

# Interim Report Q2 2024

Hellerup, August 15, 2024



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# Forward-looking Statements

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# Highlights from Q2 2024



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- Double-digit growth across all product lines driven by increased NGAL revenues in US.
- Total Q2 Sales of DKK 9.2 million and for H1 2024 DKK 18.7 million in line with expectations.
- Dialogue with several new potential global partners for distribution and instrument expansion of NGAL products.
- Clinical process for US FDA submission of ProNephro AKI (NGAL) for adults with strong momentum – enrolment to start in 2024.
- Completion of oversubscribed direct share issue at market price with gross proceeds of USD 11.7 million.
- New highly in-vitro experienced management team in place.
- Guidance for 2024 maintained.

## TOTAL REVENUE (H1 2024)

**DKK 18.7 million**

An increase of 18% compared to same period last year

## ADJ. EBITDA (H1 2024)

**DKK (31.5) million**

Loss reduced by DKK 2.9 million compared to same period last year

## CASH POSITION

**DKK 103.9 million**

Including DKK 81.4 million in gross proceeds from direct share issue

# 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 Q2 2024

### Status:

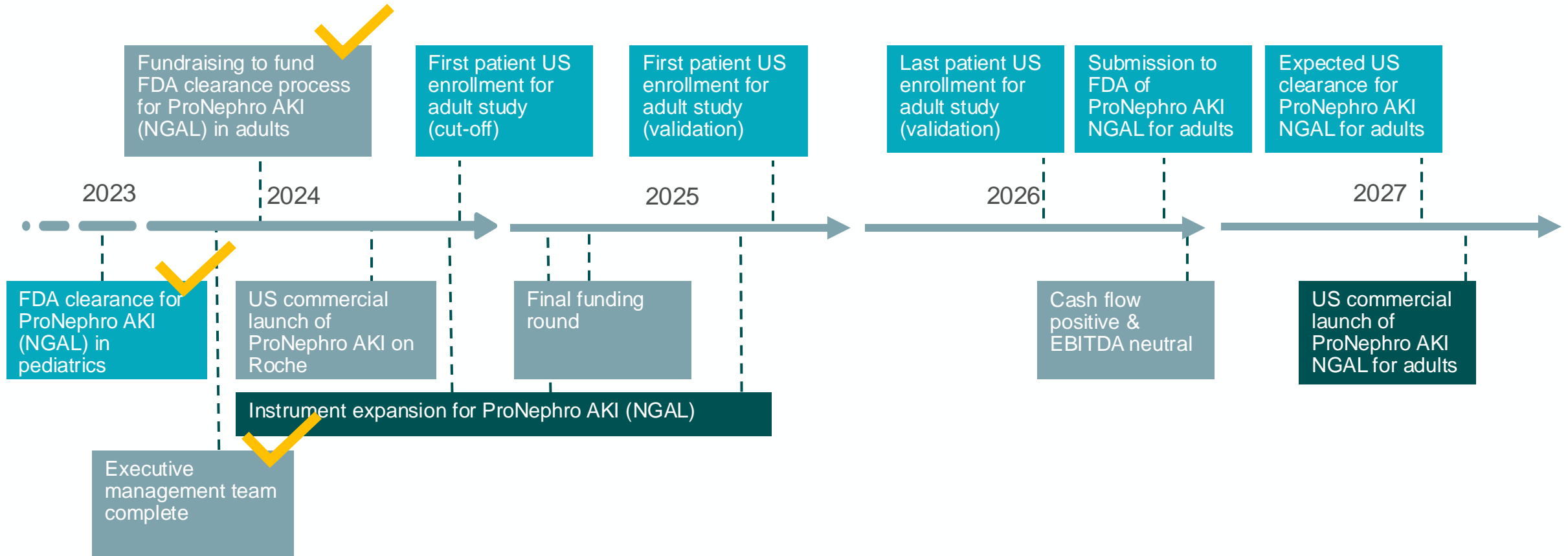
- ✓ Continued growth in US revenue with first standing order.
- ✓ Site selection for clinical studies for ProNephro AKI NGAL for adults initiated.
- ✓ Close dialogues with several potential new strategic partners.
- ✓ Oversubscribed direct share issue at market price with proceeds of USD 11.7 million
- ✓ Group CEO appointed and new Executive Leadership Team established.

## Remaining part of 2024

### Q3 and Q4 2024:

- Accelerate sales of NGAL products and initiate US launch for US ProNephro AKI (NGAL) with Roche.
- Sign new NGAL distribution partnership and instrument expansion.
- Enrolment of first patient for ProNephro AKI (NGAL) adult study.
- Commence evaluating of antibody portfolio to increase value creation.
- Ongoing assessment of financing options to fund strategic execution.

# Important future milestones



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# Strategic Roadmap



# Unlocking a USD 3 billion market for ProNephro AKI (NGAL) and the NGAL Test in AKI

## TAM Global USD 3 billion

Worldwide, all big 5 instrumentations,  
all AKI indications



QuidelOrtho™



Adult US USD 1.1 billion

Pediatric US USD 60-80 million

Adult RoW USD 1.7 billion

Pediatric RoW USD 90-120 million



# 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)

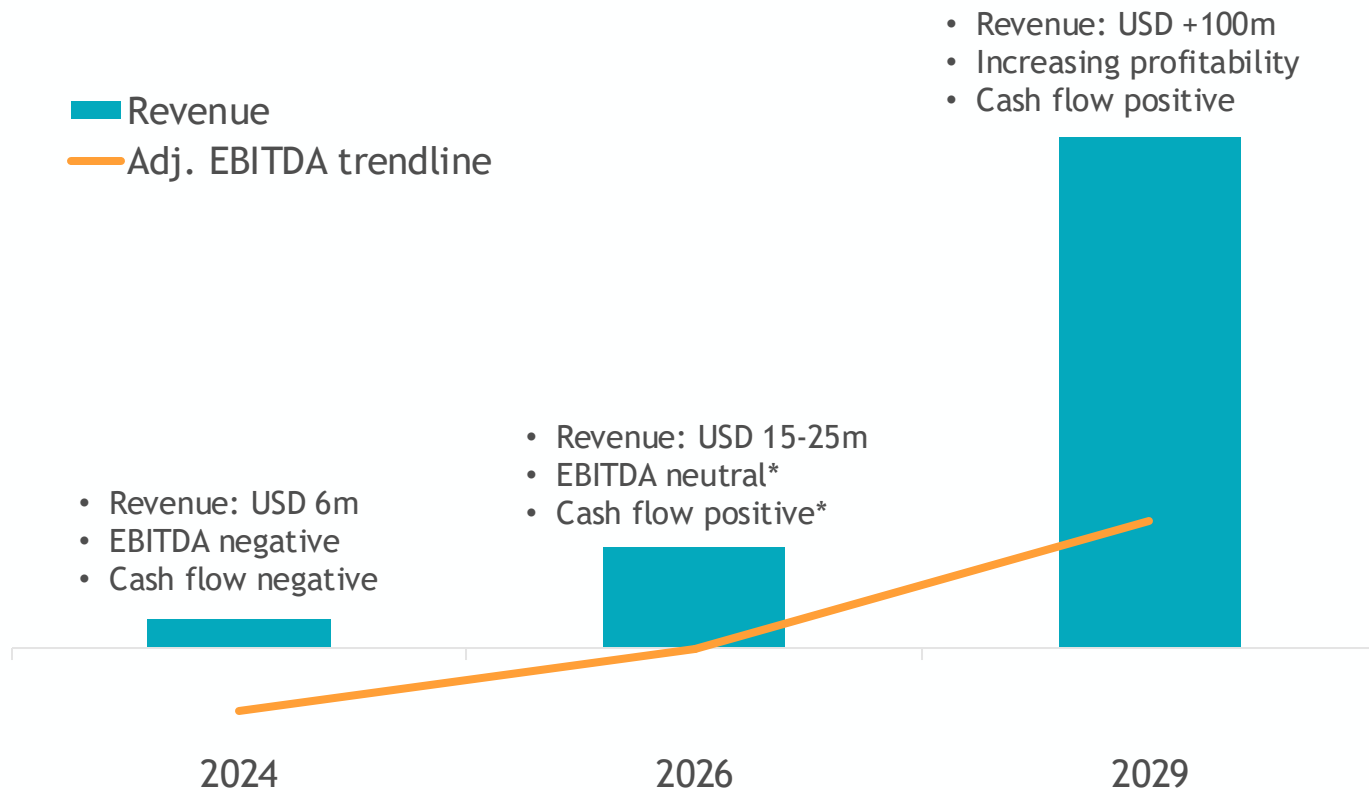
#### Key Objectives:

- 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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# Execution in Q2 2024



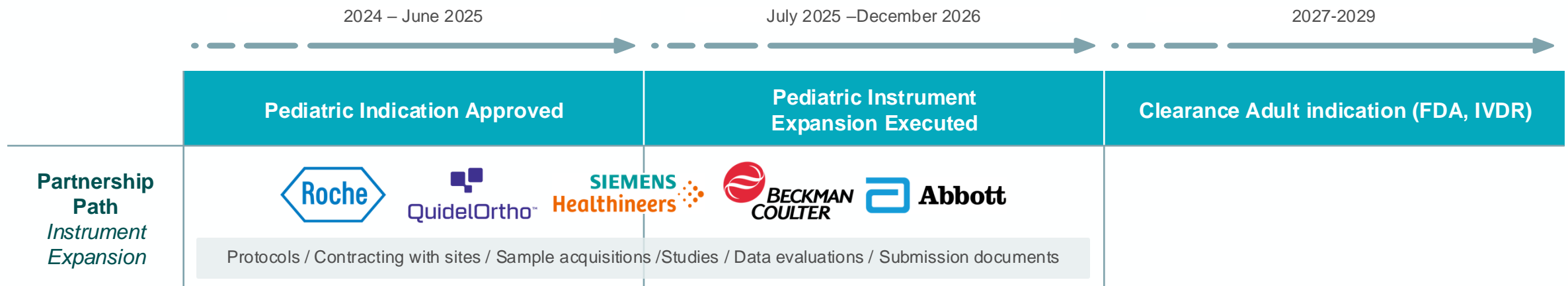
# Preparations for US launch with strong momentum in Q2 2024

- BioPorto expanded its business development and sales staff in US (and Europe) with new hires to build further momentum ahead of expected commercial launch in H2 2024.
- High activity in building knowledge of ProNephro AKI (NGAL) via intensified conference attendance and Grand Rounds with KOLs and MSLs.
- Participation 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.
- Jeff Haas, new US-CEO, responsible for global sales.



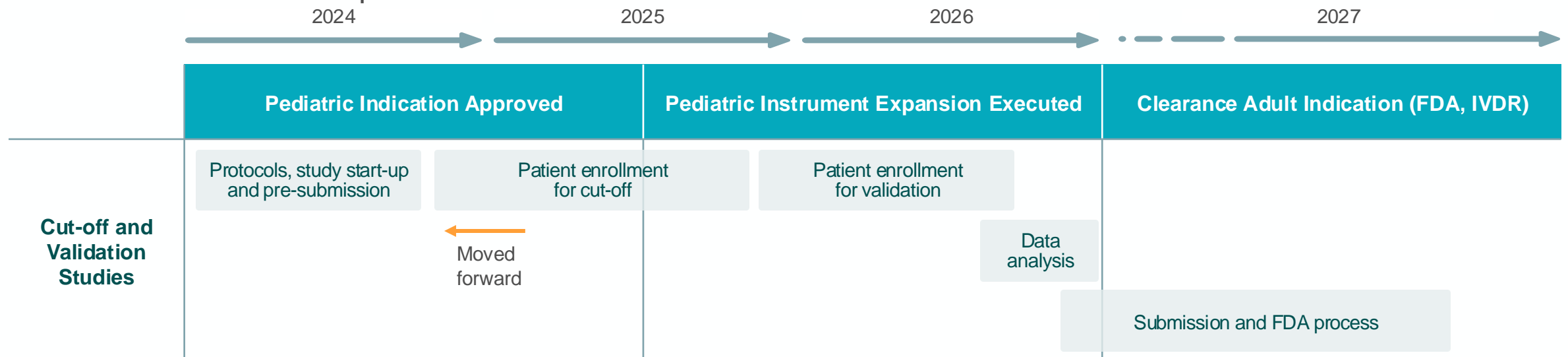
# New distribution and instrument expansion partnerships are in progress

- In February 2024, BioPorto and Roche expanded original global distribution partnership on Roche cobas c 501 to include Roche c 503.
- In Q2 2024, BioPorto has advanced partnership dialogues with other leading instrument manufacturers to enable use of NGAL test on their platforms following technical and clinical requirements.
- First new addition to the partnership portfolio is expected in H2 2024.



# Enrolment of patients for adult ProNephro AKI (NGAL) use expected to commence in Q4 2024

- Leveraging experience from the pediatric FDA clearance, BioPorto has progressed the FDA clearance process for ProNephro AKI (NGAL) forcefully in Q2 2024.
- Draft protocol has been finalized and site engagement has begun. Enrolment of patients for cut-off study is now expected to commence in Q4 2024 rather than early 2025.
- BioPorto is evaluating opportunities to increase number of sites from 12 on the cut-off and validation studies to accelerate process further.



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# Antibody portfolio under review to increase value creation

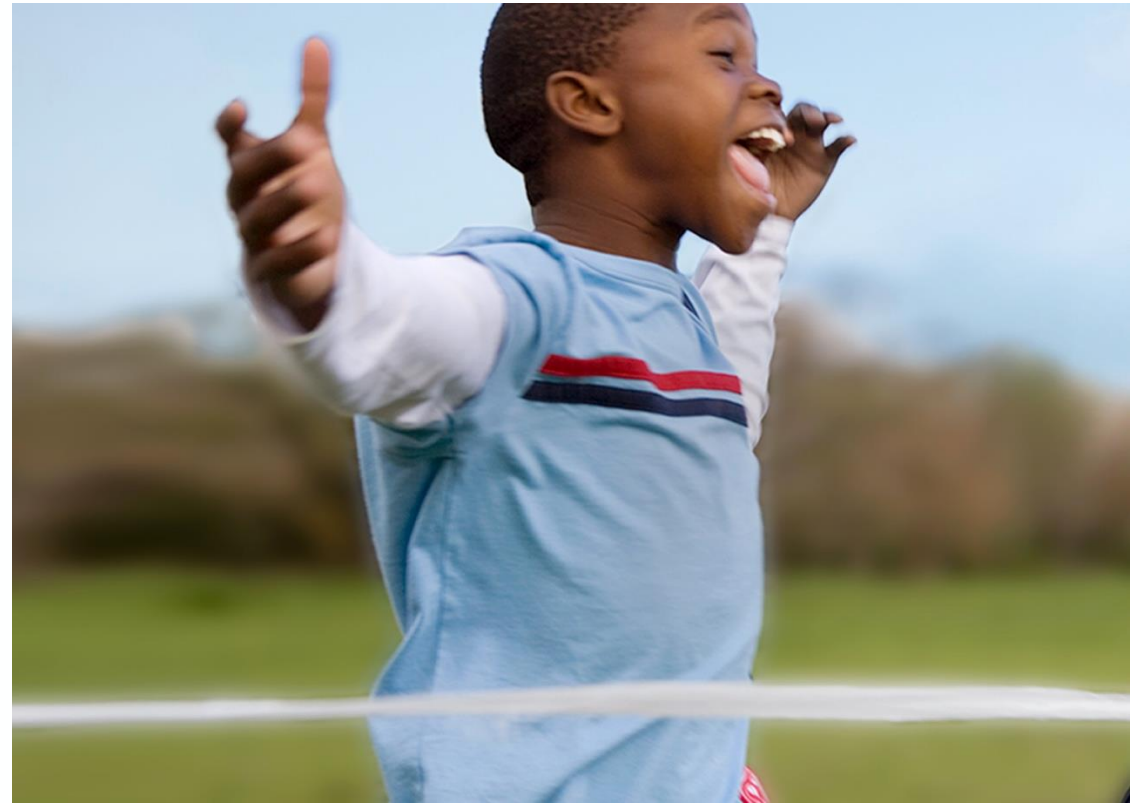
- Revenue from BioPorto's antibody business grew 15% in Q2 2024 compared to the previous year period.
- BioPorto has decided to assess further value creation potential from antibody business by initiating a thorough AI-based data analysis of the more than 1,000 different antibodies in its library.
- Intent is to categorize opportunities for further long-term inhouse development for new diagnostics tests and candidates for divestment to partners – fully or under royalty schemes.
- Results from the analysis are expected to materialize from 2025 onwards.





# Oversubscribed direct share issue at market price with proceeds of USD DKK 81.4 million

- On June 18, BioPorto successfully completed an oversubscribed direct issue of 50 million new shares at market price with gross proceeds of DKK 81.4 million (USD 11.7 million) – the largest in the Company’s history.
- Issue is part of funding strategy to raise a total of USD 20 million by June 2025 to fund operations and complete clinical studies for a ProNephro AKI (NGAL) US adult indication.
- BioPorto will consider several options for the remaining part of the funding under the current strategy to optimize shareholder value and limit future dilution (equity, debt and divestment of non-core, participation in new development partnerships etc.)







# Management team with strong in-vitro diagnostic track-record established



**Peter Mørch Eriksen**  
**Group CEO**

Peter Mørch Eriksen has served as CEO of BioPorto from 2013 – 2021 and has been a part of the Board of Directors since 2021. He has more than 25 years of experience in MedTech/Life Science industries, including as CEO of Sense A/S and VP of Medtronic. Before this, he has held several board positions and served as both CFO and CEO at Brüel & Kjaer A/S, a major Danish company. He also holds a BBA in Economics and Accounting from the Copenhagen Business School (DK).



**Gry Husby Larsen**  
**Group CLO**

Gry Husby Larsen was appointed Chief Legal Officer in April 2024. Prior to joining BioPorto, she was an Attorney-at-law at Knop & Co. Law Firm. She has served as BioPorto's General Counsel since 2011, and from 2019 to 2024 she acted as external General Counsel whilst working as part-time General Counsel for FluoGuide A/S, Algiecel A/S and Unibio A/S. Gry holds a Master of Law from the University of Copenhagen (DK).



**Niels Høy Nielsen**  
**Group CFO**

Niels Høy Nielsen joined BioPorto as Chief Financial Officer in August 2024. He has more than 20 years of leadership experience in finance, operations, M&A and capital markets. From 2022 to 2024, Niels was CFO in ChemoMetec A/S, and before this he served as VP of Finance in ConvaTec, Infusion Care. Prior to this, Niels had a 10-year tenure with LEO Pharma A/S, leading teams in finance, sales and production. Neils holds a MSc. in accounting and finance from Århus Business School (DK).



**Jeffrey Haas**  
**US-CEO**

Joined BioPorto in May 2024, Jeffrey Haas is leading BioPorto's US activities and is responsible for the commercial introduction of ProNephro AKI™ NGAL for pediatric and young adult clinical use. Before joining BioPorto he previously served as President of Rapid Diagnostics Infectious Diseases Developed Markets Business Unit in Abbott Laboratories (US) from 2017. and before then as Vice President of AbbVie (US). Jeffrey holds a BA in Biology from Indiana University, IN (US).

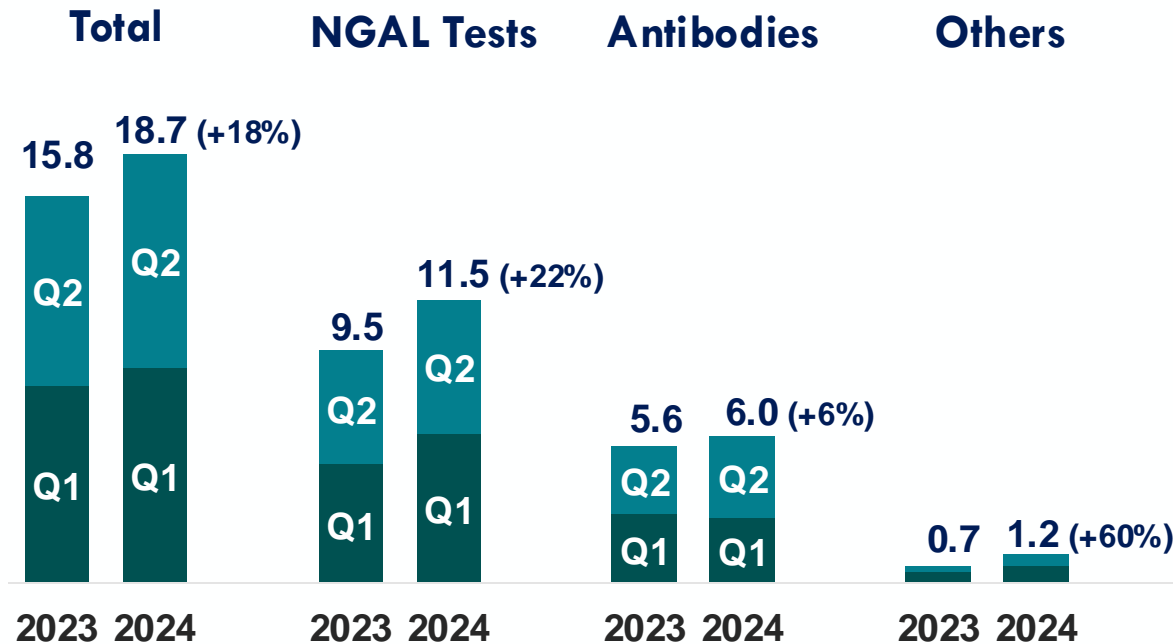
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# Financial results in Q2 2024

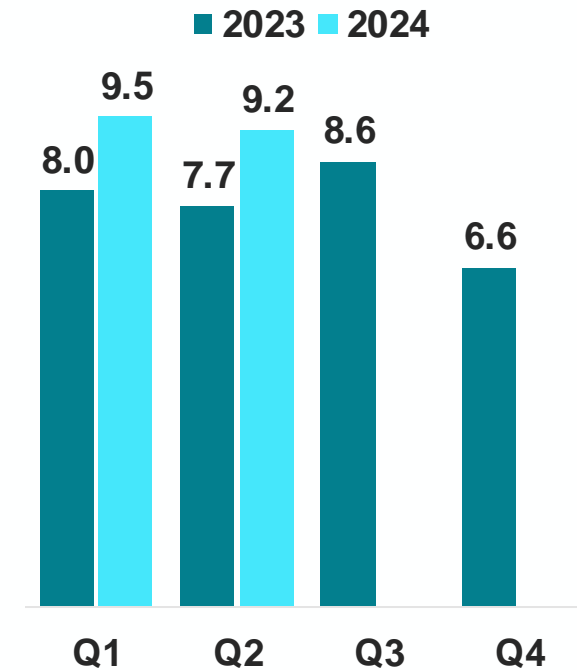


# Total revenues up 18% in H1 2024 – Solid growth in all product groups

## Annual Revenue by Product Group\*



## Revenue by Quarter\*

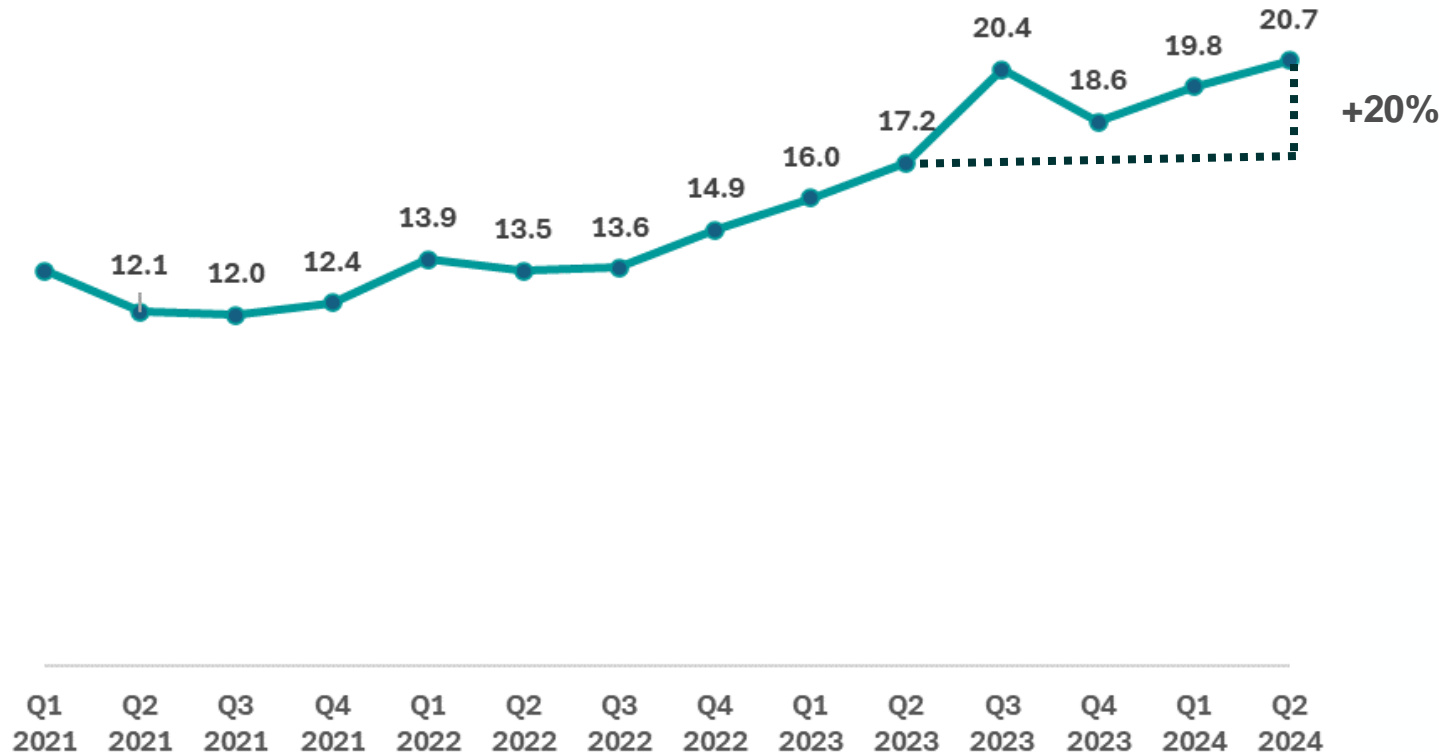


\* All amounts in DKK million



# NGAL sales increasing by 20% in the last twelve months (LTM)

Total NGAL test sales by Quarter (LTM, DKKm)



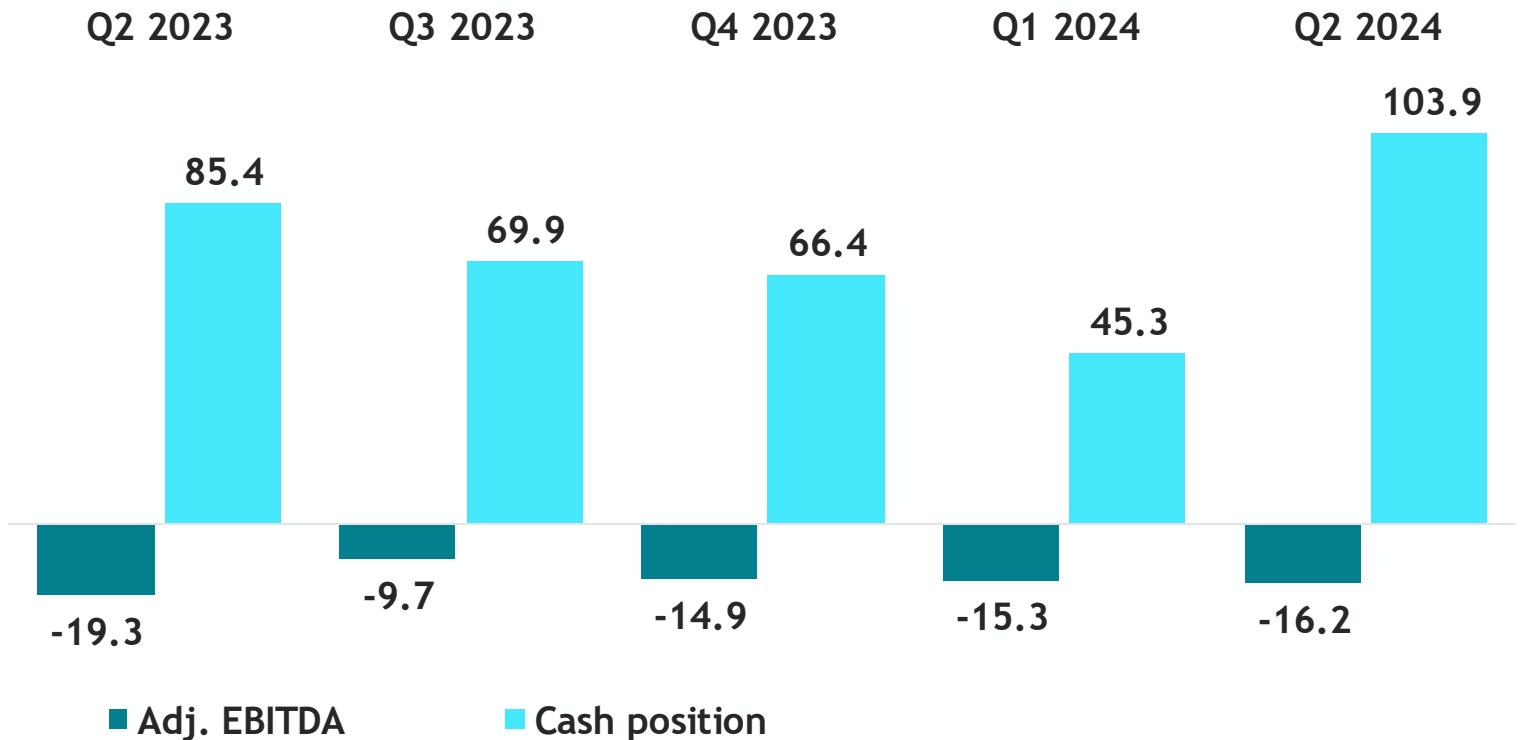
- Continued strong development in US sales of NGAL products (RUO)
- In H1 2024 US NGAL sales makes up 39% of total revenue
- Total NGAL revenues makes up 62% of total revenue
- Focused NGAL Test pipeline build-up



# Adj. EBITDA loss reduced compared to last year due to strict cost control

- EBITDA loss in Q2 2024 reduced by DKK 3 million compared to last year.
- Sales and marketing cost increased due to higher activities and organizational build-up - R&D lower due to restructuring last year.
- Increased marketing spend in US for launch of ProNephro AKI (NGAL) and clinical cost for adult FDA process will increase EBITDA loss in coming quarters.

### Adjusted EBITDA and cash position (DKKm)



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# Financial Outlook for 2024



# 2024 Financial outlook unchanged

## Key revenue drivers for 30% revenue growth

- Increased sales of NGAL products, primarily in the US with halo effect in RoW.
- Roche commercialization in US expected to kick-off late 2024.

## EBITDA drivers

- Increased US marketing spending for ProNephro AKI NGAL in H2 2024.
- Higher cost associated with initiation of clinical studies to support FDA clearance for ProNephro AKI NGAL for adults.

**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 6.87..*

*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.*

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# Compelling fundamental investment case



ProNepro AKI™ (NGAL) is the first FDA-cleared biomarker for pediatric AKI assessment (ages 3 months through 22 years) - a USD +200 million global market



Clear regulatory pathway towards FDA marketing authorization of ProNephro AKI™ NGAL opening up a global market of USD +2.8 billion



Detailed strategy with focus on revenue growth, profitability and business development execution towards 2029



Strong and experienced leadership with a record of successfully launching novel diagnostics



Transparent funding strategy to secure steep growth case with attractive profitability - first step of total USD 20 million funding program taken with USD 11.7 million round in June 2024



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# Q&A

## Financial calendar for 2024

November 14, 2024

Interim Report, Q3 2024

