



Annual Report 2023 BioPorto A/S

Hellerup, April 4, 2024



Forward-Looking Statements

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Highlights from 2023

FDA 510(k) clearance of ProNephro AKI (NGAL) received 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. Global distribution agreement expanded to include Roche c 503 on February 20, 2024.

Dialogue 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).

Peter Mørch Eriksen appointed CEO effective April 2, 2024, and process for hiring CFO and US CEO is progressing.



Result for financial year 2023 on par with preliminary results (February 22, 2024)

TOTAL REVENUE

DKK 31 million

a 7% increase over prior year

ADJUSTED EBITDA

DKK (56) million

CASH POSITION

DKK 66 million



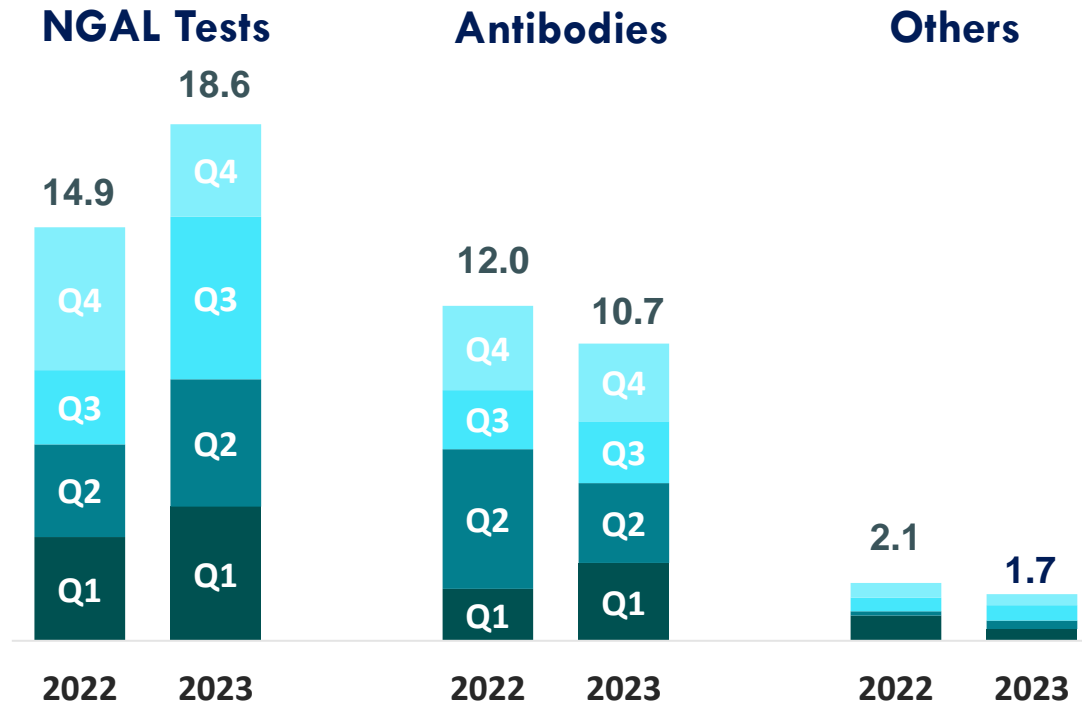
Financial results 2023



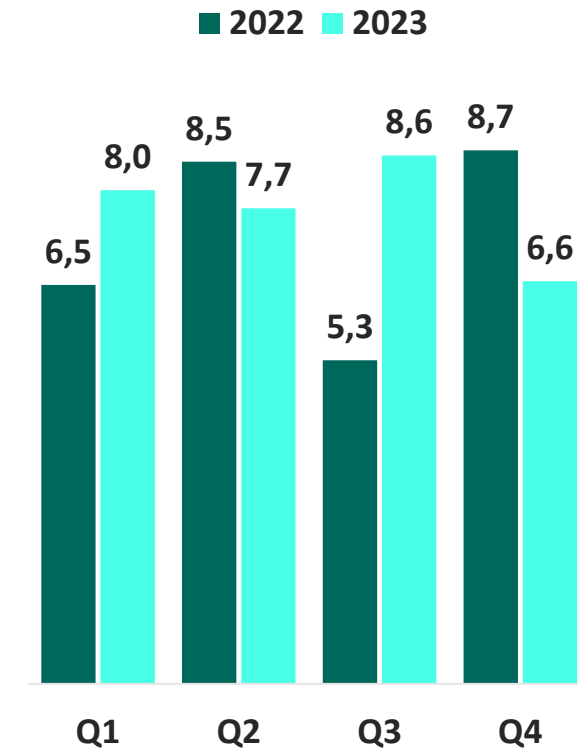


Revenue increased 7% to DKK 31 million in 2023

Annual Revenue by Product Group*



Revenue by Quarter*

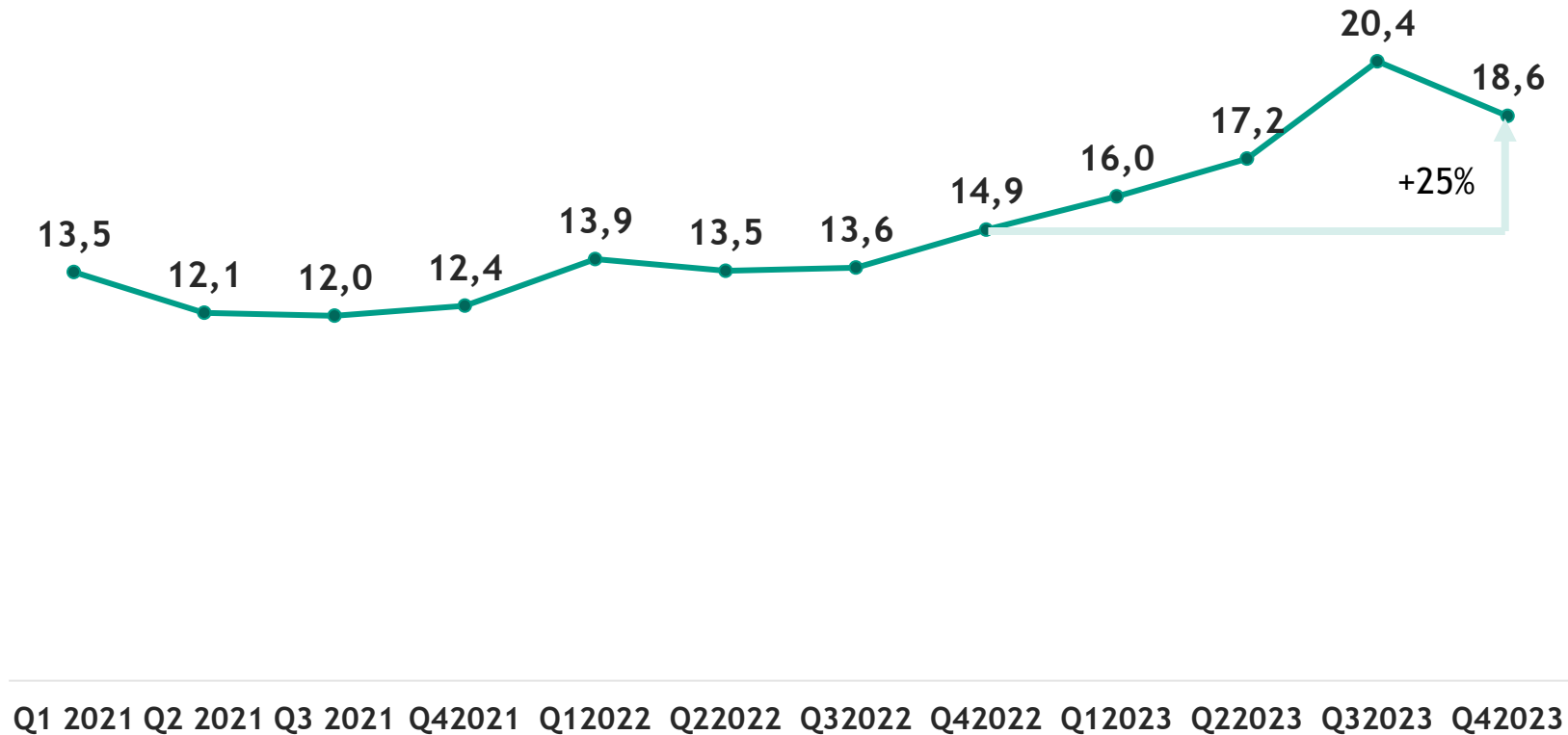


* all amounts in DKKm



NGAL test sales grew 25% in 2023

NGAL test sales by Quarter (LTM, DKKm)

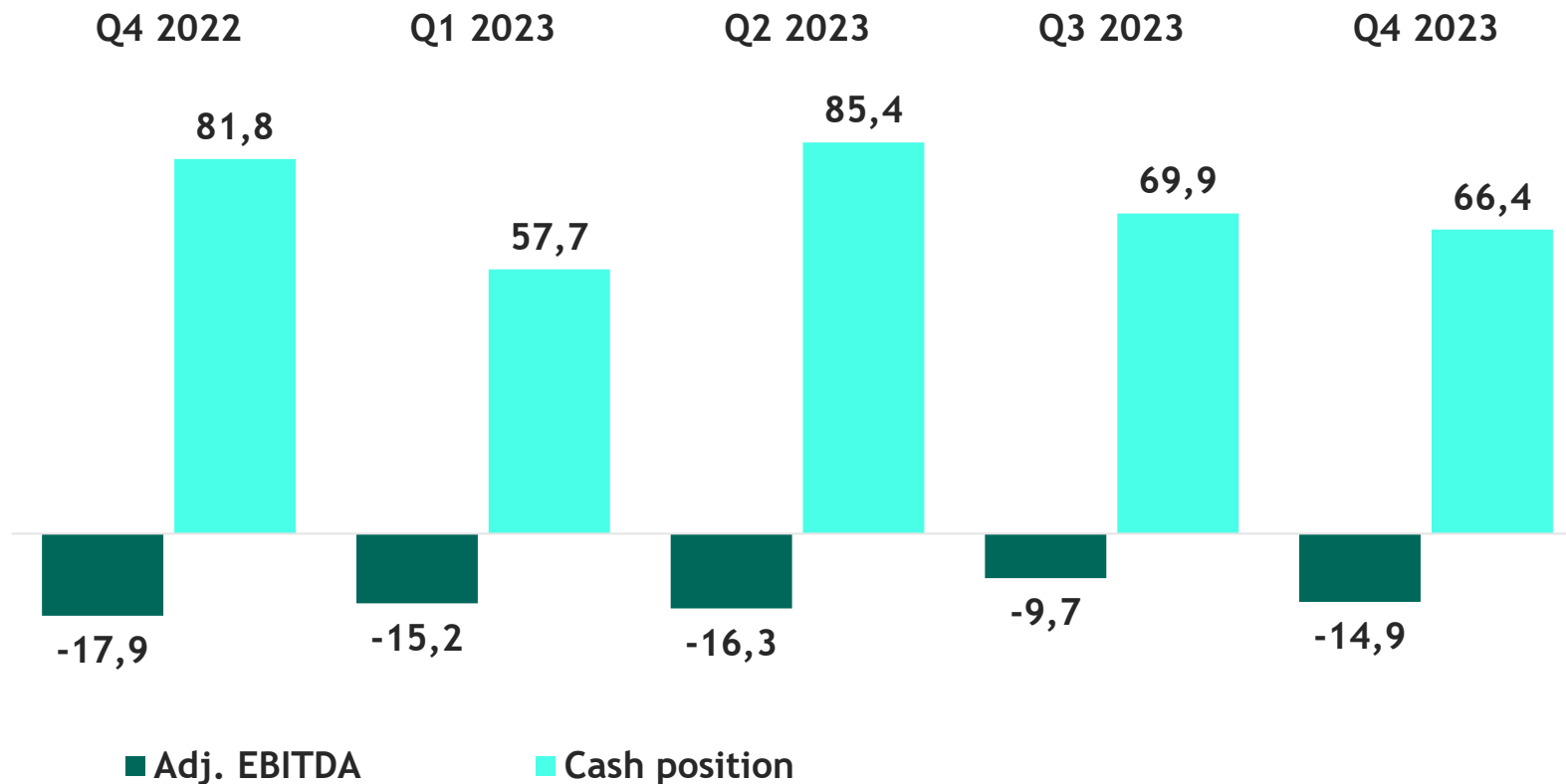


YoY growth in NGAL sales relates to research use only in the US, and general use in Europe, Canada, Israel and South Korea and other markets where the test is CE marked.



Tight cost control preserves solid cash position

Adjusted EBITDA and cash position (DKKm)



- **Adj. EBITDA:**
DKK (56) million in 2023 vs. DKK (67) million in 2022
- **YTD 2023 cash use from operations:**
DKK 62 million, primarily reflecting payment of salary, benefits, costs to achieve FDA clearance and restructuring costs
- **Restructuring charge:**
DKK 3 million to align resources with strategic priorities
- **Cash balance:**
DKK 66 million, including DKK 41 million in net proceeds from pre-emptive rights offering in June 2023.

Strategy follow-up





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 AKI³:

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



Increased Length of Stay
7 – 23 DAYS⁶



Increased need for Dialysis
12% OF CRITICALLY ILL ADULTS⁵



Overall Mortality Rate
21%⁶



**\$7,000
increase
per episode⁷**



**\$5-20
billion
annual cost⁷**






1. Susantitaphong P. CJASN. 2014;9(6)
2. Kaddourah A. N. Engl J Med. 2017

3. Zeng X. CJASN 2014
4. Sutherland SM, CJASN. 2013;8(10)

5. Hoste EA. Intensive Care Med. 2015
6. Mehta RL. Lancet. 2015
7. Silver SA. Nephron. 2017;137



Unlocking a USD 3 billion Market Potential for ProNephro AKI

TAM Global USD 3 billion World wide, all big five instrumentations, all AKI indications     	US	
	Adult	USD 1.1 billion
	Pediatric/Young Adults	USD 60-80 million
	RoW	
Adult	USD 1.7 billion	
Pediatric/Young Adults	USD 90-120 million	

From Diagnostic Innovator to attractive, profitable company with USD +100 million topline in 2029



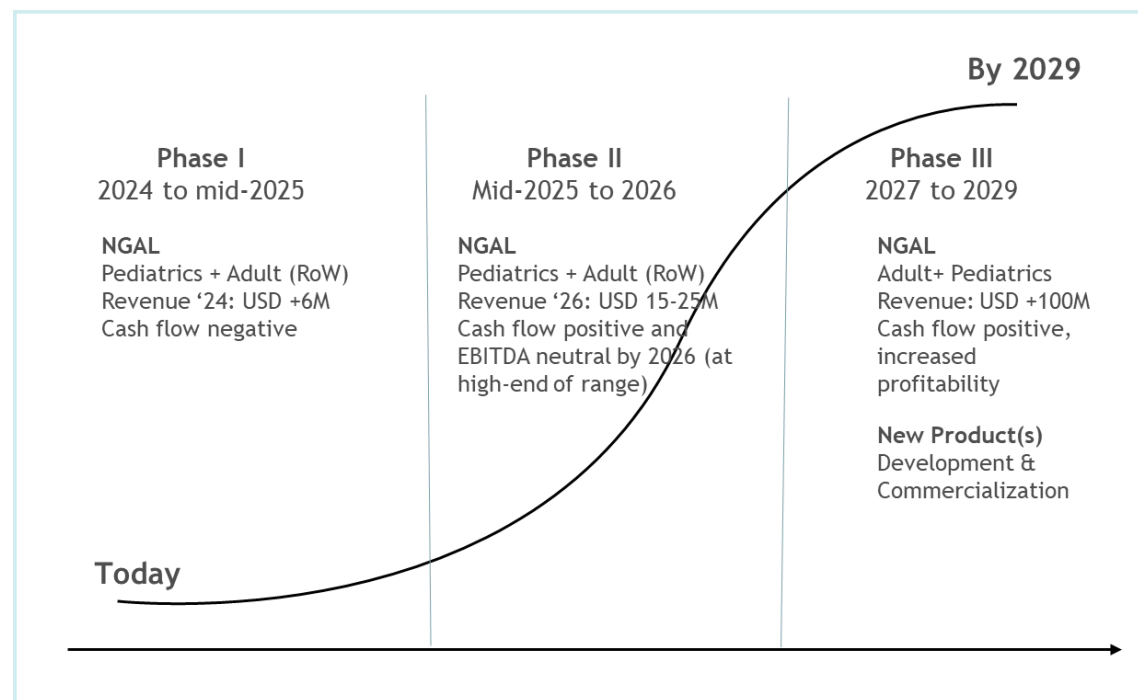
Today

BioPorto is NGAL test Market Maker
-> we need to build authentic demand

NGAL awareness is high, but education on how to use in clinical setting is low

Key to success:

- Performance in pediatric/young adults
- Initiating Adult usage in Europe + US RUO*

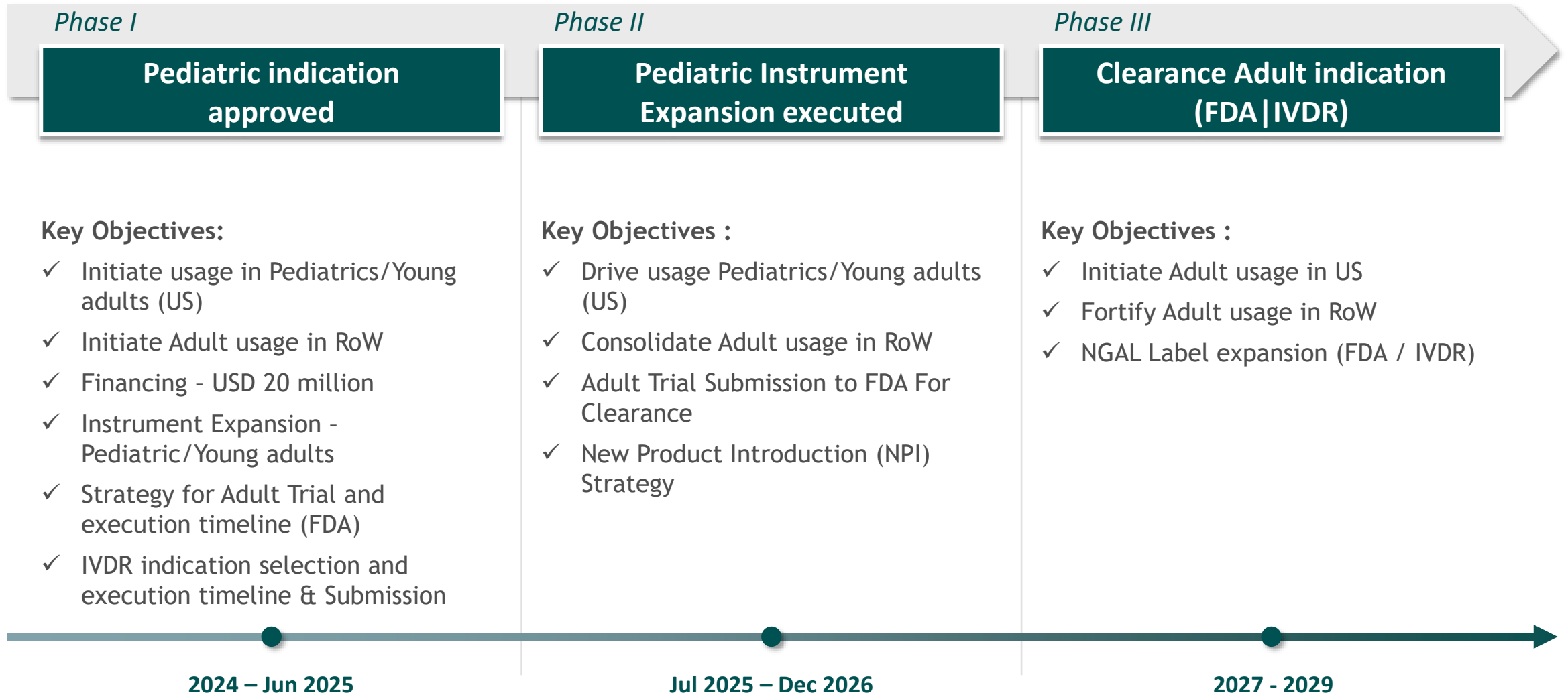


Key initiatives

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



Strategy initiatives and milestones towards 2029





Execution on Phase I strategic targets well under way

Targets for period until mid-2025

Key Objectives :

- Initiate usage in Pediatrics/young adults (US).
- Initiate Adult usage in RoW.
- Financing - Up to 20 MUSD over 2 years
- Instrument Expansion - Pediatrics/Young Adults.
- Strategy for Adult Trial and execution timeline (FDA).
- IVDR indication selection and execution timeline & Submission.

Status by March 2024

Status:

- ✓ Instrument expansion process initiated (US pediatrics/young adults).
- ✓ FDA Protocol for ProNephro AKI for adults drafted.
- ✓ US organisation expanded with new sales staff and MSLs to build commercial momentum for ProNephro AKI.
- ✓ Global cooperation agreement with Roche expanded to include additional analyzers.
- ✓ Continued discussion with KDIGO.
- ✓ New CEO appointed.

Remaining part of 2024

Q2 2024:

- Expand sales of NGAL products and finale preparations for US ProNephro AKI launch with Roche.
- Supplement management team with CFO and US CEO.
- FDA meetings for adult studies.
- Initiate funding process for first tranche.

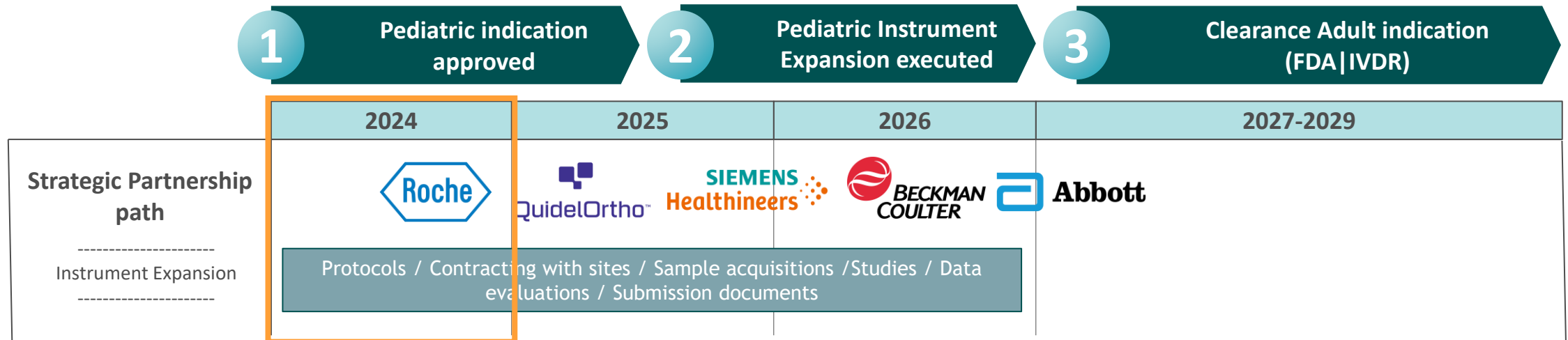
Second half of 2024:

- Commercial launch on Roche cobas c501.
- Instrument expansion with Roche family.
- New instrument partnerships signed.



Instrument Expansion Program on Track - extending Serviceable Obtainable Market for ProNephro AKI

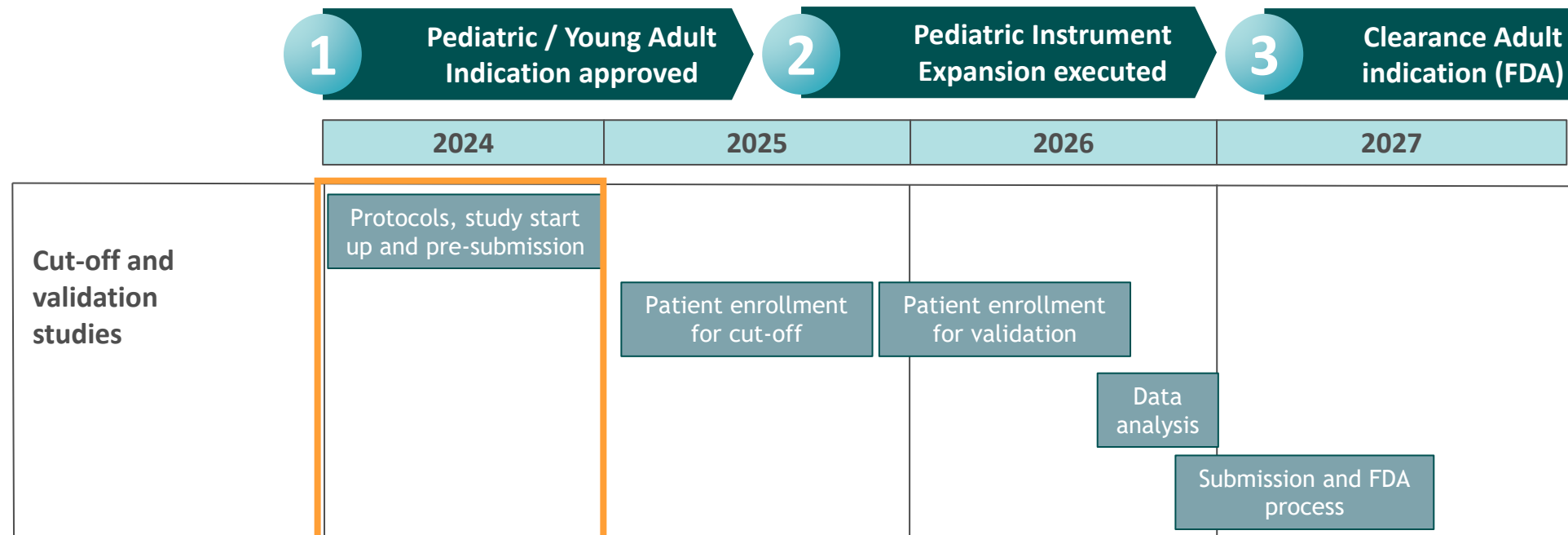
- ProNephro AKI cleared by FDA for marketing on Roche cobas c 501 analyzers in Pediatric and Young Adult indication.
- New global agreement with Roche for cobas c503 in addition to the c501 and c502 analyzers - initiated via a family approach as defined in FDA guidelines which will require limited technical evaluations and studies (CLIA categorization).
- BioPorto has in beginning of 2024 initiated dialogues to extend instrument use to other instrument providers.





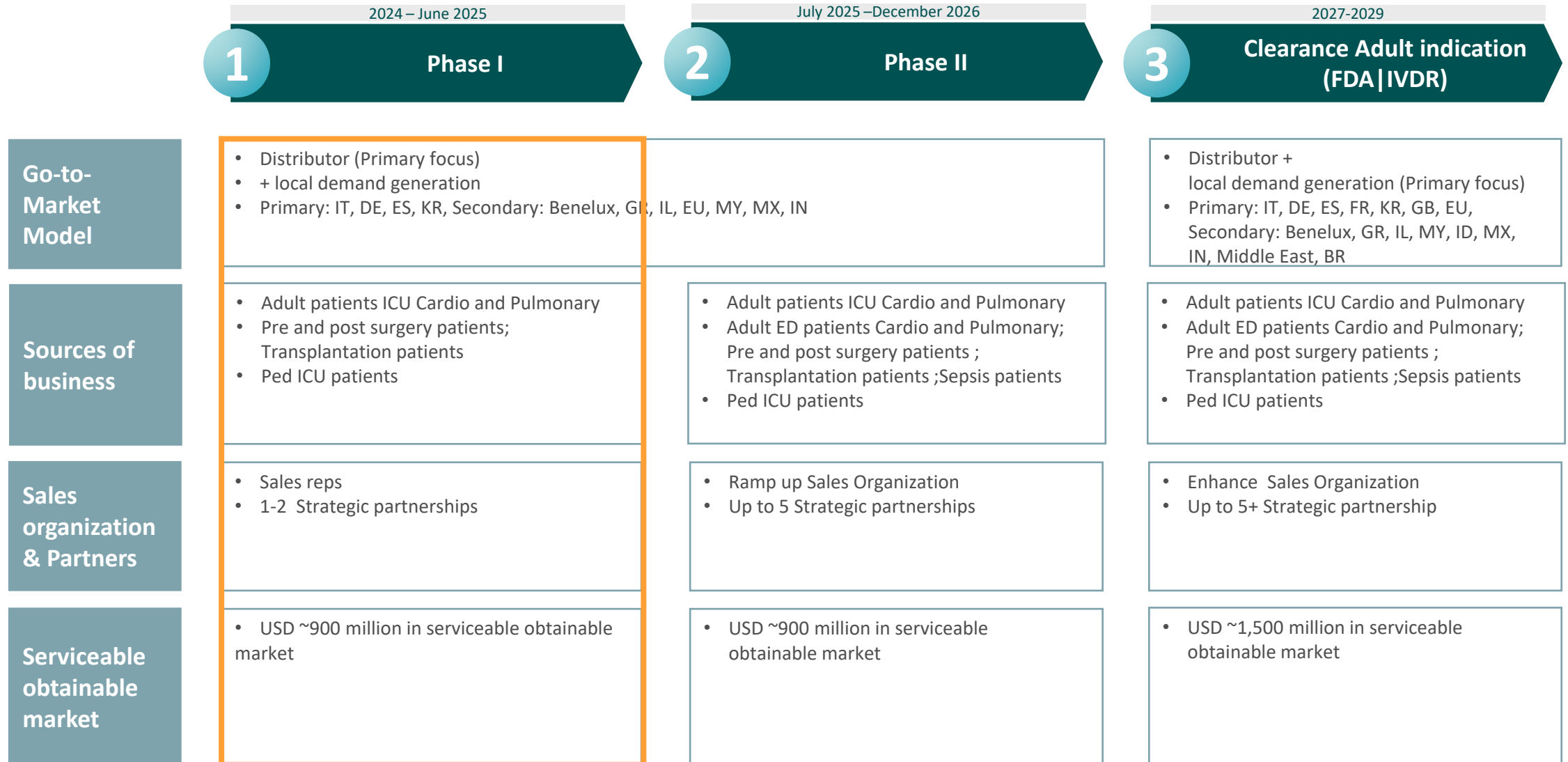
Protocol for Adult ProNephro AKI indication for *General ICU Risk Assessment* drafted - next step is FDA dialog

- Primary Regulatory Target is FDA clearance for General ICU Risk Assessment - similar to pediatric indication.
- Project initiation begun – literature review completed, KOLs and biostatisticians have been engaged protocol draft has been completed in Q1 2024.
- Next step is to engage in further dialogue with FDA and start preparing for enrollment for clinical studies.





FDA clearance is driver for clinicians to consider NGAL's broad clinical Value and increase sales in Rest of the World



BioPorto to raise up to USD 20 Million by 2025 and use proceeds to Unlock the USD 2.8 Billion Adult Market for ProNehpro AKI



- To maximize BioPorto's growth and value creation potential, opportunities to bolster its financial position are being investigated.
- The company anticipates raising up to USD 20 million in new capital in tranches 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 expects to carry out a share issuance in end of Q2 2024.



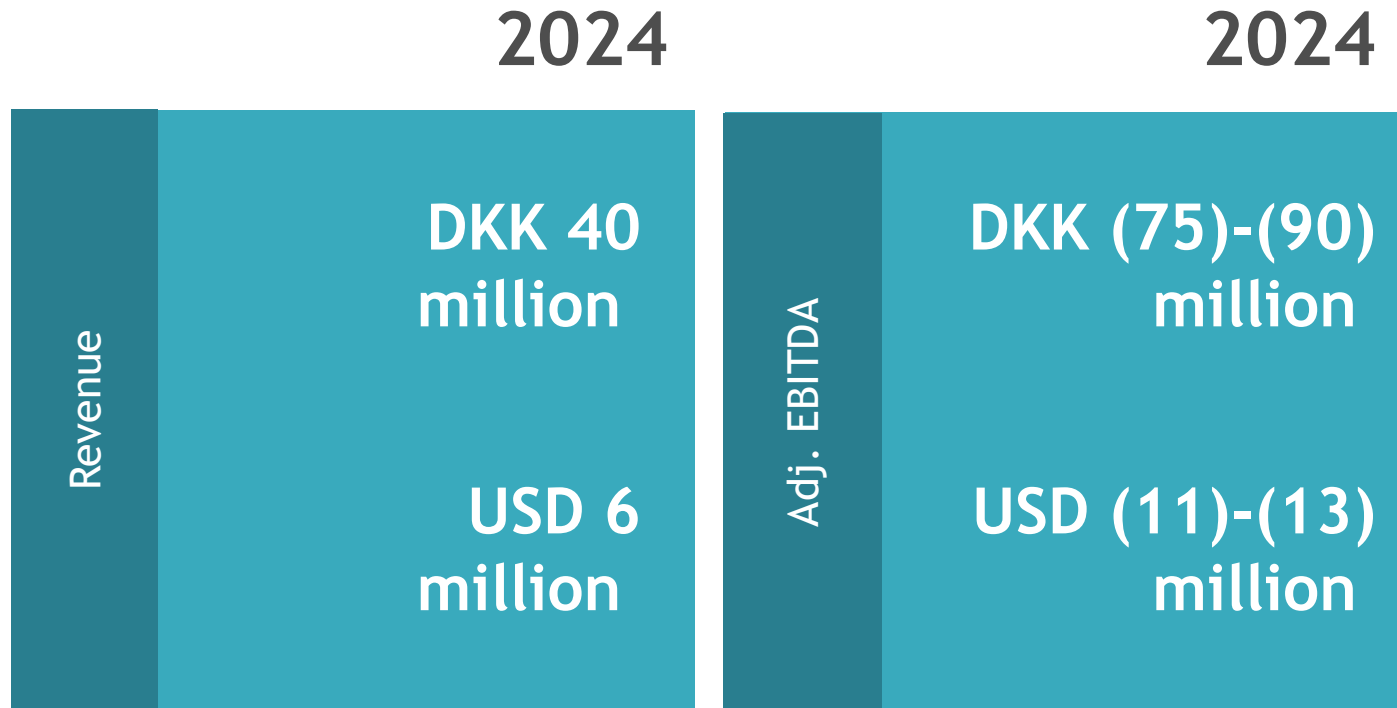
Financial outlook





2024 Financial outlook (unchanged)

Amounts in millions of Danish Kroner and US Dollars¹



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 ProNeophro AKI.
- Cost of clinical process to support FDA clearance for ProNephro AKI for adults.

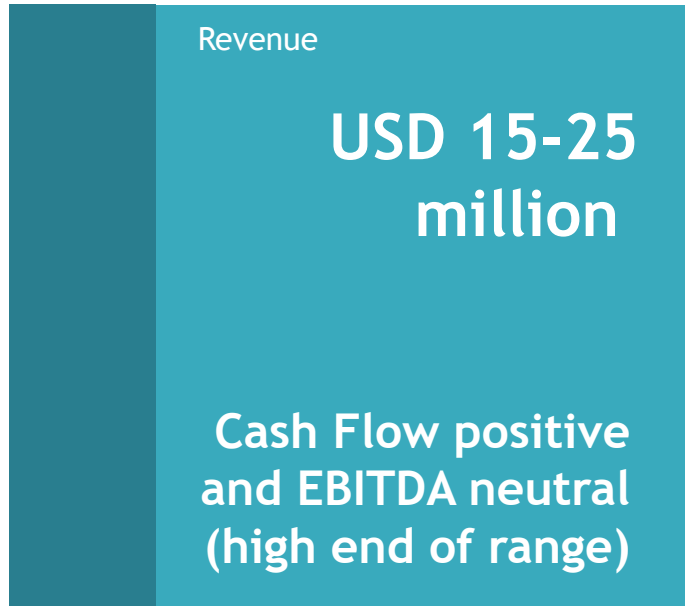
¹All Financial Figures Converted from DKK to USD at a rate of 6.75, except for cash which is converted at rate of 6.7447. ²Audited.

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.



Long term financial ambition (unchanged)

2026



2029



- 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

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Q&A

Financial Calendar

April 30, 2024

May 8, 2024

August 1, 2024

October 30, 2024

Annual General Meeting

Interim report, Q1 2024

Interim report, Q2 2024

Interim report, Q3 2024

