

2023-Q2 Financial Results

& Business Update



**Empowering Early Detection of Kidney Injury** 

## **Forward-Looking Statements**

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## **Q2 2023 Highlights: Meaningful Progress**

- Recorded year-to-date revenue of DKK 15.8 million, 5% above from last year driven by an increase in NGAL sales
- Submitted comprehensive response to US FDA Additional Information Letter for De Novo application of NGAL tests for pediatric patients (aged 3 months – 22 years)
- Closed DKK 43.0 million rights issue (DKK 41.4 million net proceeds) bolstering cash position
- Total cash of DKK 85.4 million as of June 2023
- Maintain 2023 Revenue and Adjusted EBITDA guidance



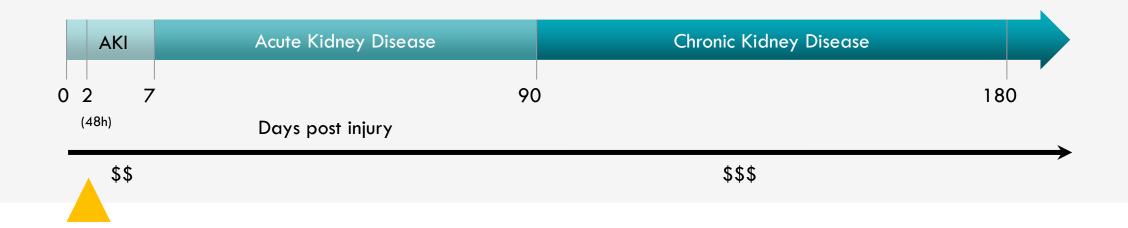




# Acute Kidney Injury (AKI) - an unmet clinical need

- 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.

The NGAL Test™





## **AKI is Common and Costly**



# 1 in 5 ADULTS<sup>1</sup> & 1 in 4 CHILDREN<sup>2</sup>

is affected with AKI during hospitalization

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

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

1. Susantitaphong P. CJASN. 2014;9(6)

2. Kaddourah A. N Engl J Med. 2017







**Increased Length of Stay** 

7 - 23 DAYS<sup>4</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>



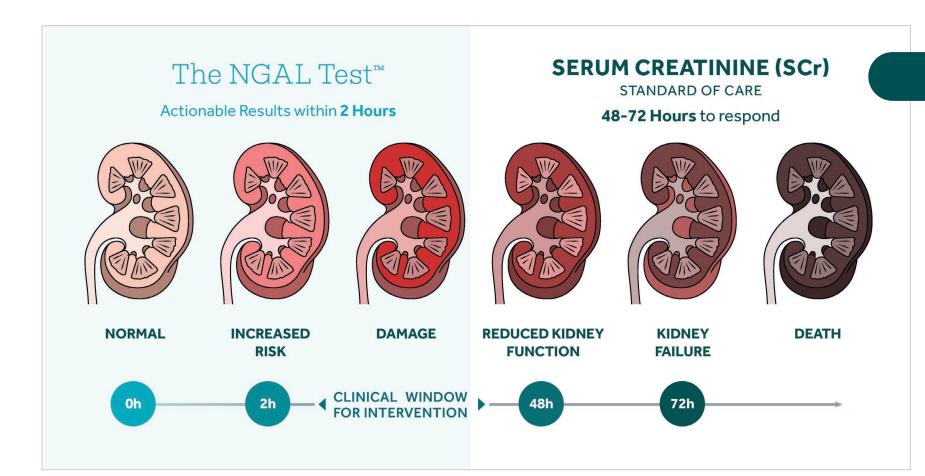
<sup>3.</sup> Zeng X. CJASN 2014

<sup>4.</sup> Sutherland SM, CJASN. 2013;8(10)

<sup>5.</sup> Hoste EA. Intensive Care Med. 2015

<sup>6.</sup> Mehta RL. Lancet. 2015

## **NGAL:** Improving the Standard of Care



### Serum Creatinine is Inadequate

2-3 days delayed

**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>

# Reagent-only product run on standard clinical chemistry instruments





### High-Value Diagnostic price point

No investment in capital equipment

High margins even at today's scale













### **US Market: Initial FDA Clearance for Pediatric Patients**

- Currently, 30+ US hospitals utilize the RUO NGAL test clinically as a Lab Developed Test (LDT)
- Pediatric market has potential for more rapid adoption of new breakthrough products that can save the lives of children
- Achieved Breakthrough Status with the FDA due to the significant unmet need for pediatric patients
- Initial Clearance for testing patients in the Intensive Care Unit: Will then expand to FDA clearance outside of the ICU,
   including the Emergency Department
- This beachhead will demonstrate the life and cost saving value of NGAL that will enable rapid adoption for testing the
   Adult population market following FDA clearance

We will establish a beachhead in the US market focused on testing pediatric patients



#### **US TAM Growth: Broadening Compatibility & Adult Label Expansion** TAM $$1.2B^3$ Addition of 3rd Adult Label **PEDIATRIC ADULT** Indication **United States FDA Label Expansion** with 1st Adult Indication Addition of 2<sup>nd</sup> Adult Label Indication Indication **Expansion Beyond ICU Expansion of** Instrument **Roche** Agnostic Instruments<sup>2</sup> Compatibility **ICU** Approval for \$134M<sup>4</sup> **Single Roche** Approx. 66% of Instrumentation Market Instrument<sup>1</sup>



Time

Approx. 33% of Instrumentation Market

<sup>1.</sup> Roche \*c 501 Instrument

<sup>2.</sup> Following subsequent CLIA filing to expand compatibility with expanded Roche family of Instruments

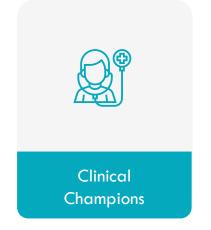
<sup>3.</sup> Combined Emergency Room, Cardiac ByPass Surgery, Cirrhosis, Kidney Transplant, Initiation/Liberation from Dialysis, etc.

## **Kickstarting European Sales with CE-marked product**

### Multi-pronged sales approach:

- Select and train qualified distributor partners on clinical sales
- Provide expert Medical Affairs support
- Engage in Direct Marketing
- Leverage KOLs experienced in NGAL testing



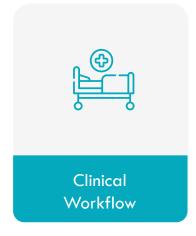












No additional registration requirements to access adult and pediatric markets



## Drive European Sales, Gain FDA Approval, Reduce Costs



# Drive Market Adoption & Pipeline Development



# Strengthen to Scale & Execute



# Attract, Develop & Retain the Best Employees

- Support FDA approval of NGAL test for Pediatrics
- Expand market opportunity in US by performing studies to expand instrument and clinical indications
- Drive NGAL sales in Europe and where CE mark is accepted

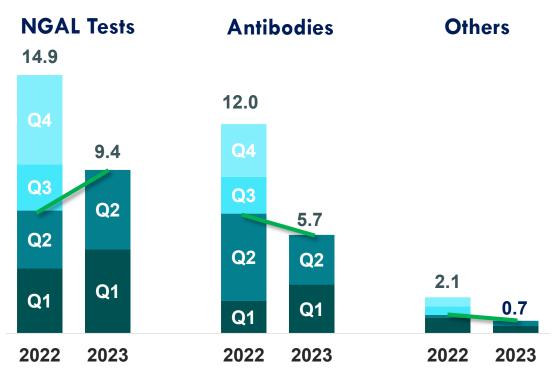
- Execute appropriate financing rounds
- Drive high-margin antibody sales to offset future capital requirements
- Suspend new biomarker development activities
- Ensure systems and backup data files are FDA audit-ready

- Proactively recruit the most qualified talent to drive success
- Motivate and incentivize employees to stay & build shareholder value



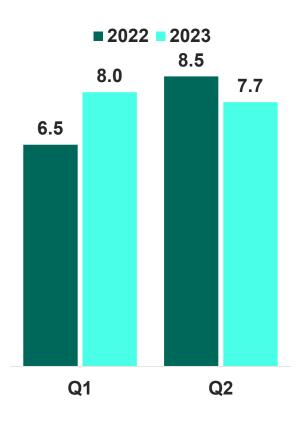
## Revenue: DKKm 15.8, up 5% YTD over prior year

### Annual Revenue by Product Group\*



#### \* all amounts in DKKm

## Revenue by Quarter\*

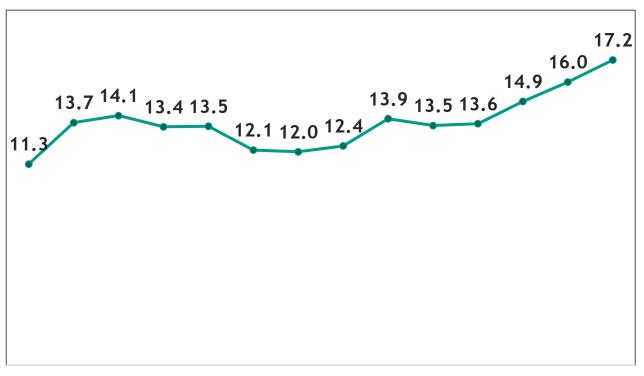




## NGAL test sales up 27% on LTM basis



### NGAL test sales by Quarter (LTM, DKKm)

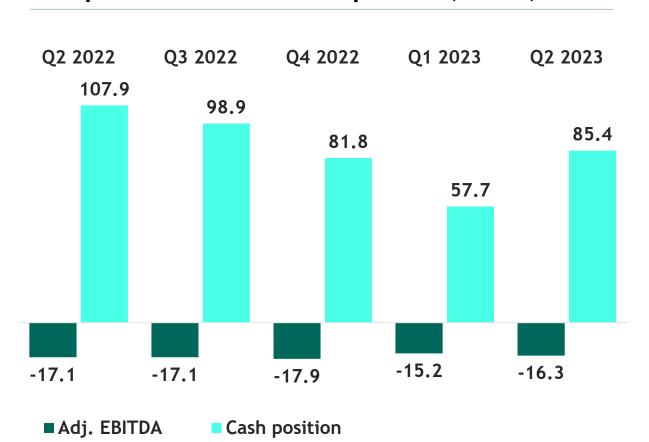


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## Cash position and working capital management

### Adjusted EBITDA and cash position (DKKm)

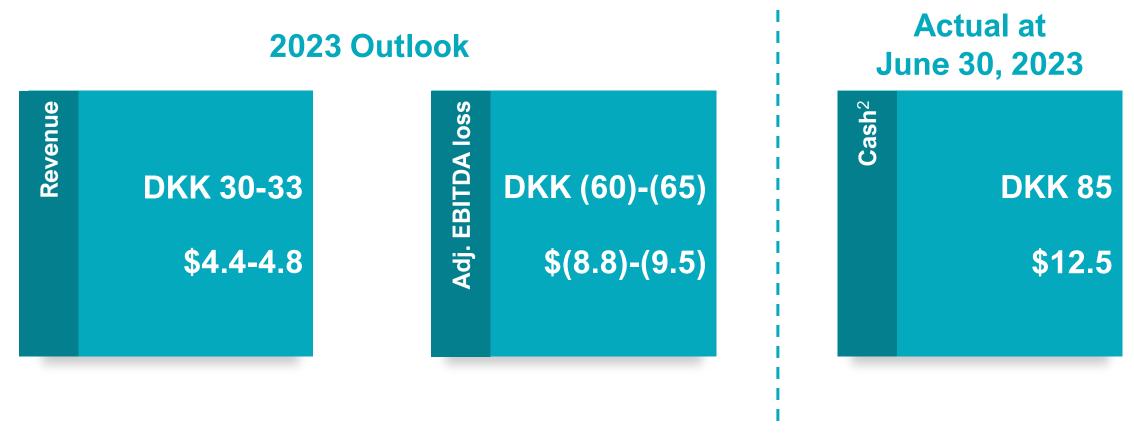


- YTD 2023 cash use from operations:
   DKKm 39.3, primarily reflecting payment of clinical trial and restructuring costs
- Restructuring charge: DKKm 3.0 to better align resources with BioPorto's strategic priorities
- Cash balance: DKKm 85.4
   Includes DKKm 41.4 million net proceeds from pre-emptive rights offering



### **2023 Reiterated Outlook**

#### Amounts in millions of Danish Kroner and US Dollars<sup>1</sup>



<sup>&</sup>lt;sup>1</sup>All Financial Figures Converted from DKK to USD at a rate of 6.8539 as of June 30, 2023. <sup>2</sup>Unaudited.

Note: BioPorto's performance and guidance for 2023 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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