A photograph of a male doctor with grey hair, wearing a white lab coat over a purple and white checkered shirt and a purple and white striped tie. He is leaning over a young girl with blonde hair lying in a hospital bed. The girl is wearing a blue hospital gown and has a clear nasal cannula. She is smiling up at the doctor. The background shows a hospital room with medical equipment and a blurred monitor.

*“A good diagnosis  
is half the cure”*

**AGM 2017, April 21 2017**

# Forward looking statements

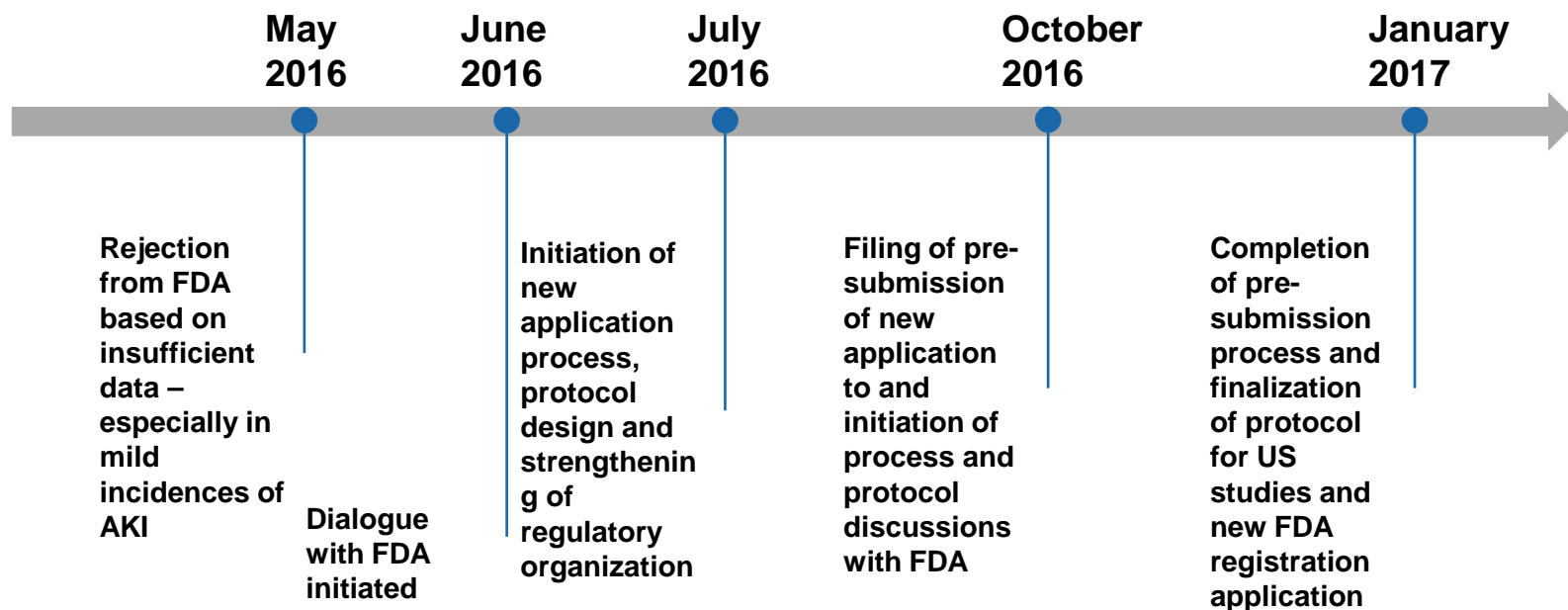
**This presentation contains forward-looking statements. Words such as “believe”, “expect”, “may”, “plan”, “strategy”, “estimate”, “target” and “plan” and similar expressions identify such forward-looking statements. Statements other than historical facts included in this presentation concerning our plans, objectives, goals, future events and performance are forward looking statements. They involve risks, uncertainties and other factors, which may cause actual results, performance and achievements to differ materially from the results discussed in the forward-looking statements. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date of this presentation.**

# Agenda

- **Highlights of 2016**
- Financial performance in 2016
- Initiation of new FDA-process
- Future focus and 2017 milestones and future opportunities



# Fast and very efficient planning for new FDA registration approval of The NGAL Test™



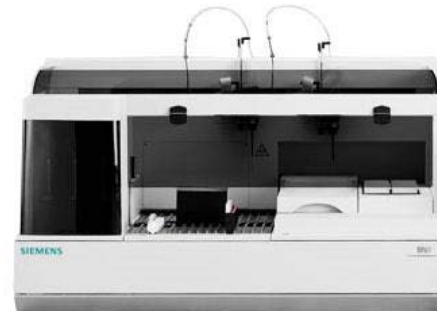
Supported by leading medical experts in the US and strong core believe in the potential of a new diagnostic biomarker for AKI, BioPorto has fast forwarded a revised FDA registration process in 2016

# Distribution agreement with Siemens Healthcare will increase knowledge and availability of NGAL

- Exclusive global distribution agreement for a NGAL test adapted for Siemens Healthcare's BN II and BN ProSpec Systems
- First order placed in January 2017 after adaption of the test to instruments has been completed
- Will impact P&L positive in 2017



**SIEMENS**  
Healthcare



# IP and patent portfolio for NGAL strengthened and expanded in 2016

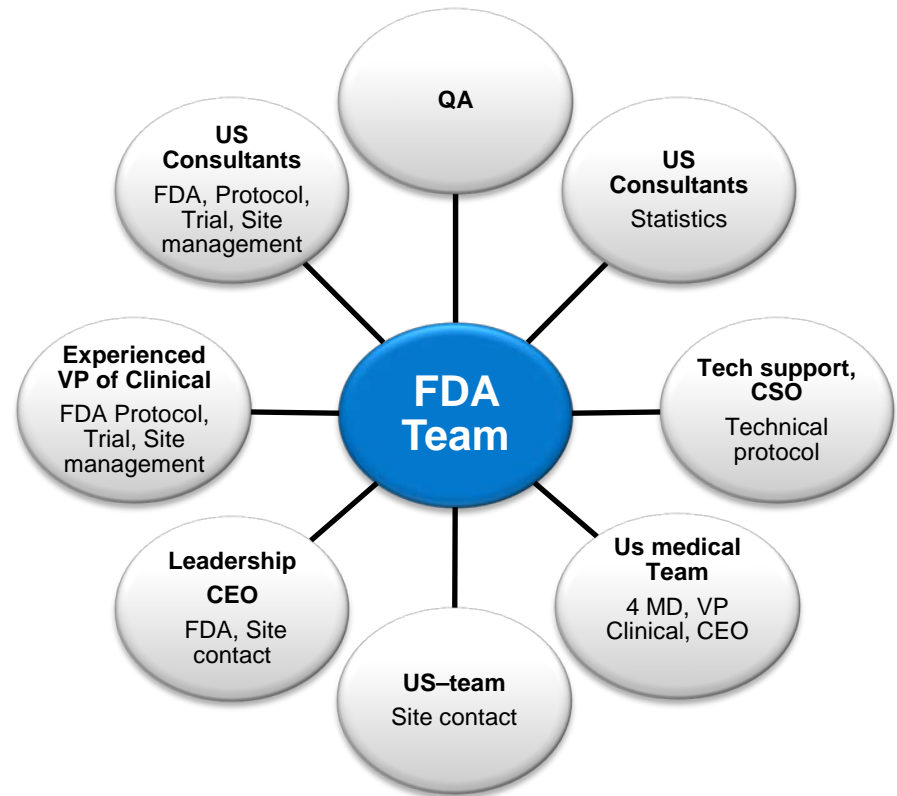
- Validity of NGAL Forms (EU) patent verified in Q3 2016
- The NGAL Cut-off patent (EU) approved for issue in November 2016
- In December 2016 BioPorto entered into an exclusive license agreement with The Trustees of Columbia University regarding several world-wide NGAL patents and applications, with the right to sublicense these patents
- In July 2016, the NGAL Exclusion patent was ruled invalid by EPO – the decision has been appealed by BioPorto





# New organization to support FDA registration approval, future US roll-out and sales in general

- Jan Kuhlmann Andersen new Chief Operation Officer (COO) and Elisabeth Erhardtsen new VP Clinical and Regulatory Affairs
- US organization focused on supporting pending FDA approval process and RUO of The NGAL Test™ which is currently conducted at 8 hospitals and clinics
- DK organization restructured in 2H 2016 – head count reduction of 20% brings down cost by DKK 4m p.a. from 2018



# Capital increase provides financial strength for conducting FDA approval process

- Issue of 12,895,096 new shares in direct issue at price of 1.69 kr/share in November 2016
- Corresponding to 9.95% of existing shares
- Fully subscribed with net proceeds of DKK 20.8m, primarily to be allocated to financing of new FDA approval process for The NGAL Test™
- Year-end cash position of DKK 35.6m



# Agenda

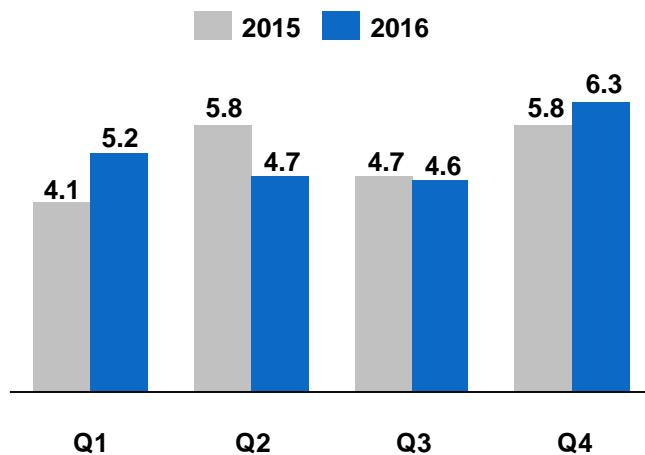
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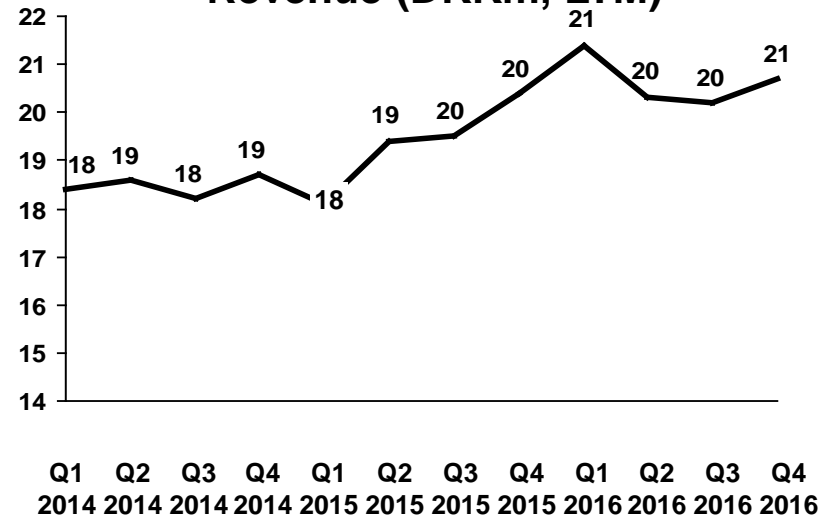
# FDA rejection impacted expected revenue growth considerably in 2016

- Revenue in 2016 of DKK 20.7m (2015: DKK 20.4m), slightly off recent guidance as sales of ELISA kits disappoints in Q4
- Overall growth in 2016 impacted severely by FDA's rejection of registration application for The NGAL Test™

### Quarterly revenue (DKK m)

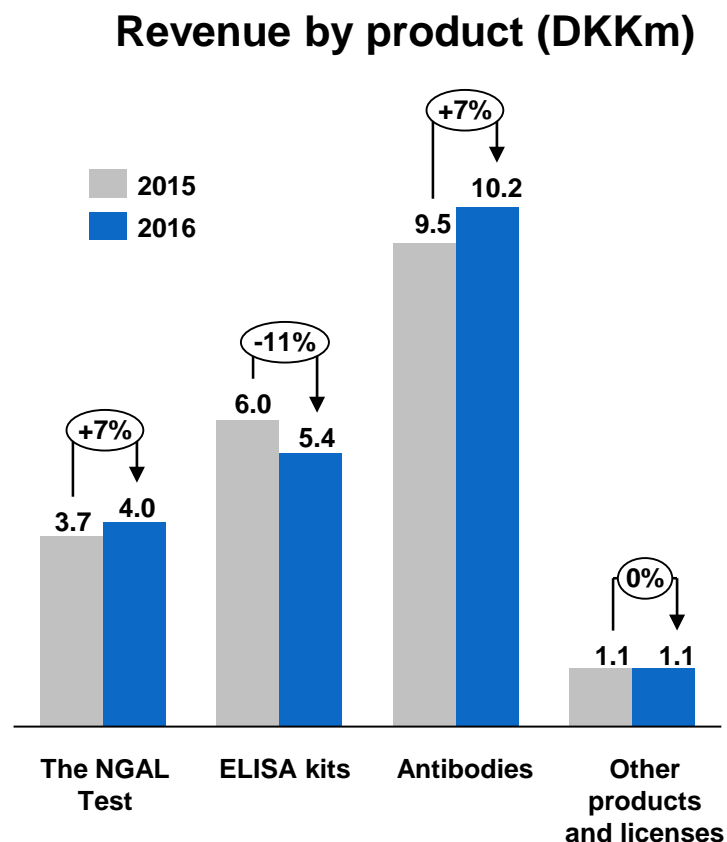


### Revenue (DKK m, LTM)



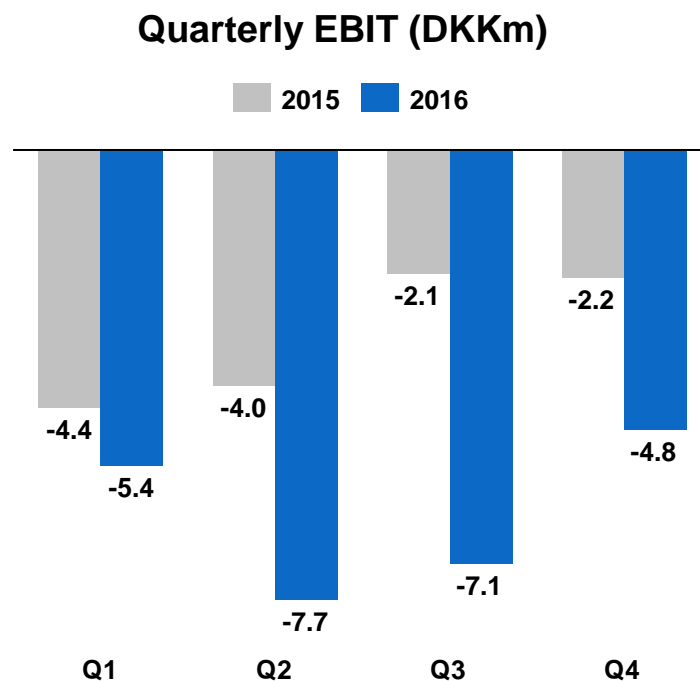
# Moderate increase in sales of The NGAL Test™ and antibodies in 2016

- 7% increase in revenue from the NGAL Test™ as demand is picking up in Europe and RUO-sales in US is starting to develop
- Good rebound in antibody in Q4 secures healthy 7% growth on yearly basis
- Reduction in ELISA kits due to large on-off order in 2015 and consolidation of distributor portfolio



# Increase in capacity cost as US site was established and organization has been strengthened

- EBIT reduced from DKK -12.8m in 2015 to DKK -25.0m in 2016
- Overheads increased in 2016 as a result of:
  - Establishing and operating the US subsidiary
  - Costs for resuming the FDA application process
  - Strengthening the BioPorto management team
  - Implementation of warrant program (not cash constraining)
- The Danish organization was restructured in the last half of 2016
  - Cost reduction of around DKK 3 million in 2017 and DKK 4 million in 2018.

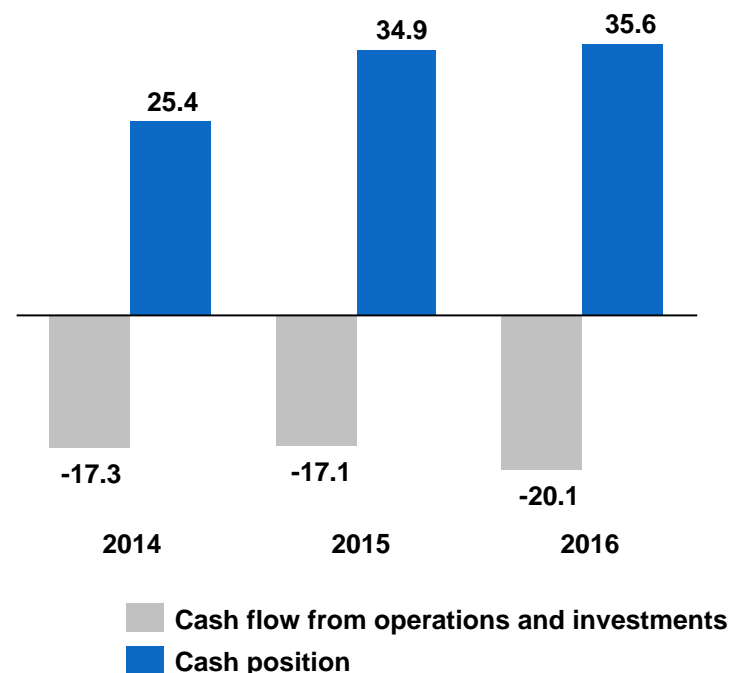


## Solid cash position year-end

- Cash position strengthened by issue of 12,895,096 new shares in November 2016 with net proceeds of DKK 20.8m
- Cash burn of DKK 20.1m in 2016
- DKK 35.6m in cash at hand as of December 31 2016 – deemed sufficient to obtain FDA approval of The NGAL Test™ mid 2018 \*

\* Assuming realization of 2017 budget and ordinary FDA process with no delays.

### Cash flow and cash position (DKKm)



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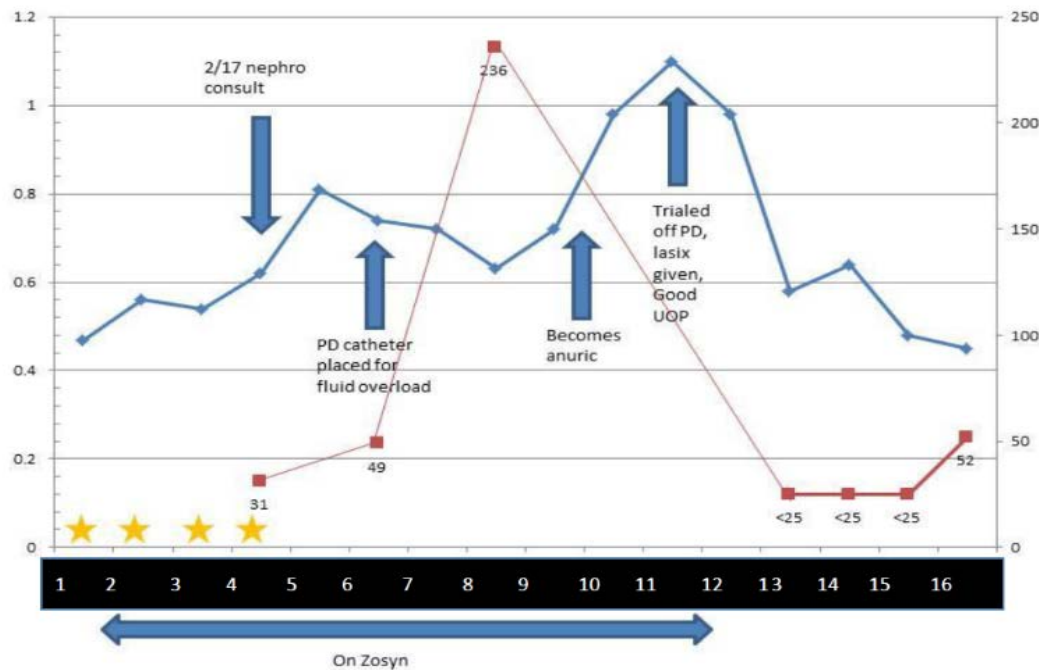
# Market opportunity and need for a biomarker like The NGAL Test™ is huge

- +13,000,000 incidents of AKI globally every year and 25% result in the death of the patient
  - No visceral symptoms to AKI
  - Current methods based on measurement of creatinine react slowly and with large deviations
- Incidence is high (patients with or will develop AKI)
  - 3-5% of all hospitalized patients
  - 30% of cardiac surgery patients
  - 30% of critically ill patients
  - 30% of patients receiving nephrotoxic medications
- Limited knowledge of AKI and almost no treatments other than dialysis which is very invasive, time consuming and costly for the patient and the health care system





# The use of NGAL can save thousands of dollars – and make the difference between life or death



Source: Dr. Rajit K. Basu, Cincinnati Children's Hospital

- Contrary to existing markers, NGAL provides clinicians with a real time tool determine the actual development in kidney function
- This provides a much sharper tool to make the right diagnosis and prognosis
- Will prevent unnecessary dialysis or other invasive treatments in case without a need – or highlight a worsening development much earlier than other methods

# Huge support from clinical experts to seek FDA approval for The NGAL Test™



***“At CCH we firmly believe that the implementation of NGAL as an early predictive biomarker of AKI severity after cardiopulmonary bypass surgery in our pediatric patients has significant clinical impact.”***

**Dr. Prasad Devarajan,  
Cincinnati Children's  
Hospital**



***“..the information yielded by real-time NGAL testing can improve a doctor’s ability to make informed choices for patients suffering AKI and associated problems like fluid overload. These kinds of decisions carry a ripple effect, potentially saving patients and the medical system time and money, while simultaneously improving healthcare outcomes.”***

**Dr. Rajit K. Basu,  
Cincinnati Children's  
Hospital**



***“The use of NGAL in patients with elevated serum creatinine levels provides valuable clinical information to identify patients more likely to have sustained AKI.”***

**Dr. Jonathan Barash,  
Columbia University  
Medical Center**



***“The incorporation of a structural biomarker indicating active kidney damage such as NGAL will greatly enhance our understanding of AKI/CKD and allow us to devise prevention and management strategies.”***

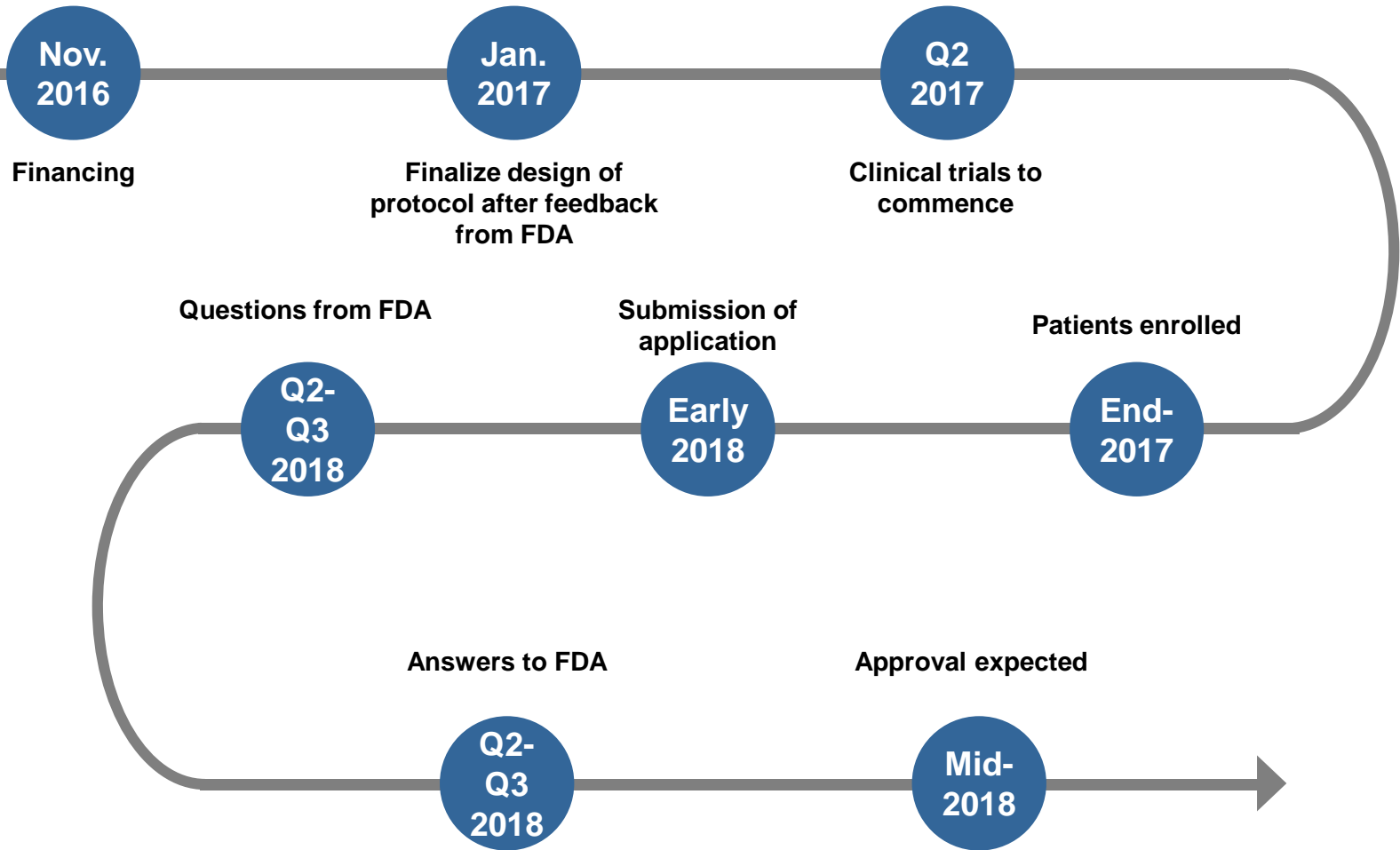
**Dr. Peter McCullough,  
Baylor University  
Medical Center**

# New FDA process has been successfully initiated in beginning of 2017

- Protocol for clinical trials has been finalized – registration approval will be according to De Novo classification
- Sites for clinical trials has been selected – the trials will be conducted in collaboration with a total of 20 hospitals and clinics across the US
- A total of 530 patients will participate - enrolment of first in April 2017
- Total cost of concluding the FDA registration approval process is expected to be DKK 20-21m spread across 2016 (DKK 3m), 2017 (DKK 10m) and 2018 (DKK 7-8m)



# Process for FDA approval of The NGAL Test™



# Agenda

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# Focus on sustaining strategic momentum in the US and on increasing sales in 2017

	2017	2018 and on
<b>Primary targets</b>	<ul style="list-style-type: none"> <li>• Completion of protocol for FDA study in Q1</li> <li>• Initiate enrolment of patients for clinical trials for The NGAL Test™ in Q2</li> <li>• Increase number of users of NGAL in Europe and Asia</li> <li>• Increase number or RUO of NGAL in US</li> <li>• Launch new NGAL and innate immune defense products</li> </ul>	<ul style="list-style-type: none"> <li>• Submit FDA registration of The NGAL Test™ in early 2018</li> <li>• Registration approval mid-2018</li> <li>• Increase number of distribution agreements for NGAL</li> </ul>
<b>Secondary targets</b>	<ul style="list-style-type: none"> <li>• Increase sales of ELISA kits</li> <li>• Expand portfolio of antibodies</li> <li>• New license and OEM agreements</li> </ul>	<ul style="list-style-type: none"> <li>• Continued expansion of antibody and ELISA portfolio</li> <li>• New license and OEM agreements</li> </ul>
<b>Growth in revenue</b>	<ul style="list-style-type: none"> <li>• 20-35%</li> </ul>	<ul style="list-style-type: none"> <li>• Maintain high growth rates</li> </ul>

# RUO in the US and increased sales via Siemens distribution agreement will drive sales growth in 2017

- Turnover expected in DKK 25-28m range (growth of 20-35%)
  - Growth primarily driven by higher sales of The NGAL Test™ (RUO in US, Siemens and own sales in Europe/Asia)
  - ELISA kits and antibodies also expected to grow sales
- EBIT loss of DKK 26-29m
  - Capacity cost to increase due to clinical trials in US and other approval related items (DKK 10m in total in 2017)
  - Restructuring in 2H 2016 will reduce cost by DKK 3m in 2017



## Future opportunities – What is happening outside field of detection of AKI?

- NGAL usage in treatment of cancer.
- NGAL usage in animals.
- NGAL usage with kidney toxic drugs – Acid blockers, insulin ect.
- NGAL usage in inflammatory disorders.

**BioPorto A/S**  
Tuborg Havnevej 15, st.  
DK-2900 Hellerup  
Denmark

**Phone** (+45) 4529 0000  
**E-mail** [info@bioporto.com](mailto:info@bioporto.com)  
**Web** [www.bioporto.com](http://www.bioporto.com)

