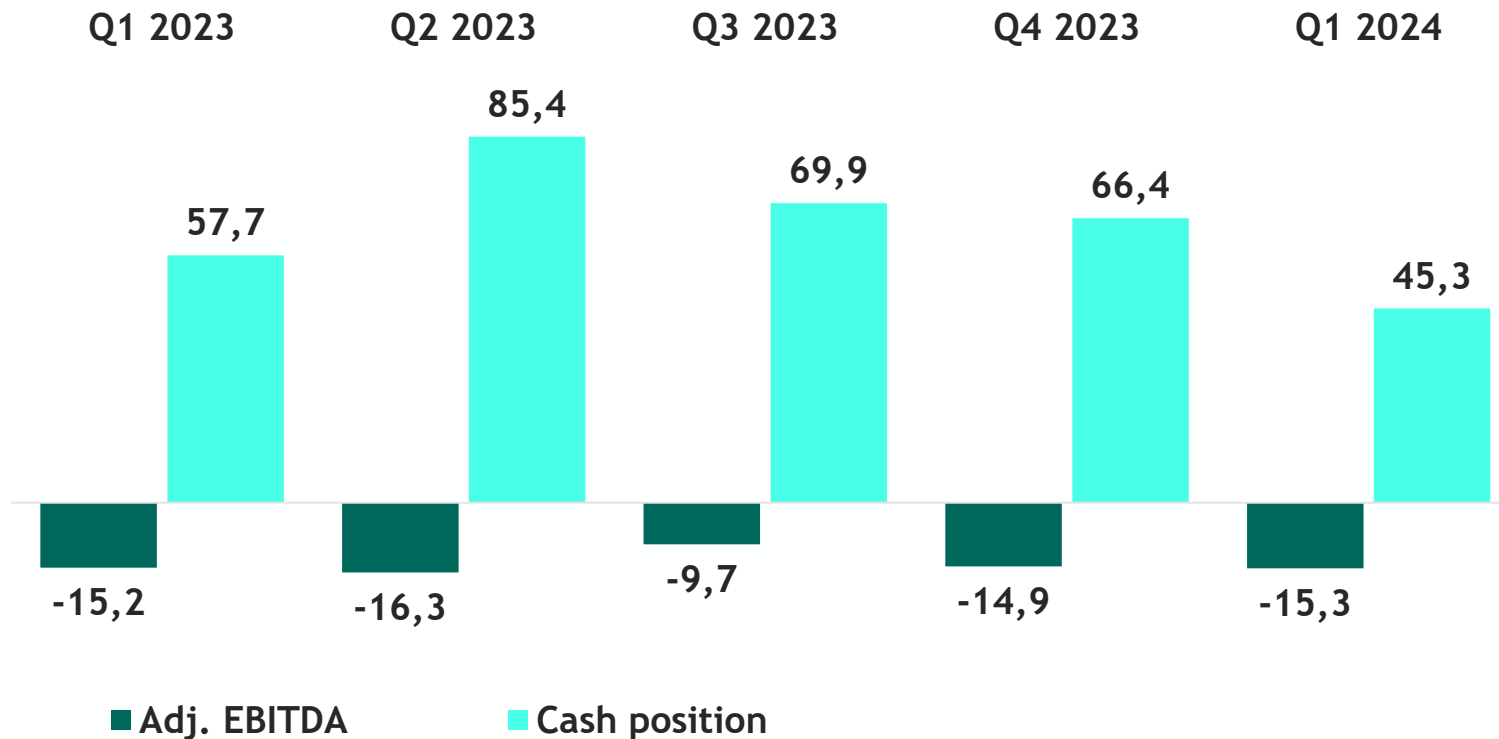
NGAL test sales by Quarter (LTM, DKKm)



- Strong performance and very satisfactory development in sales of the NGAL Test in the US for research use only.
- US interest is increasing ahead of clinical introduction in second half of 2024 with Roche.
- Sales of the test in rest of the world slightly below same quarter last year as expected.

# Adj. EBITDA level on par with last year – cost will be added in coming quarters

## Adjusted EBITDA and cash position (DKKm)



- EBIT loss in Q1 2024 reduced DKK 2.3 million compared to last year.
- Adjusted EBITDA loss on par due to severance cost and deleted warrants.
- Increased marketing spend in US for launch of ProNephro AKI NGAL and new clinical cost for adult FDA process will increase EBITDA loss in coming quarters.

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# Execution in Q1 2024



# Full focus on US commercial launch of ProNephro AKI (NGAL)

- Building knowledge of ProNephro AKI NGAL via intensified conference attendance and Grand Rounds with KOLs and MSLs.
- Issuance of new papers to address clinical results and clarify usage of the test.
- Expanding business development and sales staff in both US and Europe with new hires.
- Supply chain in place (production, packaging etc.) and preparations for partnerships.



Jeffrey N. Haas joins BioPorto as CEO for BioPorto Inc. on May 13, 2024.

Jeffrey was previously with Abbott Laboratories (US) where he since 2017 served as President of Rapid Diagnostics Infectious Diseases Developed Markets Business Unit.

The NGAL Test™

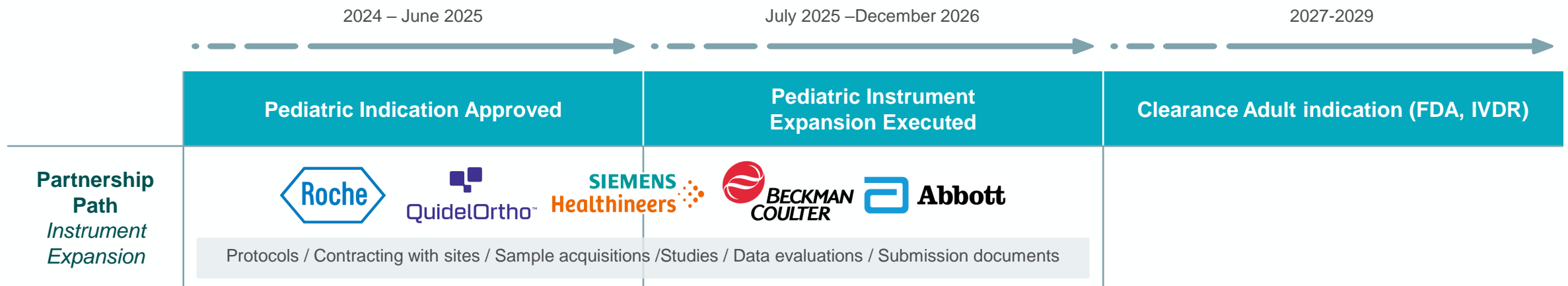


ProNephro AKI™

*The NGAL Test™ is CE-Marked for IVD use in the European Union. ProNephro AKI™ is FDA-cleared for use in the United States.*

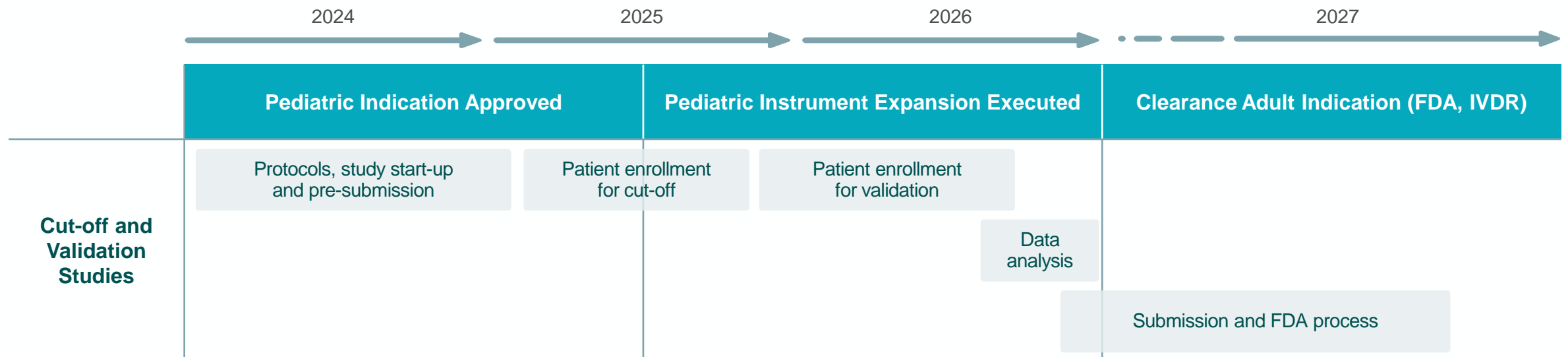
# First Milestone on Expansion Strategy Secured

- ProNehpro AKI NGAL was FDA cleared for marketing on Roche cobas c 501 analyzers - after final preparations, commercial launch will be in second half of 2024.
- In February 2024, BioPorto and Roche expanded original global distribution to include Roche c 503.
- BioPorto has in Q1 2024 initiated dialogues with other leading instrument manufacturers to enable use of ProNephro AKI NGAL on their platforms following technical and clinical requirements.



# Strong Momentum for Submission process of ProNephro AKI NGAL for adult use in US

- In Q1 2024, BioPorto has initiated process for obtaining FDA clearance ProNephro AKI NGAL for General ICU Risk Assessment in adults - similar to pediatric indication. Solid process experience from pediatric process will be heavily leveraged and utilized
- Literature review completed, staffing begun, and protocol draft been finalized in Q1 2024.
- Feasibility study and site-selection for cut-off study will commence in the coming months.





# New management team with strong in-vitro diagnostic track-record



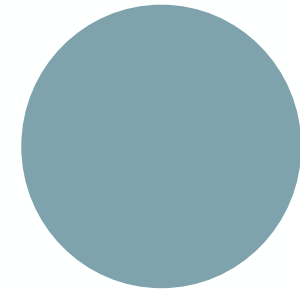
**Peter Mørch Eriksen**  
CEO



**Gry Husby Larsen**  
CHIEF LEGAL OFFICER



**Jeffrey Haas**  
US-CEO



**To be appointed**  
CFO



**Nis Kruse**  
EVP, STRATEGIC PARTNERSHIPS AND GENERAL MANAGER, EMEA & APAC



**Jennifer Zonderman**  
SVP, GLOBAL MARKETING & US COMMERCIALIZATION



**Ursula Klause**  
VP, RESEARCH AND DEVELOPMENT



**Asger Dahlgaard**  
VP, QUALITY ASSURANCE AND REGULATORY AFFAIRS



**Tabari Baker**  
VP, GLOBAL MEDICAL AFFAIRS



**George Rosa**  
VP, GLOBAL REPORTING AND CONTROLS

# Execution on Phase I targets as planned

## Targets for period until mid-2025

### Key Objectives:

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

## Status after Q1 2024

### Status:

- Cooperation agreement with Roche expanded.
- Instrument expansion process initiated (US pediatrics/young adults).
- FDA Protocol for ProNephro AKI NGAL for adults drafted.
- US organisation expanded to build commercial momentum for ProNephro AKI NGAL.
- Continued discussion with KDIGO.
- New CEO appointed.

## Remaining part of 2024

### Q2 2024:

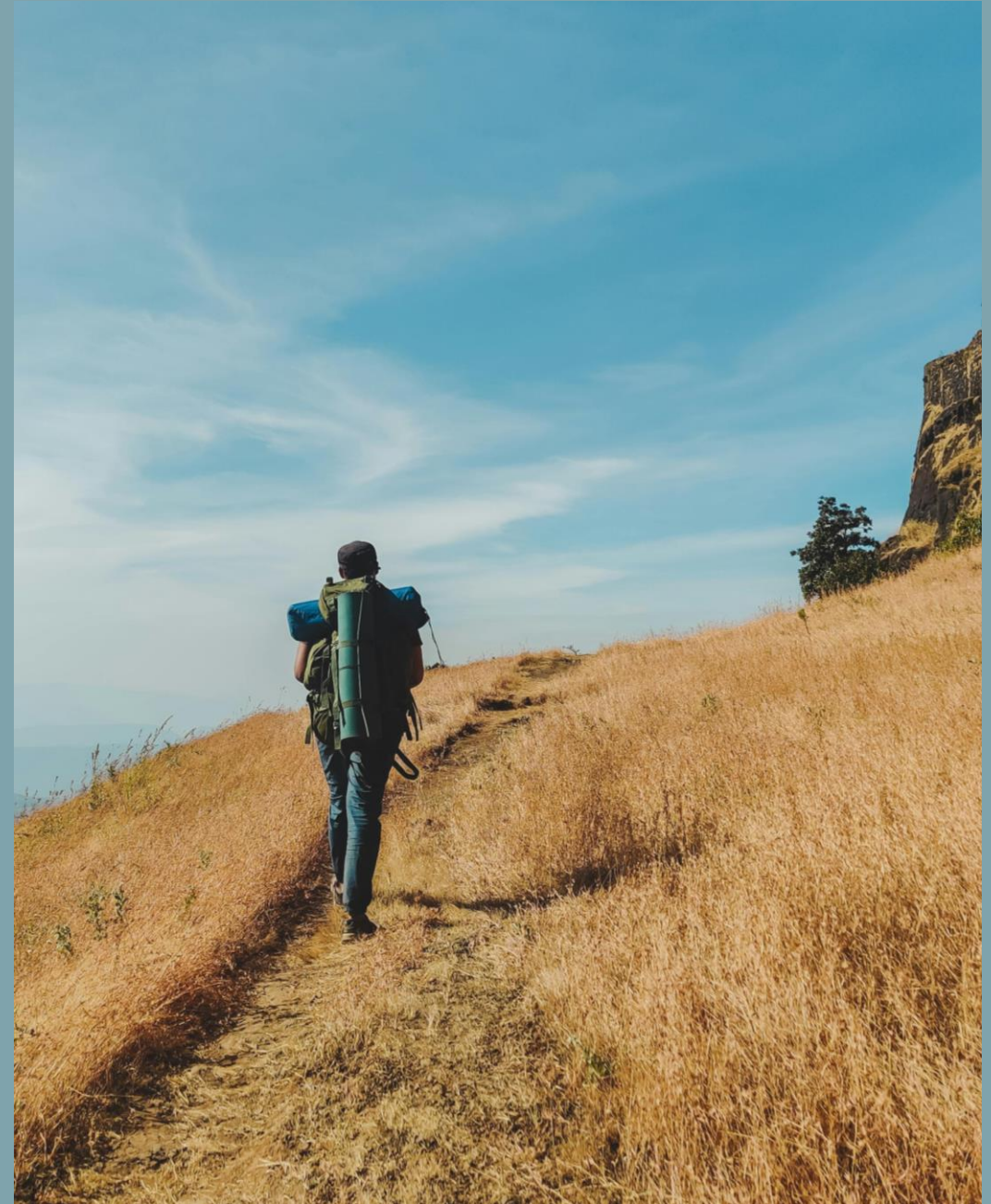
- Expand sales of NGAL products and prepare for US ProNephro AKI NGAL launch.
- Feasibility study and site selection initiation for adult study.
- Initiate funding process for first tranche.

### Second half of 2024:

- US launch of ProNephro AKI NGAL and further grow of NGAL products.
- Review further value creation from antibodies.
- New instrument partnerships.

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# Financial Outlook for 2024



# Capital increase to fund investment in Adult ProNephro AKI FDA submission



- The Company received authority by AGM in April 2024 to issue new shares and anticipates to do so at two events in 2024 and 2025 with anticipated proceeds of approx. USD 20 million.
- Proceeds will be used in increased sales and marketing and to complete the necessary clinical studies and commercialization efforts for a US adult indication launch unlocking a USD 2.8 billion adult market.
- The Board of Directors is assessing various strategies to secure funding and aims to initiate the first share issue in June 2024.

# 2024 Financial Outlook

## Key revenue drivers for 30% growth

- Increased sales of NGAL, primarily in the US with halo effect in RoW.
- Backend-loaded as Roche commercialization in US will be in second half of 2024.

## Key EBITDA driver

- Higher US marketing cost for ProNephro AKI NGAL.
- Cost of clinical process to support FDA clearance for ProNephro AKI NGAL for adults.

**Adj. EBITDA**  
DKK ~(80) Million  
USD (11)-(13) Million

**Revenue**  
DKK ~40 Million  
USD 6 Million

<sup>1</sup>All Financial Figures Converted from DKK to USD at a rate of 6.75, except for cash which is converted at rate of 6.7447.

Note: BioPorto's performance and guidance for 2024 is based on certain assumptions described in the annual and interim report(s) and continues to be subject to uncertainty due to COVID-19, including continued opening of societies and the normalization of access to hospitals, research laboratories, and regulatory bodies. Please see the Company's 2023 Annual Report and Interim Reports for further information on risks and uncertainties. Adjusted EBITDA is a non-IFRS measure. Please see BioPorto's Annual and Interim Reports for a description of this measure and a reconciliation to EBIT.

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# Q&A

## Financial Calendar 2024

- August 15, 2024      Interim report, Q2 2024
- November 14, 2024      Interim report, Q3 2024

