# Pre-Emptive Rights Issue 2020

March 23rd and 24th, 2020





## Forward-Looking Statements

This announcement contains certain forward-looking statements, including with respect to the U.S. regulatory approvals process of BioPorto's NGAL Test, the consummation of the securities offering described herein, the terms thereof and the use of proceeds therefrom. Although BioPorto believes that its expectations are based on reasonable assumptions, all statements other than statements of historical fact included in this company announcement about future events are subject to (i) change without notice and (ii) factors beyond BioPorto's control. Forward-looking statements are subject to inherent risks and uncertainties beyond BioPorto's control that could cause BioPorto's actual results, performance, or achievements to be materially different from the expected results, performance, or achievements expressed or implied by such forward-looking statements. Except as required by law, BioPorto assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

#### Legal disclaimer

The information contained herein is not for publication or distribution, directly or indirectly, in or into the United States, Canada, South Africa, Australia or Japan. This announcement and the information it contains is not a prospectus and does not constitute an offer of securities for sale nor a solicitation of any offer to buy any securities issued by BioPorto A/S in the United States or any other jurisdiction where such offer, solicitation or sale would be unlawful. This announcement and the information contained herein are not for distribution or release, directly or indirectly, in or into such jurisdictions.

© Copyright BioPorto



# Agenda

o1. Highlights from 2019

o2. Regulatory studies

o3. Pre-emptive rights issue

# Highlights from 2019







# Highlights of 2019

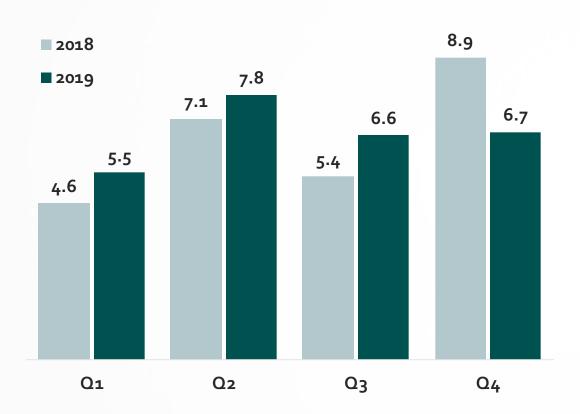
- NGAL product sales up by 14% compared to 2018
- Collecting additional data for the NGAL pediatric clearance with FDA
- Political support and increasing awareness of kidney health in the US
- Strong commercial, clinical and regulatory additions to US organization and Board of Directors
- Successful share capital increase in 2019 further capitalization in the planning



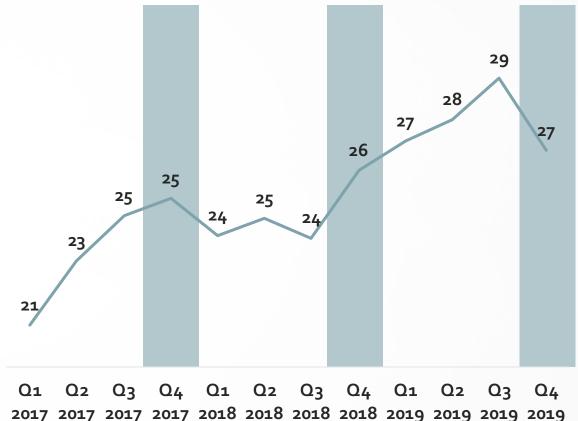


## Revenue growth of 2.3% in 2019

## Revenue by Quarter (DKKm)



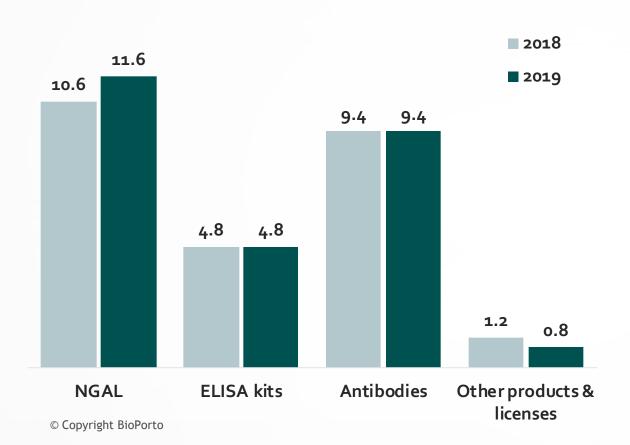
## Revenue by Quarter (LTM, DKKm)

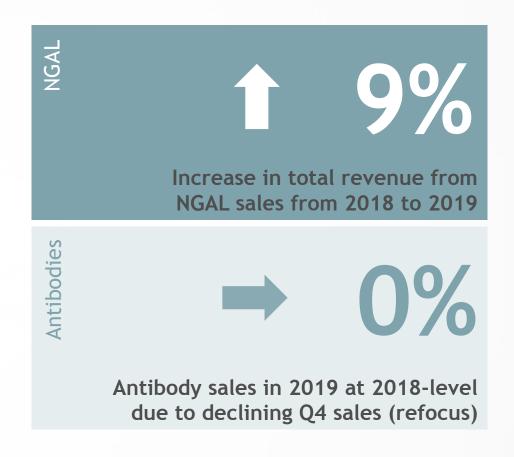


## NGAL revenue\* up 9.4% in 2019



## Revenue by Product Category (DKKm)





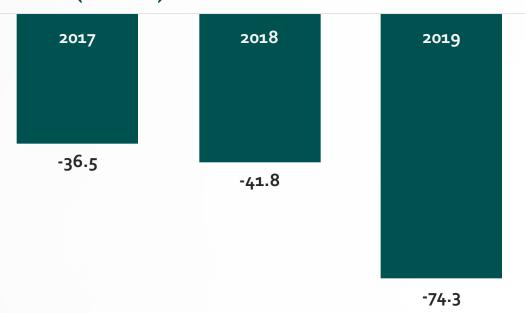
<sup>\*</sup> NGAL product sales and NGAL Other

7



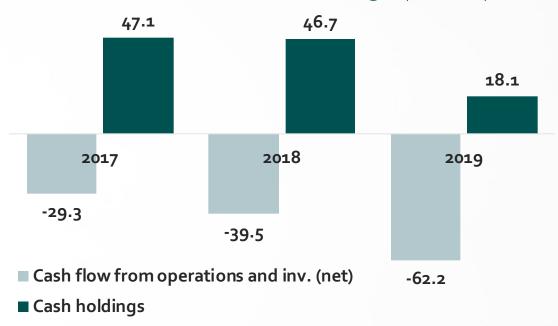
# EBIT on par with expectations - additional financing currently being pursued

## EBIT (DKKm)



EBIT loss for 2019 of DKK 74 million in line with guidance

## Cash flows and cash holdings (DKKm)



BioPorto is currently pursuing additional financing to strengthen the company's financial position

# Regulatory studies





# Pediatric FDA application process to offer insight into adult



### **Pediatrics**



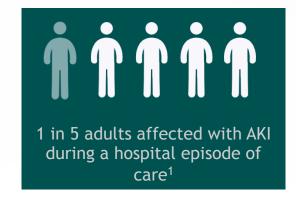
1 in 4 critically ill children affected with AKI<sup>2</sup>

Predict AKI Risk in Intensive Care Setting

- Urine samples
- Predict Stage 2/3 AKI

FDA feedback Nov. 2019, additional data to be submitted Q2 2020

## **Adults**



Predict AKI Risk in Intensive Care Setting

- Plasma sample
- Predict Stage 2/3 AKI

Application to follow pediatric clearance

## **Additional Indications**

- Nephrotoxicity
  - Oncology
  - Cardio
  - Diabetes
  - Transplant
  - Autoimmune
- Therapeutic monitoring
- Diagnosis of AKI
- Point-of-care applications

To initiate following FDA clearance of other indications



## Further Patient Data to be Collected for Application



Oct. 2018

Retrospective study for risk assessment in pediatrics initiated



Q2-4 2019

Application submitted to FDA, reviewed with determination of additional data requirements



Q2 2020

Enhanced FDA submission planned

#### Original study (AWARE 2014)

- 4,653 patients tested
- 1,261 developed AKI
- 543 developed severe AKI

Subset of samples re-tested with The NGAL Test

## Strong clinical support for The NGAL Test

- Sensitivity 65.0%
- Specificity 81.8%
- Neg. predictive value 95.4%
- Concern by FDA for clinician bias in underlying dataset (AWARE)

#### Updated regulatory filing

- Revised pediatric application will most likely be a De Novo 510(k) application
- Additional patient data to be collected in US to address FDA concerns over clinician bias
- Rapid addition of new clin/reg personnel for best-in-class study management

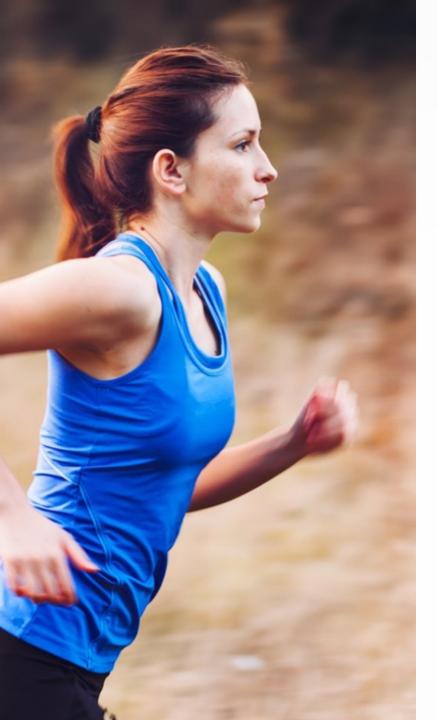
Research Use Only sales to US research hospitals



# **FDA Update**

- Aligned with the FDA on 16 March on the collection of the additional data:
  - Internal and external scientist researchers involved
  - Aligned on protocol and content
- Clinical study plan is clear, FDA feedback was productive and very positive, nothing unexpected
- Breakthrough Designation maintained, should enable more rapid and ongoing dialog with FDA
- Will enroll approximately 200 patients to validate NGAL results in children admitted to the ICU
  - Contracting with 10-12 US sites
  - Chris Bird and Miranda Deverall are acting as study managers and are responsible for the study
  - Working with CRO (L3 Healthcare), experienced clin/reg consultants







# **Expected timeline**

Q1

**Q2** 

## Complete study preparations

- · Timeline progressing well
- Hospital processes moving slower with requirements for virtual work
- 8-10 more hospitals to complete enrollment

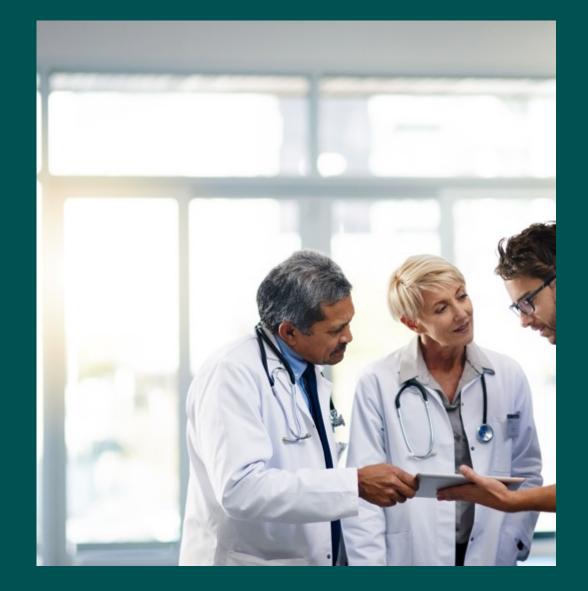
# Patient enrollment and analytical work

- Finalize all sites
- Begin patient enrollment; minimize impact of COVID-19 related hospital pressures by including more sites in our study and using virtual meetings

# Submit *De Novo* application

- Standard *De Novo* review time is 150 days after acceptance
- Working to keep timelines as short as possible
- Based on current medical environment (COVID-19), submission could be delayed into 2H

# **Pre-Emptive Rights Issue**







# Raising capital to continue strategic execution

- Proceeds from offering will together with cash position be used to fuel execution of strategic agenda
- Main objective is to support US application for regulatory clearance of The NGAL Test for use in conjunction with clinical evaluation as an aid in the risk assessment of AKI in patients under the age of 22
- If fully subscribed, proceeds and current cash position will cover BioPorto's financing requirements through Sept. 30<sup>th</sup> 2020 after which further funding is required





# Key Elements of Pre-Emptive Rights Issue

- Offering of 24,992,054 new shares at a subscription price of DKK 1.60 per share with potential gross proceeds of approximately DKK 40 million (net proceeds of approximately DKK 37.5 million) if fully subscribed
- Holders of existing shares will receive one pre-emptive right for each share held
- Seven (7) pre-emptive rights allow for subscription of one (1) new share against payment of subscription price
- Subscription period runs from March 23rd 2020 at 9:00 CET to April 3rd 2020 17:00 CET

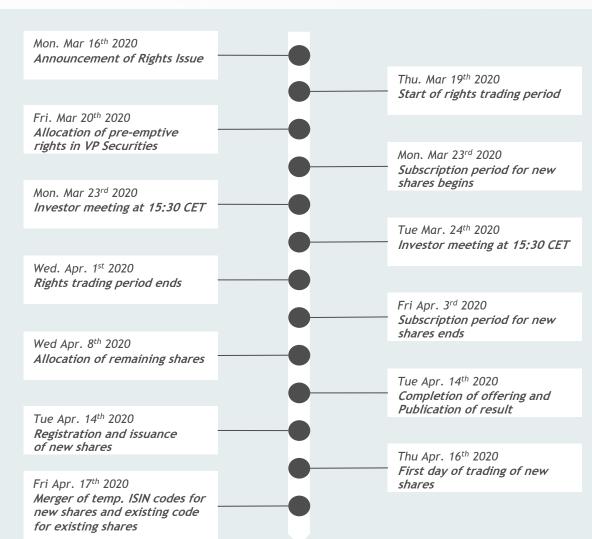
#### Principles of pre-emptive rights issue Each existing share receive one Seven pre-emptive subscription 700 100 pre-emptive subscription right 700 rights is needed to subscribe 700 one new share at a subscription preprenew shares current price of DKK 1.60 before Subscription rights can be emptive emptive At DKK 1.60 subscription period ends traded on NASDAQ in the subshares rights rights per share scription rights trading period

© Copyright BioPorto



# Key Elements of Pre-Emptive Rights Issue (con't)

- Binding commitments for 7,824,598 new shares has been received and further guarantees for subscription of 10,189,715 new shares - a total of 72% of the offering
- Any pre-emptive rights not exercised by end of subscription period will lapse without compensation
- New shares not subscribed for by holders of pre-emptive subscription by end of subscription period can be allocated to other investors or shareholders who have given investment undertakings before end of subscription period





# Key questions and answers

Question	Answer
How do I participate in the rights issue?	All existing shareholders will be allocated pre-emptive rights on Friday March 20th 2020. These can be used to subscribe new shares. Information on the issue and number of pre-emptive rights you receive will be forwarded from your deposit bank
Can I subscribe more shares than my number of subscription rights allow?	Yes, then you will have to purchase pre-emptive rights in the market. It will take 7 pre-emptive rights to subscribe one new share
What if I end up having too many pre-emptive rights?	These can be sold in the market in the period Mar. 23rd to April 1st.
What should I do if I do not want to exercise my pre-emptive rights and participate in the rights issue?	Then you should sell your pre-emptive rights in the market between Mar. 23rd to April 1st. Regardless if your do so, your existing shares in BioPorto will not be affected. You will however be diluted by approximately 14%.
What happen if I do nothing?	Any pre-emptive rights not exercised during the subscription period will lapse, and holders of pre-emptive rights will not be entitled to compensation. You will still have your existing shares in BioPorto, but you will be diluted by approximately 14%.
Can I change or delete an order already submitted?	No, a submitted order is binding
What do I do if I have shares in multiple deposits?	You will receive information on the issue and number of pre-emptive rights from each of your deposit banks
Can I buy new shares if I am not already a shareholder of BioPorto?	Yes, if you acquire pre-emptive rights in the market
Are there any costs for me in participating?	BioPorto does not allocate any costs to shareholders, but your deposit bank might charge a fee associated with the transaction

© Copyright BioPorto

# Financial calendar 2020

April 14, 2020 Annual General Meeting

May 7, 2020 Q1 2020 Results

August 19, 2020 Q2 2020 Results

November 18, 2020 Q3 2020 Results

Contact:
Ole Larsen (CFO)
ol@bioporto.com

