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# Empowering Early Detection of Kidney Injury

## 2022-Q2 Earnings Call


August 17, 2022

# Forward-Looking Statements

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# Highlights from Q2 2022

- Strong financial performance – revenue up 29% YoY in Q2 and 23% YoY in 1H 2022
- Targeted enrollment of patients for US FDA application of The NGAL Test achieved
- Appointment of Dr. Devarajan as new Senior Medical Director


 

# We save lives and improve quality of life with actionable biomarkers

## *In 2022-2023 we will Launch an FDA Cleared Product in the US*

Drive Market Adoption of the NGAL Test & have a Pipeline of Products that Deliver High Medical Value

Strengthen the Company to Scale & Execute

Attract, Develop & Retain the Best and Brightest Employees aligned with our Values and with Clear Roles and Responsibilities

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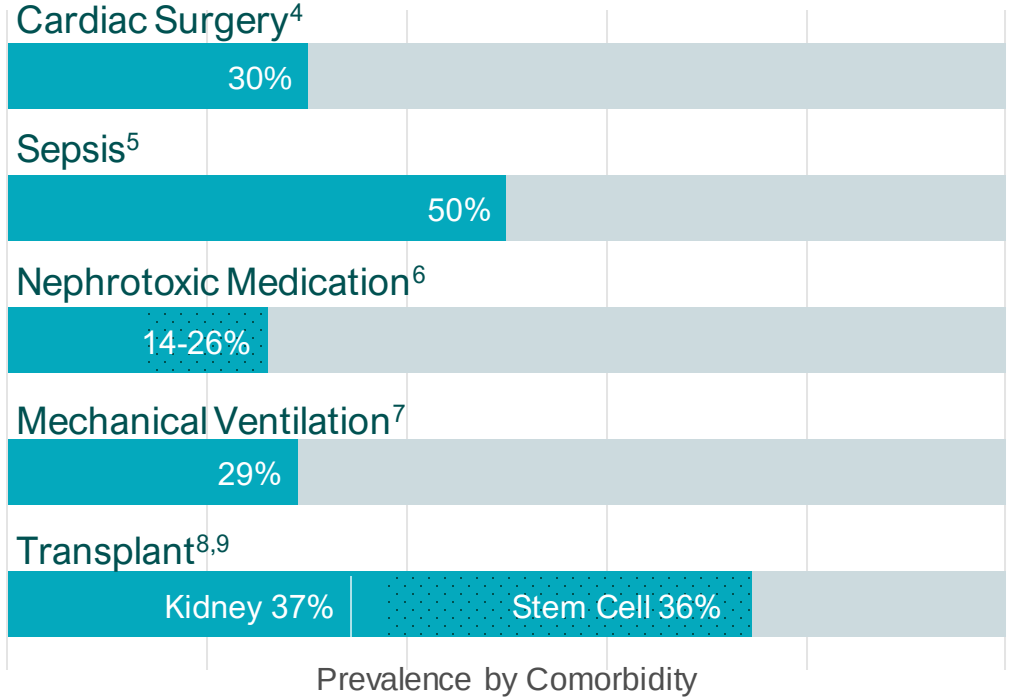
# AKI represents a $24B burden on US healthcare[1]

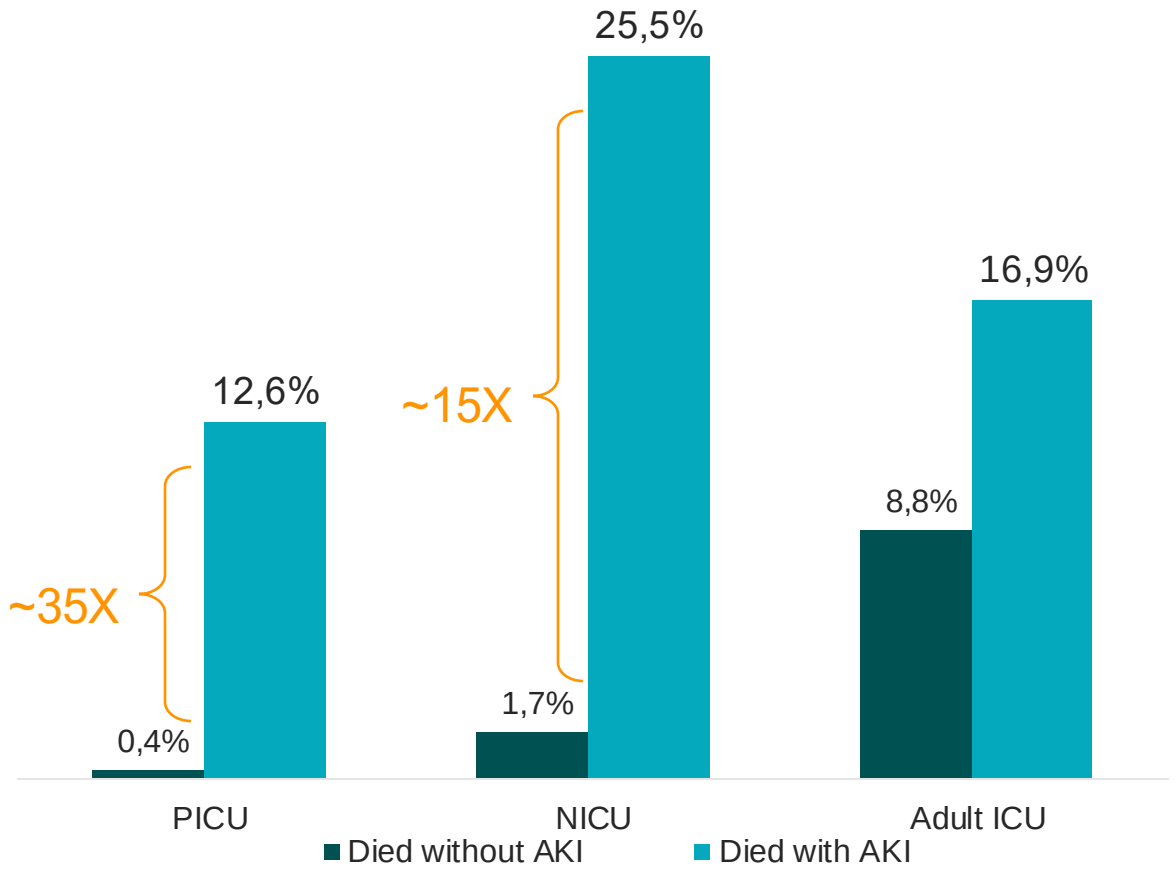
## Highly Prevalent & Costs up to $27,300/patient[1]

**1 in 5 ADULTS**[2]
**& 1 in 4 CHILDREN**[3]
Is affected with AKI
during hospitalization




Prevalence by Comorbidity

### AKI Correlates with Higher Mortality[10]




[1]Silver SA, Chertow GM. Nephron. 2017. [2]Susantitaphong P, Clin J Am Soc Nephrol. 2014. [3]Kaddourah A, et al, N Engl J Med. 2017. [4]O'Neal JB, Crit Care. 2016 [5] Alobaidi R, Semin Nephrol. 2015. [6]Perazella MA, Clin J Am Soc Nephrol. 2018. [7]Lombardi R, Clin J Am Soc Nephrol. 2011. [8]Alkandari O, CJASN. 2018. [9]Hingorani SR, Kidney Int. 2005. [10]MD SID 2019.

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# Current method, Serum Creatinine (sCr), is delayed and non-specific

In a multicenter prospective study of over 500 biopsy-diagnosed cases of moderate to severe AKI, sCr only properly identified 26% of patients[1]

## Delayed and Dampened

- Does not rise until 48-72 hours after acute injury
- >50% of kidney function can be lost, without changes in sCr

## Non-specific for AKI

- Can't differentiate structural injury from volume-responsive AKI[1]
- Diluted by fluid overload, delaying AKI identification

## Confounded by Other Factors

- Muscle mass
- Nutritional status
- Age & gender

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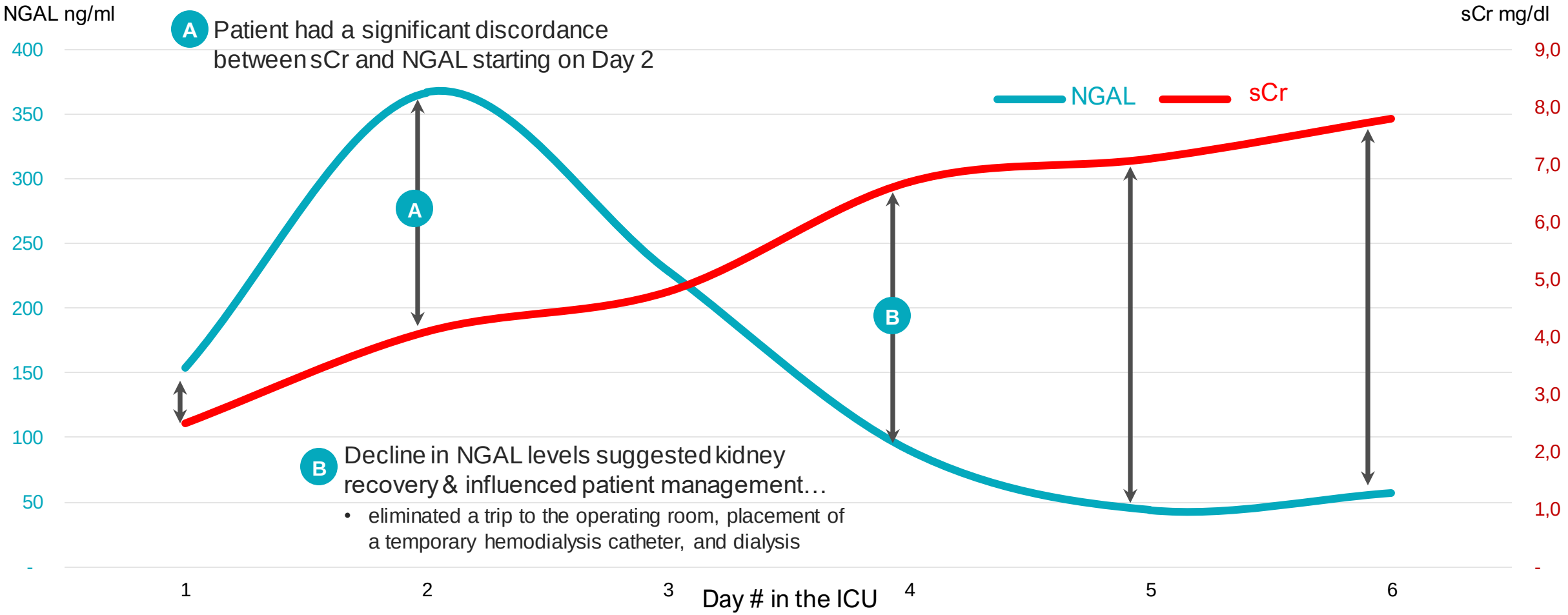
[1]Moledina DG, Hall IE, Thiessen-Philbrook H, et al. Performance of Serum Creatinine and Kidney Injury Biomarkers for Diagnosing Histologic Acute Tubular Injury. Am J Kidney Dis. 2017;70(6):807-816.

# Benefit of The NGAL Test's NPV – Case Study: Avoiding Dialysis

## NGAL closely follows AKI progression vs. sCr lags, is slow, and is non-specific




Negative Predictive Value (NPV) - The likelihood that an individual with a negative test result does NOT have the particular disease or condition

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Source: Varnell CD Jr, Goldstein SL, Devarajan P, Basu RK. Impact of Near Real-Time Urine Neutrophil Gelatinase-Associated Lipocalin Assessment on Clinical Practice. Kidney International Reports. 2017;2(6):1243-1249.

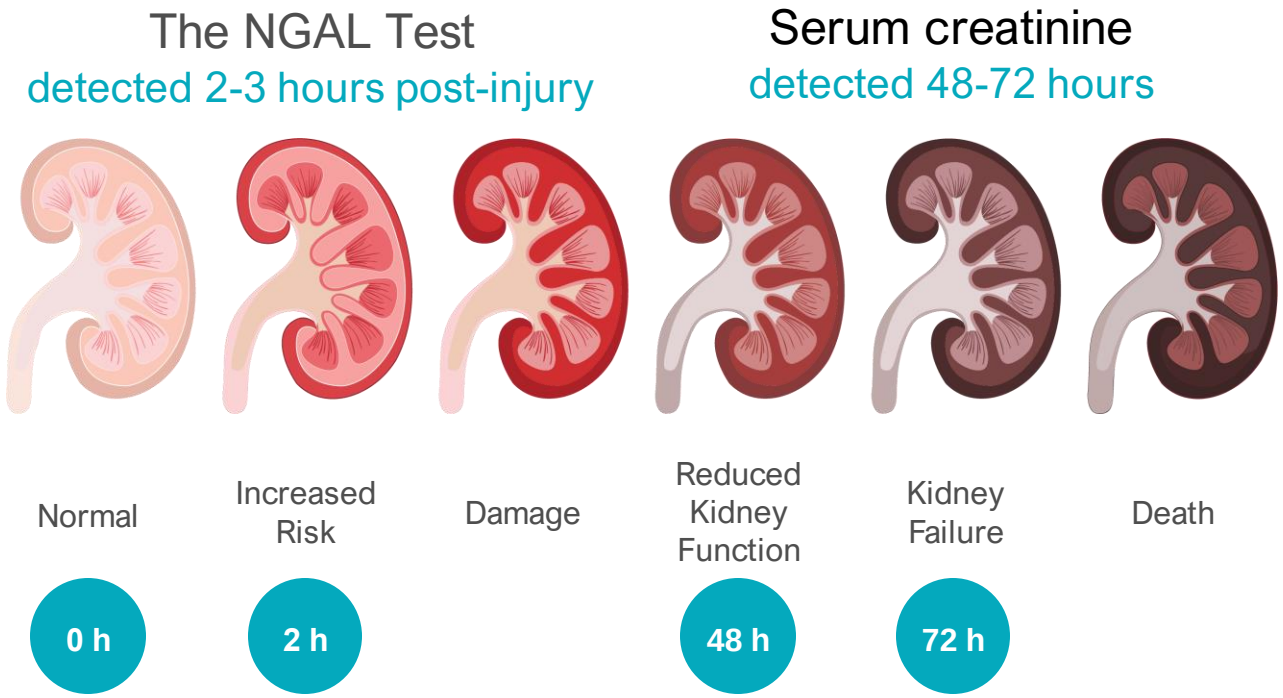
 

# NGAL results guides preventative and restorative care pathways

## Near real time information can make the difference

The NGAL Test can make the difference in informing:

- Nephrotoxic medications or dosing adjustments
- Fluid management
- The need to start or stop renal replacement therapy
- Adjustments to radiocontrast procedures and/or agents

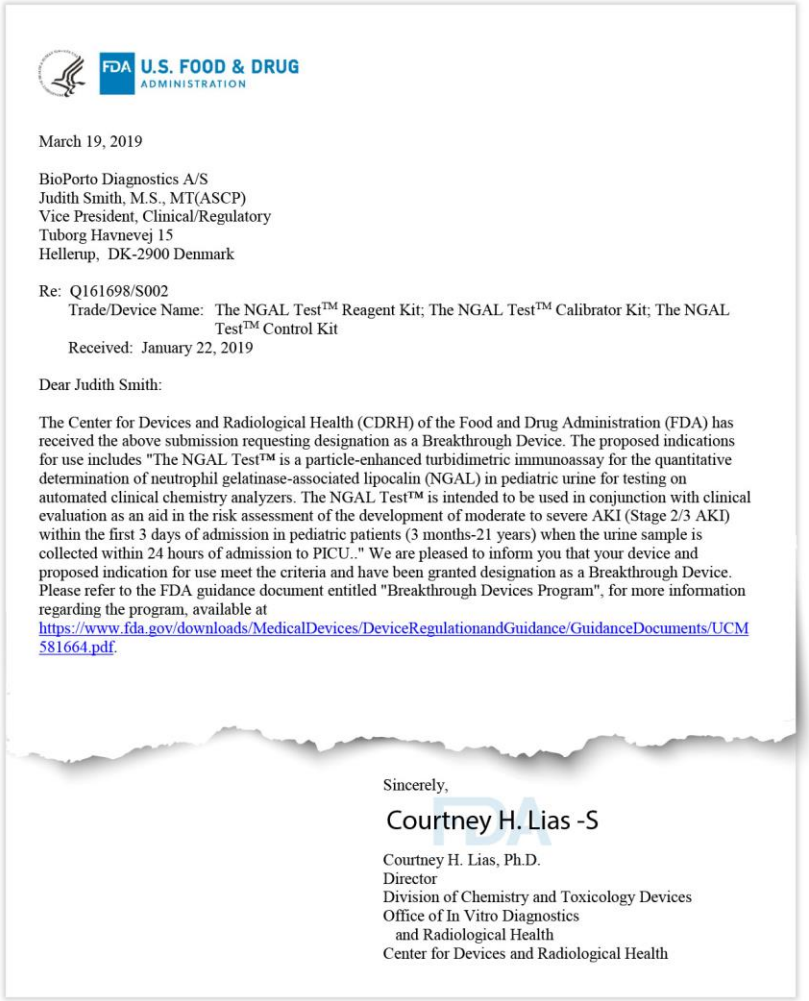




# FDA Granted "Breakthrough Device Designation"

## The Breakthrough Devices Program provides prioritized FDA review



FDA U.S. FOOD & DRUG ADMINISTRATION

March 19, 2019

BioPorto Diagnostics A/S
Judith Smith, M.S., MT(ASCP)
Vice President, Clinical/Regulatory
Tuborg Havnevej 15
Hellerup, DK-2900 Denmark

Re: Q161698/S002
Trade/Device Name: The NGAL Test™ Reagent Kit; The NGAL Test™ Calibrator Kit; The NGAL Test™ Control Kit
Received: January 22, 2019

Dear Judith Smith:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received the above submission requesting designation as a Breakthrough Device. The proposed indications for use includes "The NGAL Test™ is a particle-enhanced turbidimetric immunoassay for the quantitative determination of neutrophil gelatinase-associated lipocalin (NGAL) in pediatric urine for testing on automated clinical chemistry analyzers. The NGAL Test™ is intended to be used in conjunction with clinical evaluation as an aid in the risk assessment of the development of moderate to severe AKI (Stage 2/3 AKI) within the first 3 days of admission in pediatric patients (3 months-21 years) when the urine sample is collected within 24 hours of admission to PICU.." We are pleased to inform you that your device and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device. Please refer to the FDA guidance document entitled "Breakthrough Devices Program", for more information regarding the program, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Eligibility Criteria[1]:

- "provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions"
- Satisfies one of the following:
  a) "Represents Breakthrough Technology"
  b) "No Approved or Cleared Alternatives Exist" (Novelty)
  c) "Offers Significant Advantages over Existing Approved or Cleared Alternatives" (Superiority)
  d) "Device Availability is in the Best Interest of Patients" (Utility)
- The NGAL Test meets at least three of these criteria

[1]US Food & Drug Association: Breakthrough Devices Program (https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s2)

# On track for a 2022 FDA De Novo submission

Complete last clinical study enrollment → Data analysis → FDA submission → Commercial Preparedness Execution → FDA Approval of NGAL in ICU for up to age 22[1] → US Launch


**Next steps after FDA submission – Focused on Age 22+:**

- Conduct Scientific Advisory Board to prioritize & select indications and claims
- Develop & execute clinical and analytical test plan to support submission
- Likely 510(k) to establish equivalency to our existing test
- Typically faster and lower cost than De Novo

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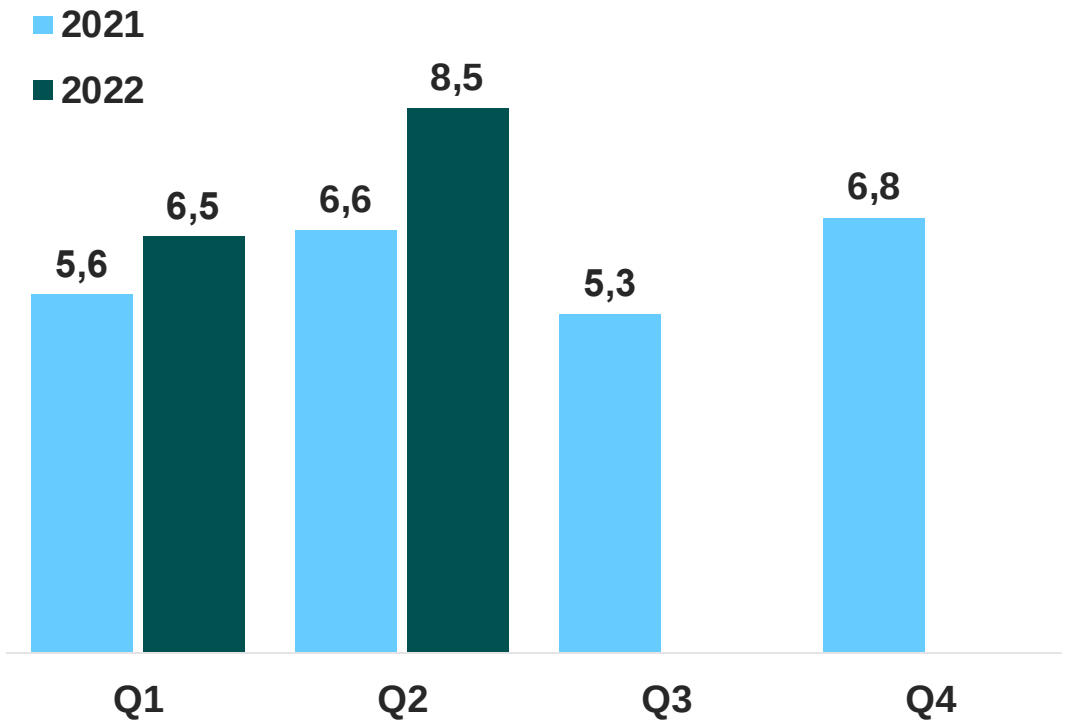
[1]Indication is above 3 months and below 22 years

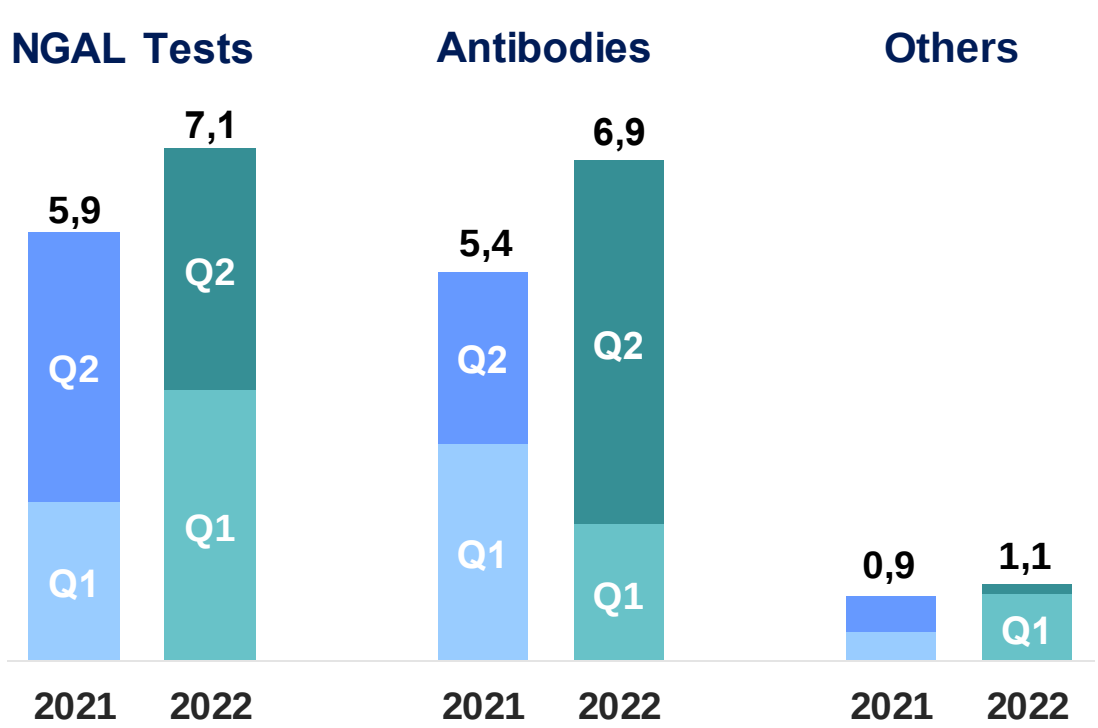
 

# BioPorto grew revenue by 29% in Second Quarter 2022

## Revenue by Quarter




## YTD Revenue by Product Group




amounts in DKKm



# Continued growth in The NGAL Test sales

US NGAL

↑ 31%

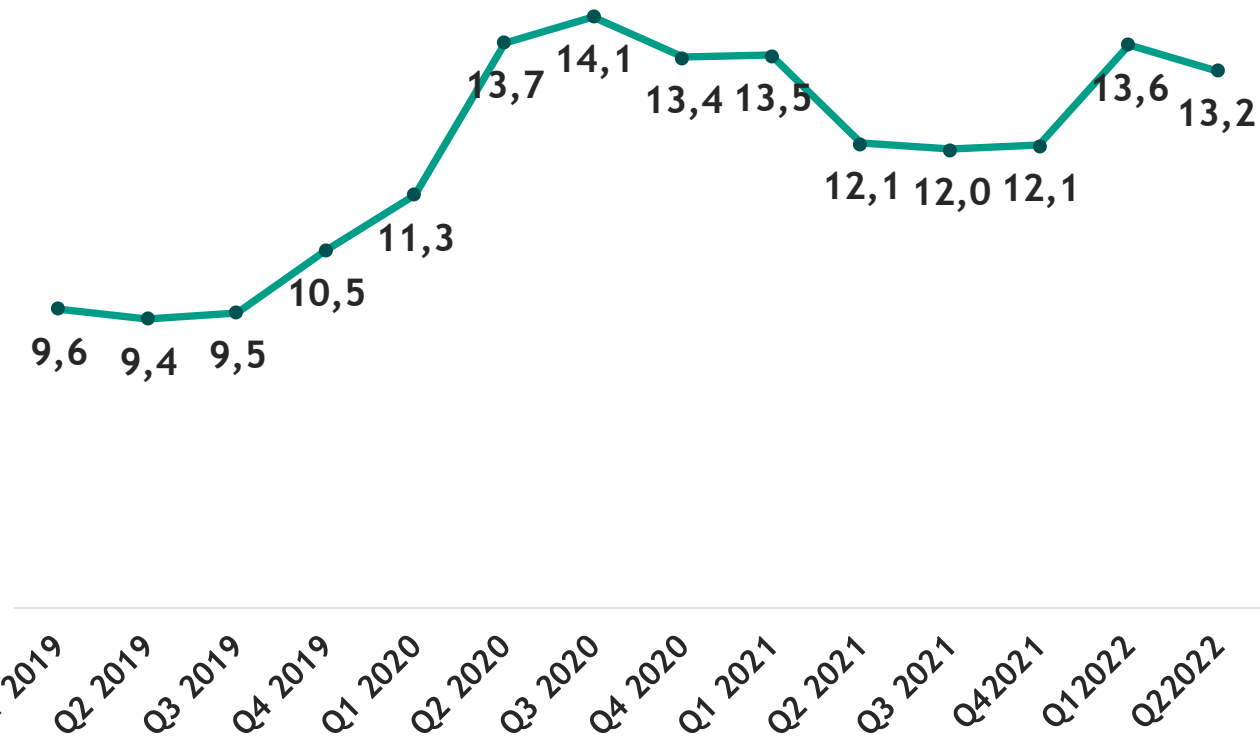
Increase in total revenue from US NGAL sales from 1H 2021 to 1H 2022

Global NGAL

↑ 19%

Development in global sales of NGAL from 1H 2021 to 1H 2022

## The NGAL Test sales by Quarter (LTM, DKKm)

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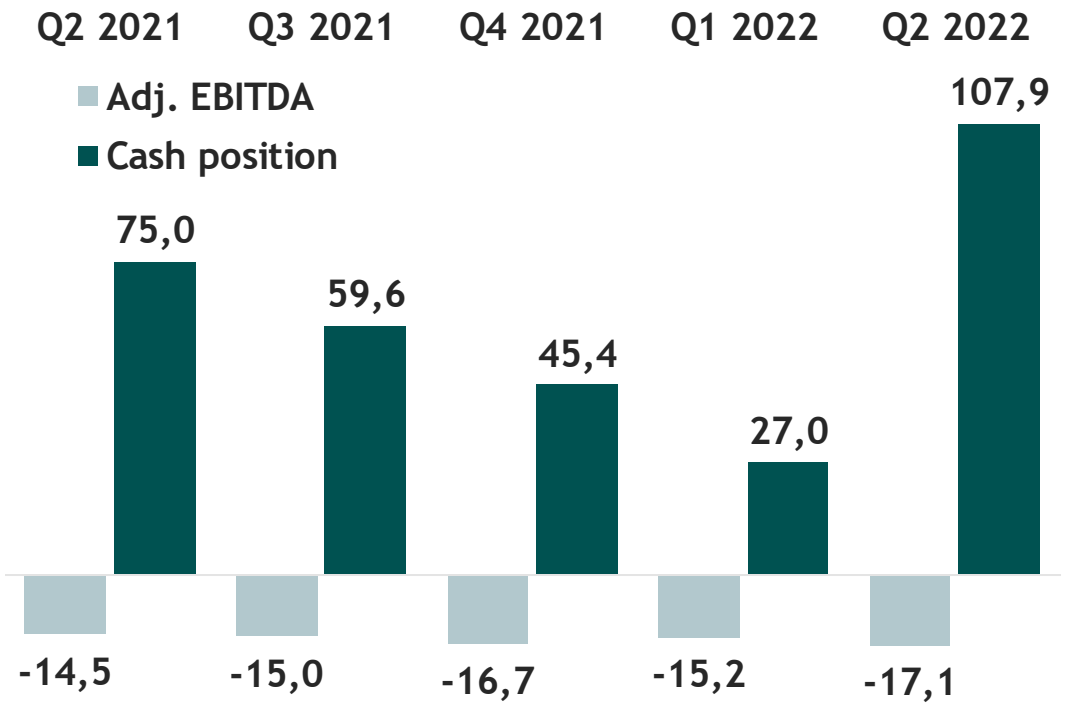
# Solid cash position and continued working capital management

## Adj. EBITDA and cash position (DKKm)




- H1'22 cash burn from operations: DKKm 28.4, a 20% reduction vs. H1'21
- Cash balance: DKKm 107.9

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# Guidance for 2022 & Q2 Cash Position

## Amounts in millions of Danish Kroner and US Dollars[1]

### Guidance

| | |
|---|---|
| Revenue | DKK 24-27<br>$3.3-3.8 |
| EBIT loss | DKK 95-100<br>$13.3-14.0 |
| Adj. EBITDA loss | DKK 76-81<br>$10.6-11.3 |

### Actual at June. 30, 2022

| | |
|---|---|
| Cash[2] | DKK 108<br>$15.1 |

[1]All Financial Figures Converted from DKK to USD at a rate of 7.162:1 as of June 30, 2022. [2]Unaudited.
Note: BioPorto's performance and guidance for 2022 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 2021 Annual Report and 2022-Q2 Interim Report for further information on risks and uncertainties.

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# Investment Thesis: The first meaningful Acute Kidney Injury (AKI) test

- Clinicians are demanding and using The NGAL Test - a better kidney injury diagnostic
- The NGAL Test saves kidneys & lives with AKI detection when the injury is clinically silent
- Serves a $3B+ global Market Opportunity in AKI as a critical care immunoassay in hospital labs
- **FDA Breakthrough Designation** received and on track for a **2022 De Novo Submission**
- New leadership and Board with a record of launching novel diagnostics and devices
- Global, strategic, non-exclusive partnership with Roche Diagnostics

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