bioporto
DIAGNOSTICS

# Interim Report Q3 2024

November 14, 2024

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# Highlights from Q3 2024

# Highlights from the Q3 2024 report

- 36% increase in US NGAL revenue YTD drives solid total revenue growth.
- Expansion of commercial activities globally to convert awareness to demand for NGAL products.
- First US standing order with a yearly value of more than USD 200,000 signed.
- Continued collaboration with distribution partner in preparation for US launch of ProNephro AKI (NGAL), now expected in first half of 2025
- New global distribution agreement with Beckman Coulter, Inc. on distribution of NGAL Tests signed in October.
- Strong momentum in process regarding US adult clinical trials for ProNephro AKI (NGAL) - first patient enrolled in October.
- Guidance for financial year 2024 maintained.

**TOTAL REVENUE (Q1-Q3 2024)**

**DKK 28.3 million**

An increase of 16% over same period last year

**ADJ. EBITDA (Q1-Q3 2024)**

**DKK (51.1) million**

Increase in headcounts to secure execution of strategic initiatives

**CASH POSITION SEP 30, 2024**

**DKK 76.3 million**

# Strong execution of Phase I expected to continue

## 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 Q3 2024

**Status:**

- ✓ Continued growth in US revenue with first standing order.
- ✓ Site selection for clinical studies for ProNephro AKI (NGAL) for adults initiated.
- ✓ Enrollment of first patient for ProNephro AKI (NGAL) adult study.
- ✓ Distribution partnership signed with Beckman Coulter.

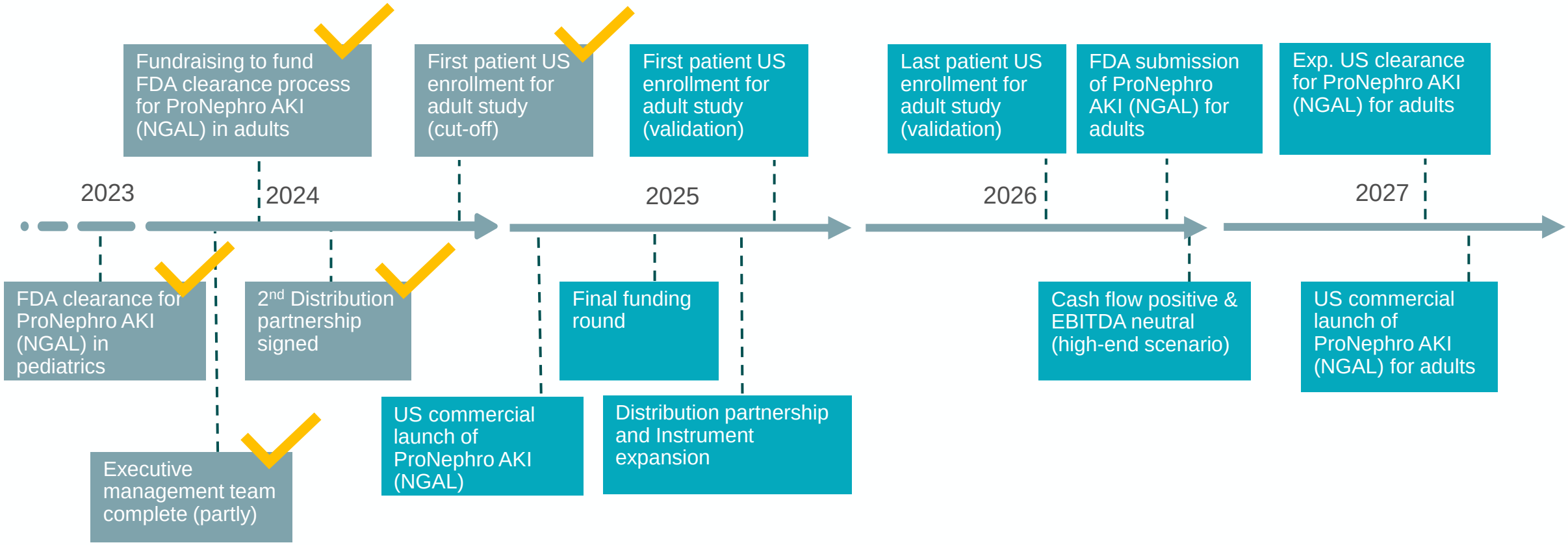
## Remaining part of 2024

**Q4 2024:**

- Continued collaboration with distribution partner in preparation for US launch of ProNephro AKI (NGAL)
- Ongoing enrollment of sites and patients for the Adult Trial.
- Ongoing assessment and exploration of financing options to fund strategic execution.
- Continue evaluating of antibody portfolio to increase value creation.

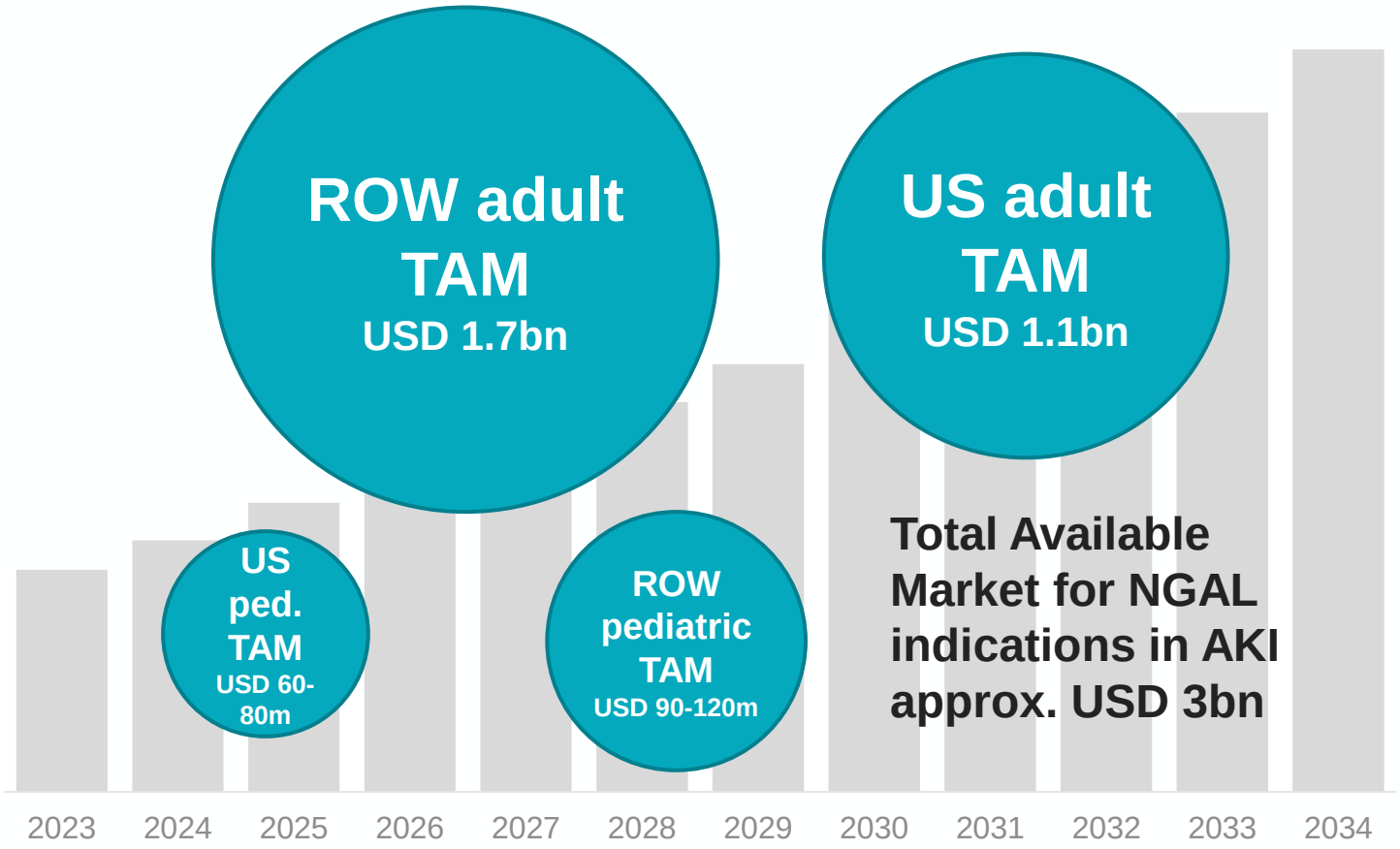
# Important future milestones



# Strategic Roadmap

# AKI Diagnostics Market Growing at +5% yearly driven by changing paradigm




- The AKI market is driven by advances in early detection and diagnostic technologies. McKinsey notes a need to move to preventative care.
- Recent advancements are transforming paradigm from Serum Creatinine to earlier and more accurate diagnosis, crucial for improving patient outcomes.
- Recent development of novel biomarkers and diagnostic assays that offer greater sensitivity and specificity in detecting AKI such as Kidney Injury Molecule-1 (KIM-1), Neutrophil Gelatinase-Associated Lipocalin (NGAL), and Interleukin-18 (IL-18) are gaining prominence.

*Source: imarc: Acute Kidney Injury Market: Epidemiology, Industry Trends, Share, Size, Growth, Opportunity, and Forecast 2024-2034, Management estimates | S2N Data, BIS data | US Ped Risk Strat indication is for 3 months through 21yoa | TAM: Total Available Market*

# NGAL assays designed to run on major clinical chemistry instruments


- High-Value Diagnostic Price Point
- High margins even at today's scale
- No investment in capital equipment

Roche

QuidelOrtho™

SIEMENS Healthineers

BECKMAN COULTER

Abbott

# 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*

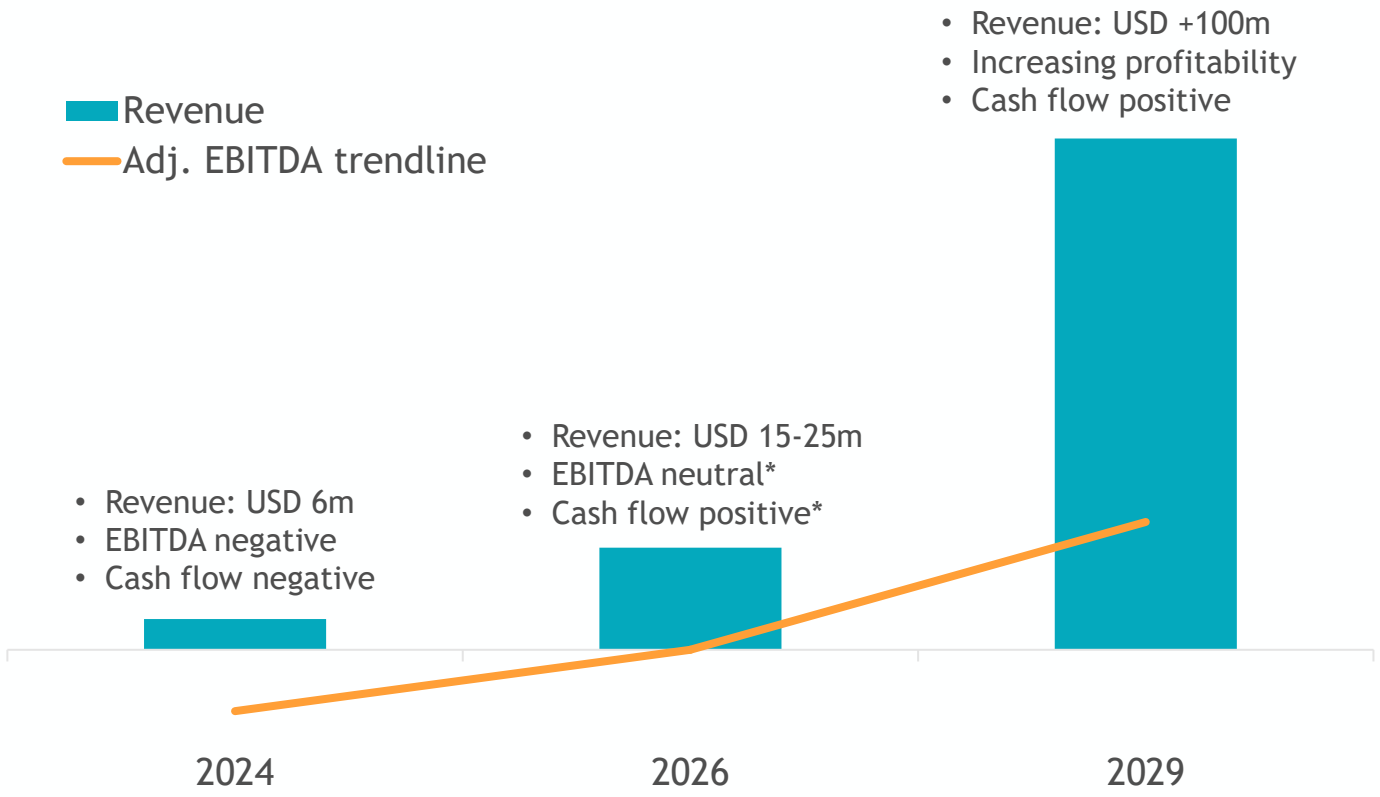
**Clearance Adult Indication (FDA|IVDR)**

**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




* At top-end of revenue range

## STRATEGIC & FINANCIAL OBJECTIVES

- **Until 2026 –** 3-4x 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.

# Execution in Q3 2024

# Strengthening of commercial activities is building pipeline

- Further expansion of business development and sales staff in US and Europe.
- High activity in converting NGAL awareness to actual NGAL Test demand is expanding pipeline both in the US and Europe.
- Conference attendance and a high level of sales activities have increased sales to existing and new customers.
- First standing order from US hospital worth USD 200,000 per year - an important milestone and proves customers perception of the tests' strong value proposition for ongoing risk assessment of AKI.

# BioPorto's NGAL presence today

**US News Best Children's Hospitals 2024-2025 Honor Roll**

- ✓ Boston Children's Hospital
- ✓ Children's Hospital Colorado
- ✓ Children's Hospital of Philadelphia
- ✓ Cincinnati Children's
- ✓ Nationwide Children's Hospital
- ✓ Rady Children's Hospital
- ✓ Seattle Children's Hospital

Children's Hospital of Los Angeles

- ✓ Children's National Hospital
- ✓ Texas Children's Hospital

**7 Current NGAL Users**

**2 Implementing NGAL**

The NGAL Test, Research Use Only, implemented as a Lab Developed Test

# New Global Partnership with Beckman Coulter for distribution of NGAL Tests

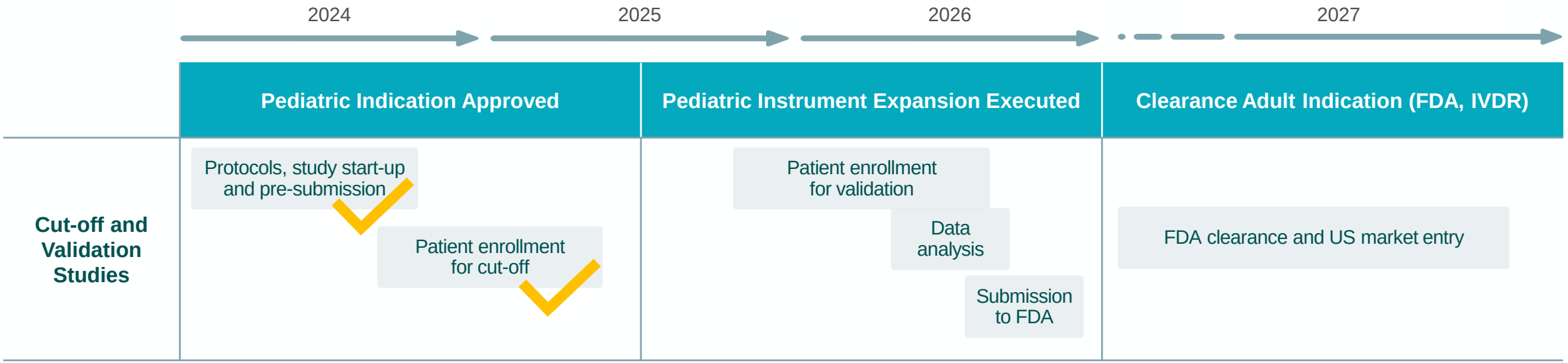
- First step in expansion of distribution agreements which is a cornerstone in BioPorto's commercial strategy for NGAL Test products.
- The agreement covers Beckman Coulters DxC and AU clinical chemistry analyzer families which already has a large installed base around the World.
- Beckman will initiate with distribution in Europe and follow with distribution in the US, once the ProNephro AKI test has been cleared by the FDA on their instruments.
- Dialogues with additional global distributors for NGAL Test products are ongoing and is expected to lead to additional agreements in 2025.

A global leader in clinical diagnostics, with a history that dates back more than 80 years.

Its diagnostic solutions are used in complex clinical testing, and are found in hospitals, reference laboratories and physician office settings around the globe.

# Enrolment of patients for adult ProNephro AKI (NGAL) commenced in October 2024

- First patient for first of two US clinical studies for adult usage of ProNephro AKI (NGAL) for AKI enrolled in October 2024 at Massachusetts General Hospital – well ahead of original schedule.
- First study will determine cut-off for risk stratification of moderate to severe AKI in adults.
- BioPorto is evaluating opportunities to increase number of sites from 12 on the cut-off and validation studies to accelerate process further.

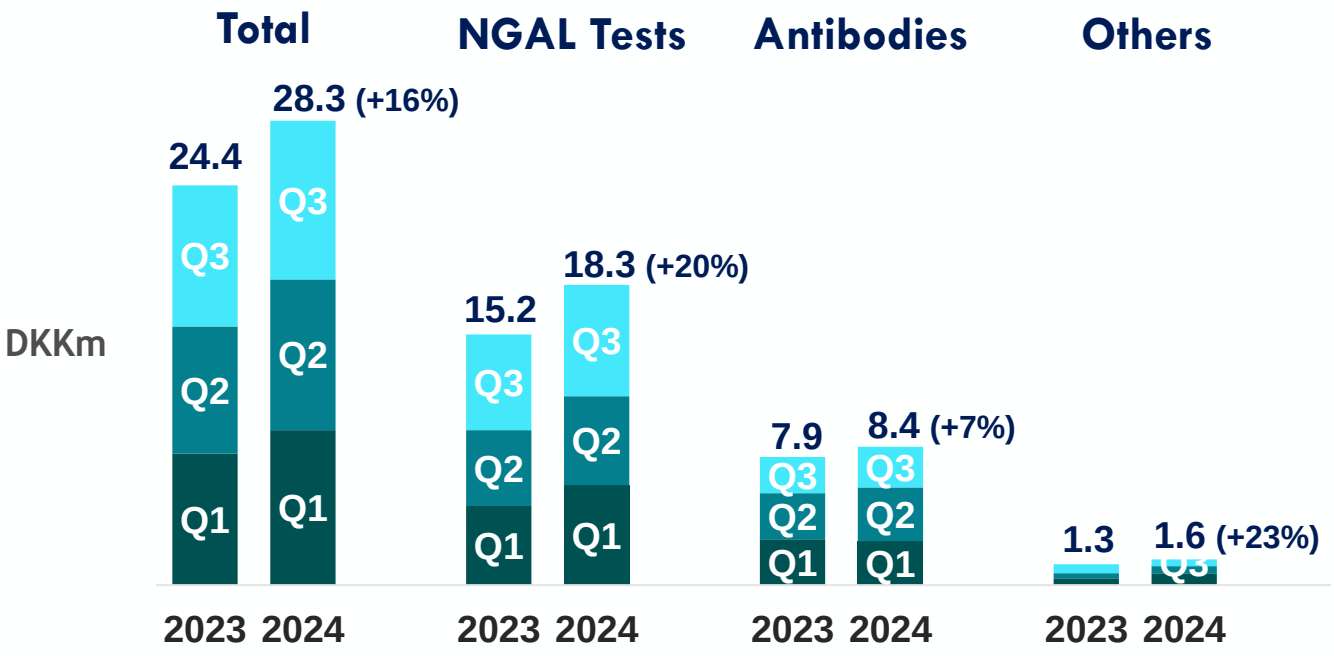


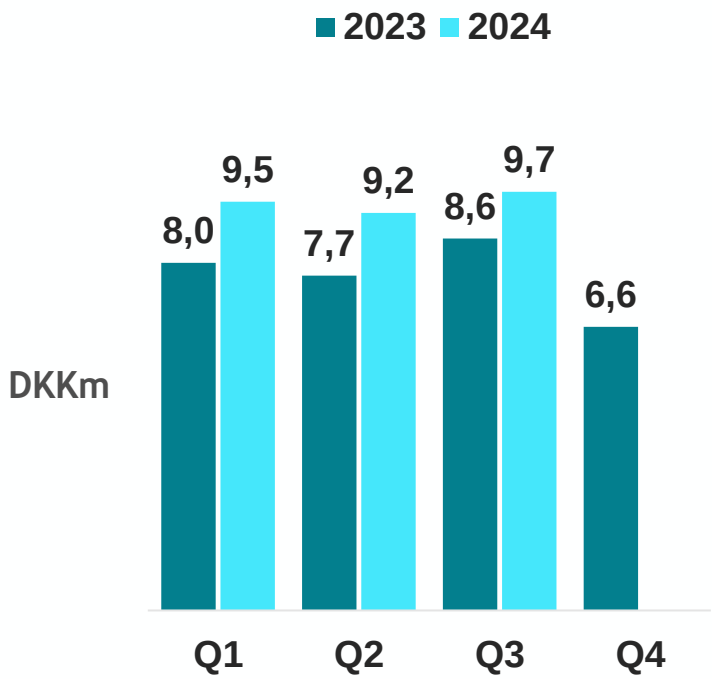
# Financial results in Q3 2024

# Total revenues up 16% YTD Q3 2024 – Growth in all product groups

## Annual Revenue by Product Group



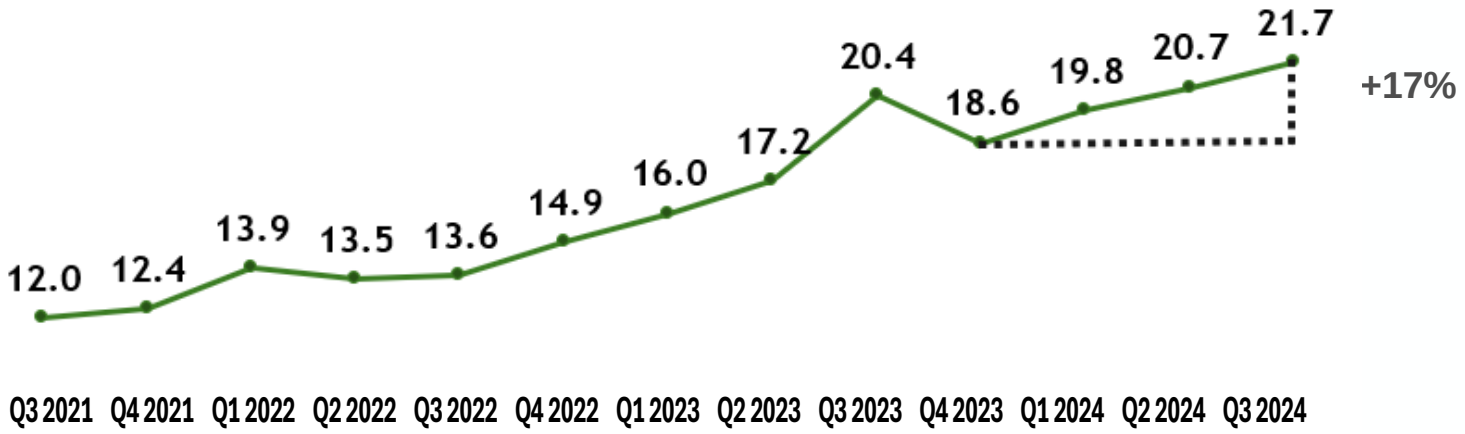

## Revenue by Quarter



# NGAL sales increasing by 17% in the last twelve months (LTM)

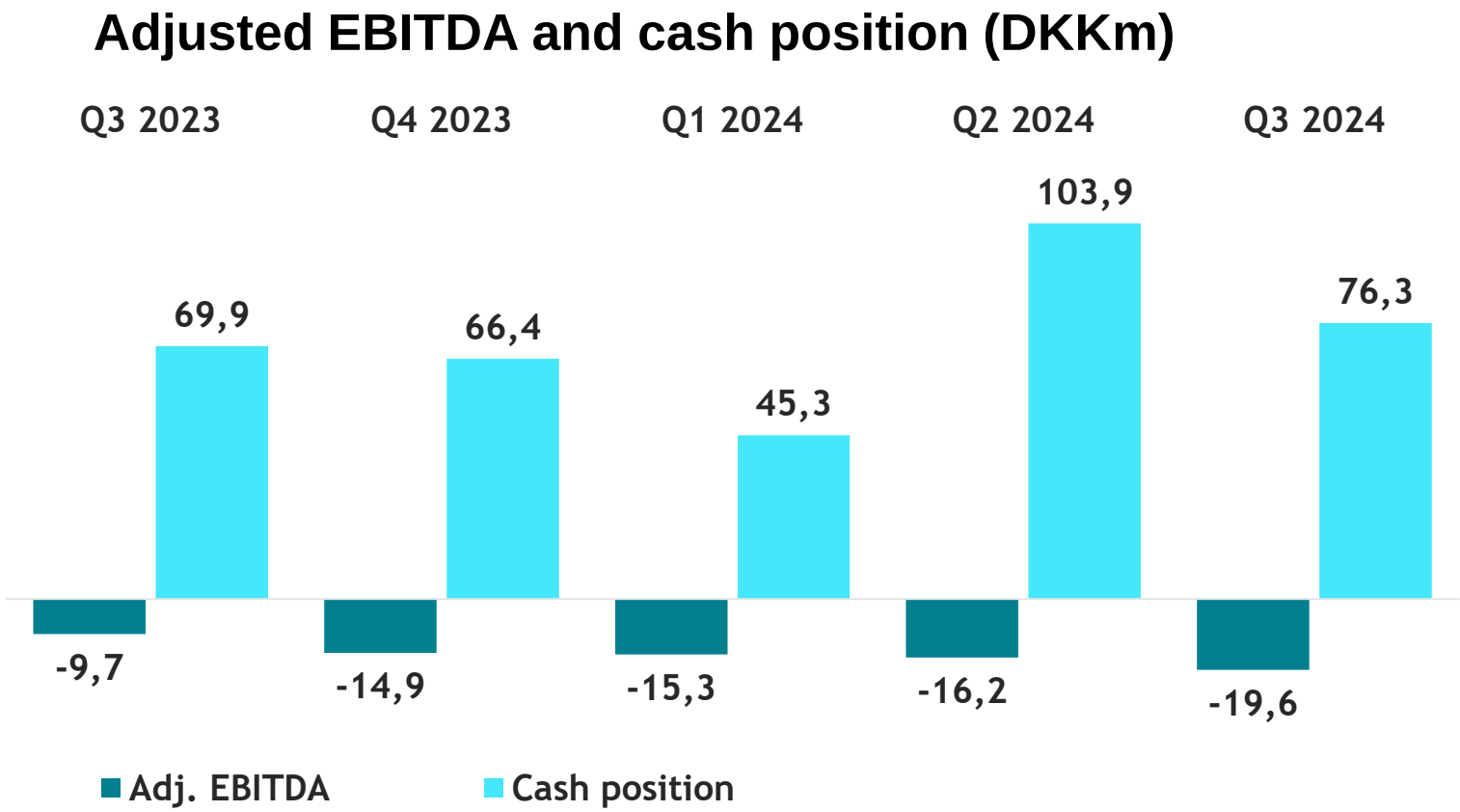
**Total NGAL test sales by Quarter (LTM, DKKm)**




- Continued strong development in US sales of NGAL products (RUO).
- In YTD Sep 2024 US NGAL sales makes up 40% of total revenue.
- Total NGAL revenues makes up 65% of total revenue.

# Adj. EBITDA loss increased compared to last year

- EBITDA loss in Q3 2024 increased by DKK 9.9 million compared to last year.
- Sales and marketing cost increased due to higher activities and organizational build-up - R&D increase due to increase in clinical costs and increase in headcount.
- Increased marketing spend in US for launch of ProNephro AKI (NGAL) and clinical cost for adult FDA process should increase EBITDA loss in Q4 2024.



# Financial Outlook for 2024

# 2024 Financial Outlook

**Key revenue drivers for 29% revenue growth for the full year**

- Increased sales of NGAL products, primarily in the US.

**EBITDA drivers**

- Increased US marketing spending for ProNephro AKI (NGAL).
- Higher cost associated with initiation of clinical studies to support FDA clearance for ProNephro AKI (NGAL) for adults.
- Increased headcount to achieve strategic initiatives.

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

**Adj. EBITDA**
DKK (75)-(90) Million
USD (11)-(13) Million

*1All Financial Figures Converted from DKK to USD at a rate of 6.75, except for cash which is converted at rate of 6.9664.*

*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. 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.*

# Q&A


November 14, 2024 - Interim Report, Q3 2024