



## Q3 Presentation 2019

Oslo, 7<sup>th</sup> November 2019

Hilja Ibert, CEO  
Njaal Kind, CFO

---

***gentian***

# Important notice

This presentation has been prepared by and is the sole responsibility of Gentian Diagnostics AS (the “Company” or “Gentian”). The presentation is furnished to you solely for your information and may not be reproduced or redistributed, in whole or in part, to any other person. The information herein and any other material discussed is subject to change

The presentation contains certain forward-looking statements relating to the business, future financial performance and results of the Company and/or the industry in which it operates. Forward-looking statements concern future circumstances and results and other statements that are not historical facts, sometimes identified by the words “believes”, “expects”, “predicts”, “intends”, “projects”, “plans”, “estimates”, “aims”, “foresees”, “anticipates”, “targets”, and similar expressions. Any forward-looking statements contained herein, including assumptions, opinions and views of the Company or cited from third party sources are solely opinions and forecasts which are subject to risks, uncertainties and other factors that may cause actual events to differ materially from any anticipated development. Potential investors are expressly advised that financial projections, such as the revenue and cash flow projections contained herein, cannot be used as reliable indicators of future revenues or cash flows. Neither the Company (nor any of its parent or subsidiary undertakings) or the Managers (or any such person’s representatives, officers, employees or advisors) provide any assurance that the assumptions underlying such forward-looking statements are free from errors nor does any of them accept any responsibility for the future accuracy of the opinions expressed in this presentation or the actual occurrence of the forecasted developments. No obligation is assumed to update any forward-looking statements or to conform these forward-looking statements to our actual results.

The distribution of this presentation may also in other jurisdictions be restricted by law. Accordingly, this presentation may not be distributed in any jurisdiction except under circumstances that will result in compliance with applicable laws and regulations. The Company require persons in possession of this presentation to inform themselves about, and to observe, any such restrictions.

Nothing in this presentation shall constitute an offer to sell or a solicitation of an offer to buy any shares in the Company in any jurisdiction in which such offer or solicitation is unlawful.

Nothing contained in this presentation is or should be relied upon as a promise or representation as to the future. Except where otherwise expressly indicated, this presentation speaks as of the date set out on its cover. In addition, no responsibility or liability or duty of care is or will be accepted by the Company for updating this presentation (or any additional information), correcting any inaccuracies in it which may become apparent or providing any additional information.

# Agenda



**1** Introduction and Highlights

**2** Q3 Financials

**3** Sales, Operations, R&D

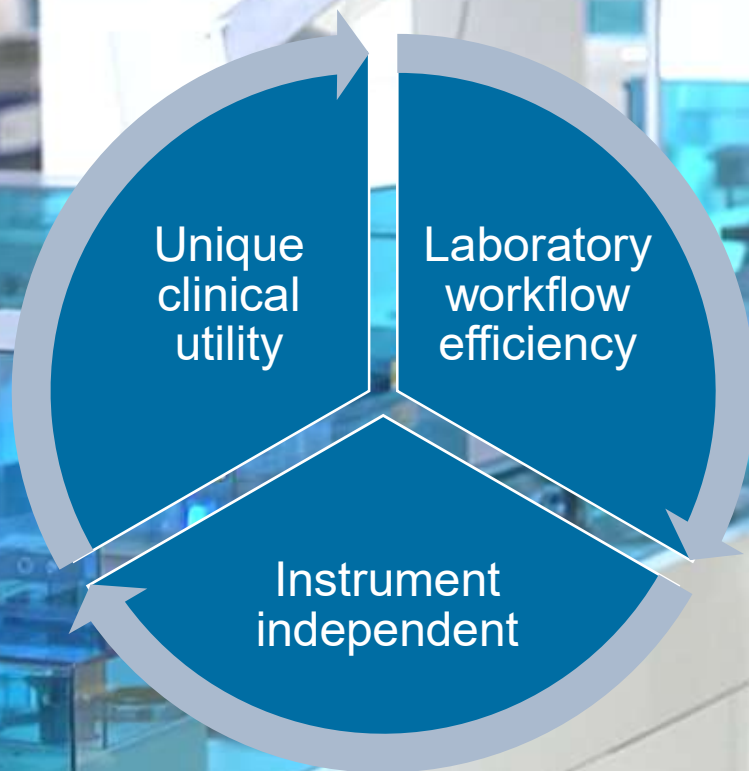
**4** Outlook



## **Gentian is a developer of highly efficient in vitro diagnostics products**

- Estimated total market value of \$80B
- Target market is immunochemistry
- Focus on inflammatory/infectious, cardiac and renal diseases
- Value of target market is estimated to be \$7B

# We innovate diagnostic efficiency



**gentian**

CE

REF  
1101

LOT  
1602408

Cystatin C  
Reagent Kit

1 x 10 mL Immunoparticles, lot no. 1602408-3  
1 x 58 mL Assay Buffer, lot no. 1708403-3

2018-02-17

IVD



Gentian AS, Bjørnåsvæien 5, N-1596 Moss, Norway



**Lab efficiency**

2.000 versus 170 tests/hr

# Highlights for Q3 2019

- Record sales revenues of MNOK 13.1 in 3Q19, up from MNOK 10.4 in 3Q18, totalling a 26 % growth compared to 3Q18
- Record sales revenue for the first nine months of MNOK 33.9 representing 18% growth compared to the same period of 2018
- In July, Beckman Coulter, one of the top 5 global diagnostics companies, and Gentian prolongedated their partnership agreement for Cystatin C by 6 years
- In August, Gentian announced the sales channel agreement for fCAL® turbo between Roche Diagnostics and Gentian's sales partner Bühlmann Laboratories AG



# Agenda



**1** Introduction and Highlights

**2** Q3 Financials

**3** Sales, Operations, R&D

**4** Outlook

## Financial highlights 3Q 2019

MNOK	3Q 2019	3Q 2018
Sales	13.1	10.4
Other Revenues	1.6	8.0
<b>Total Revenues</b>	<b>14.7</b>	<b>18.4</b>
COGS	2.7	2.7
Production Costs	4.2	3.9
R&D Costs	5.4	5.4
SG&A	7.4	7.4
Capitalization	-0.5	-1.2
OPEX	19.2	18.2
<b>EBITDA</b>	<b>-4.5</b>	<b>0.2</b>
<b>EBIT</b>	<b>- 5.8</b>	<b>-0.7</b>

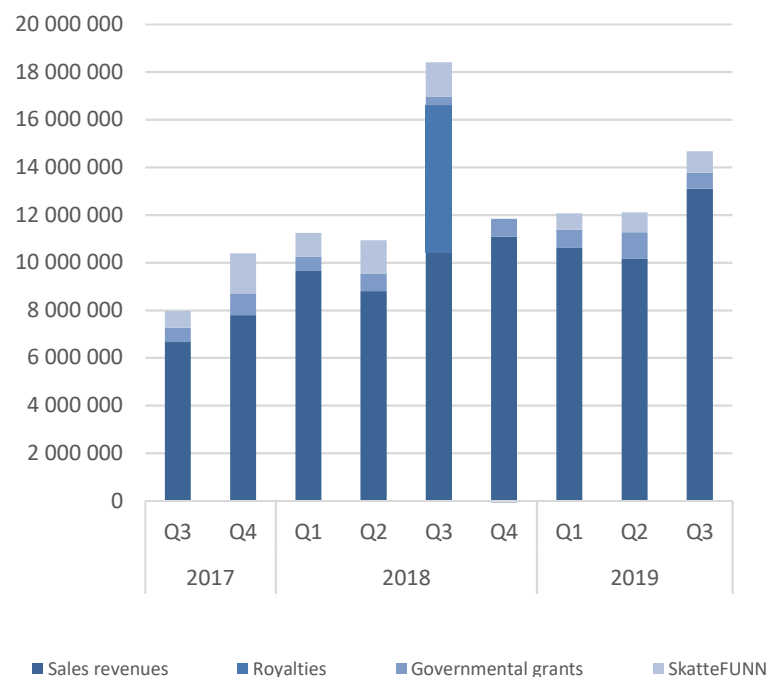
## Financial highlights Per 3Q 2019

MNOK	2019	2018
Sales	33.9	28.9
Other Revenues	5.0	11.7
<b>Total Revenues</b>	<b>38.9</b>	<b>40.6</b>
COGS	7.5	6.5
Production Costs	11.3	10.1
R&D Costs	14.7	14.1
SG&A	22.1	17.3
Capitalization	-1.9	-3.1
OPEX	53.7	44.9
<b>EBITDA</b>	<b>-14.9</b>	<b>-4.3</b>
<b>EBIT<sup>1</sup></b>	<b>- 33.7</b>	<b>-7.2</b>

<sup>1</sup> EBIT includes an impairment charge related to capitalized development costs and other intangible assets of MNOK 14.0

# Sales and revenues

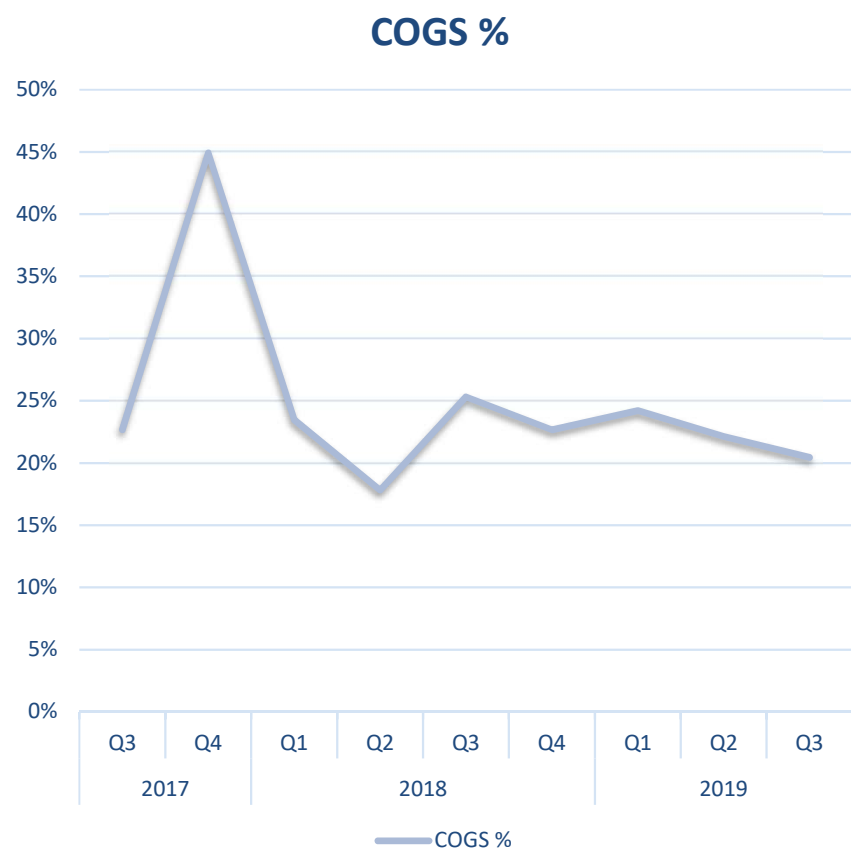
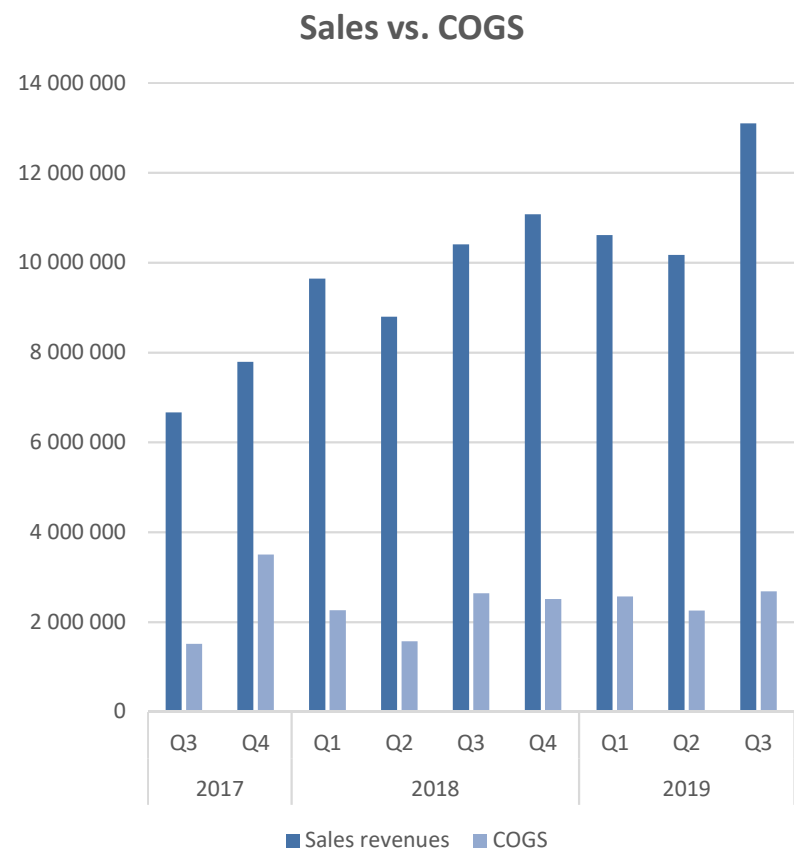
Revenues and Grants Consolidated (NOK)



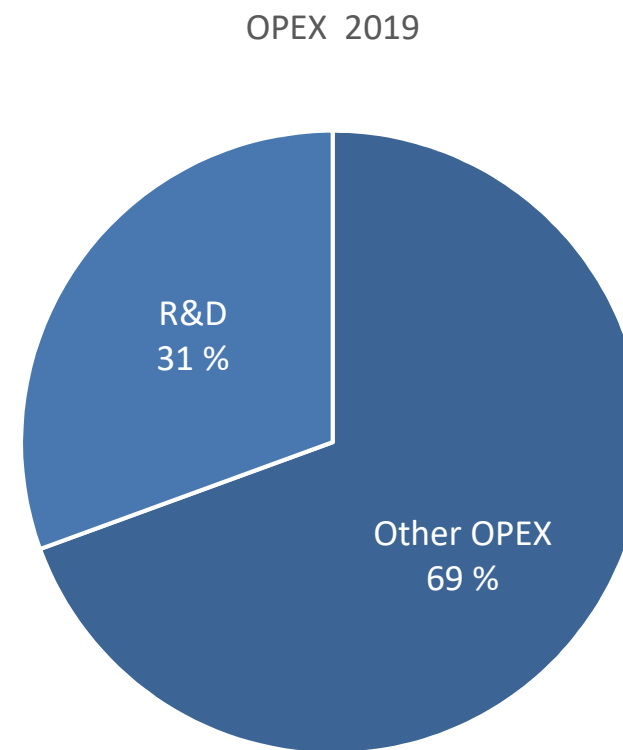
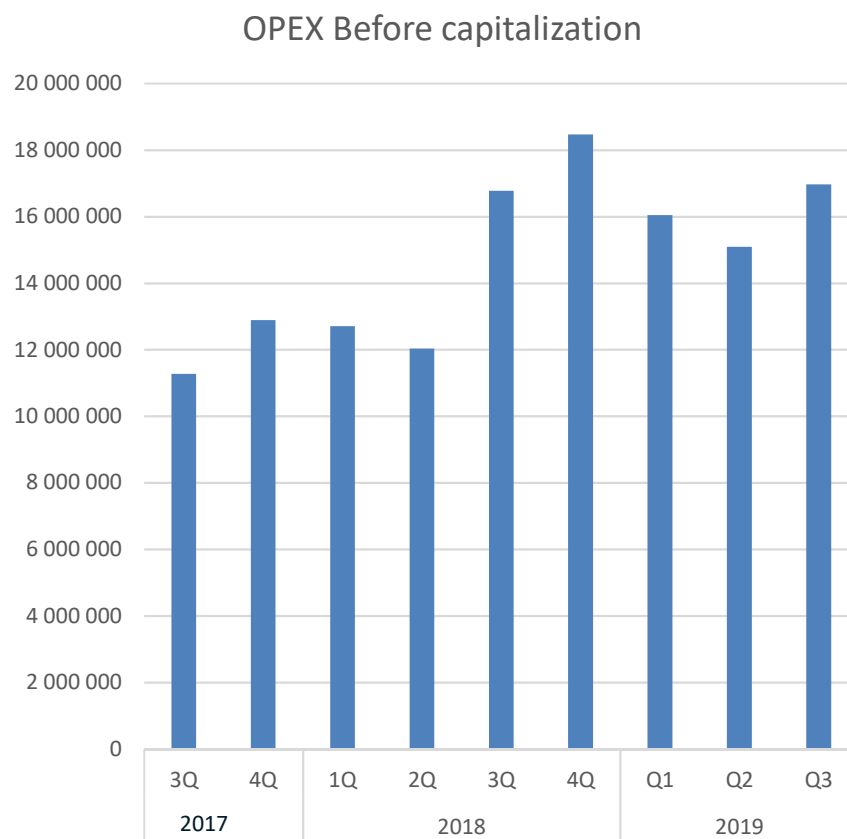
Sales revenues - geographic split

MNOK	3Q19	3Q18	9M19	9M18
US	0.3	0.3	1.4	1.3
Europe	7.7	6.0	22.8	19.6
Asia	5.0	4.1	9.6	7.9
<b>Total</b>	<b>13.1</b>	<b>10.4</b>	<b>33.9</b>	<b>28.8</b>

# Cost of Goods Sold



# OPEX



Total OPEX before capitalization: 48.1MNOK

## Cash flow and cash position

MNOK	3Q19	9M19	9M18
Operating activities	-8.1	- 25.7	- 17.0
Investing activities	- 1.5	- 3.3	- 3.9
Other changes in financial items	0.0	0.0	0.0
Financing activities	0.5	0.5	68.8
<b>Changes in cash and cash equivalent</b>	<b>-9.1</b>	<b>-28.5</b>	<b>47.9</b>
Cash and cash equivalent at the beginning of period	179.3	198.6	146.9
<b>Cash and cash equivalent at the end of period</b>	<b>170.2</b>	<b>170.2</b>	<b>194.8</b>

# Agenda



1

Introduction and Highlights

2

Q3 Financials


3

Sales, Operations, R&D

4

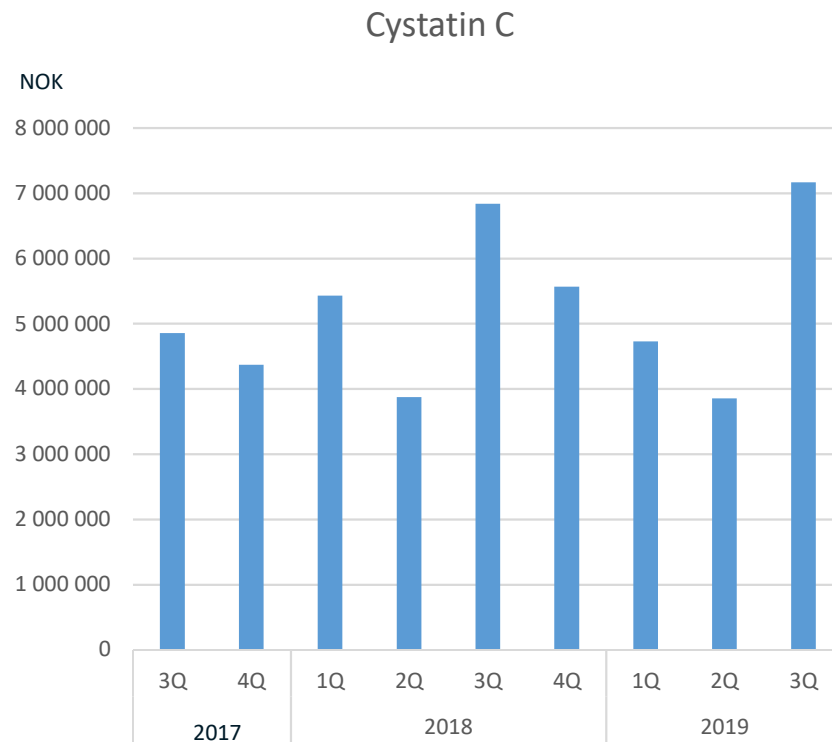
Outlook

# Cystatin C

- 
- Body mass independent kidney function marker
  - Early detection of reduced kidney function
  - Estimated global market value of \$0.5B
  - Continued growth for the company mainly coming from China and US

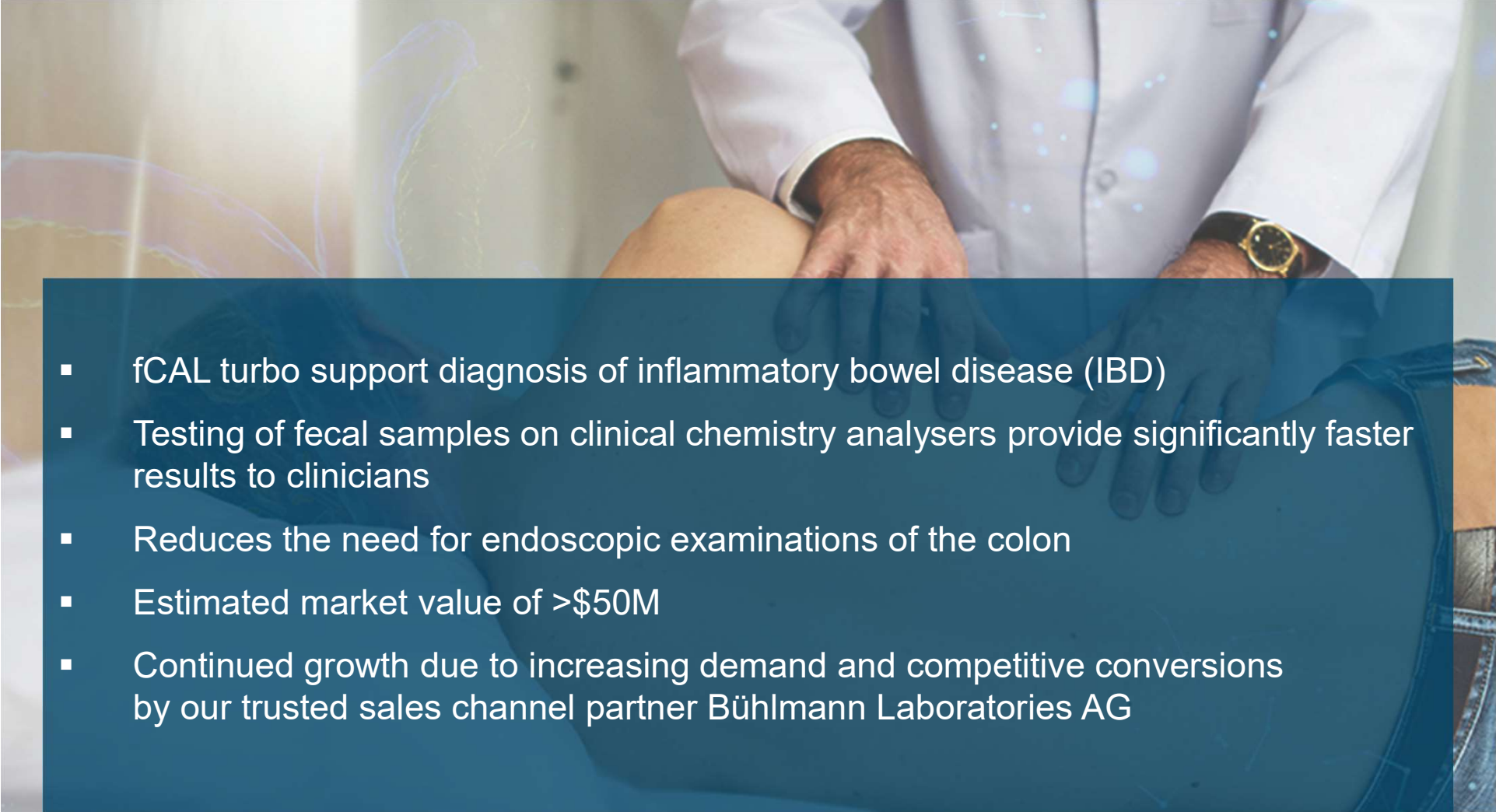
## Sales Cystatin C

*Kidney function test, diagnosis and monitoring*



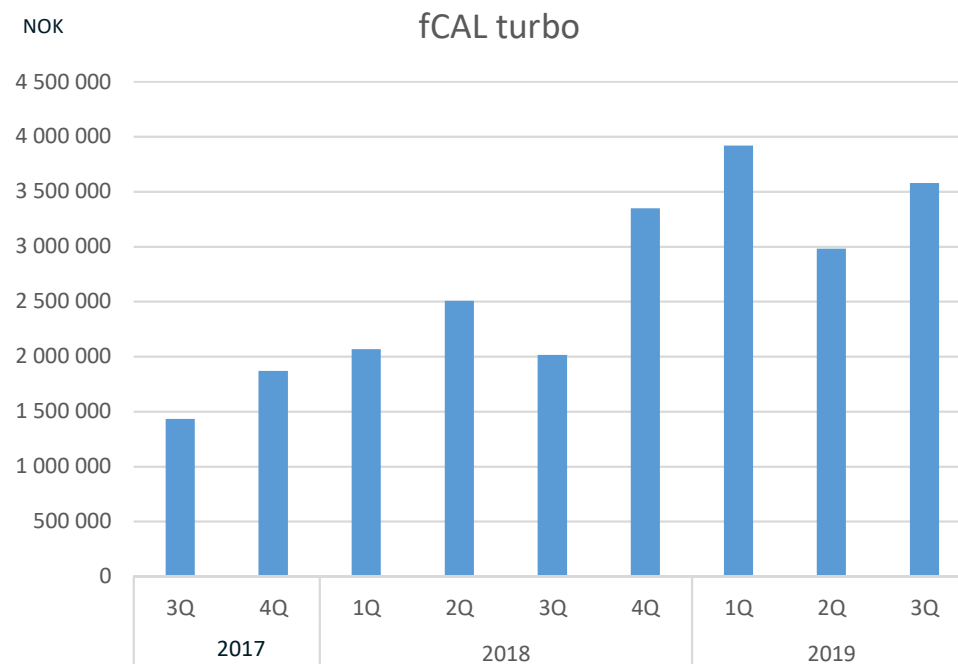
- Record sales of Cystatin C, carry-over effect from 1H partly a factor
- Soft 1H19 due to warehouse consolidations in China and Europe
- Strong increase in shipments to Asia
- Warehouse situation in Europe seems to be normalized

## fCAL® turbo

- 
- fCAL turbo support diagnosis of inflammatory bowel disease (IBD)
  - Testing of fecal samples on clinical chemistry analysers provide significantly faster results to clinicians
  - Reduces the need for endoscopic examinations of the colon
  - Estimated market value of >\$50M
  - Continued growth due to increasing demand and competitive conversions by our trusted sales channel partner Bühlmann Laboratories AG

## Sales fCAL® turbo

*Test for inflammatory bowel disease (IBD), diagnosis and monitoring*

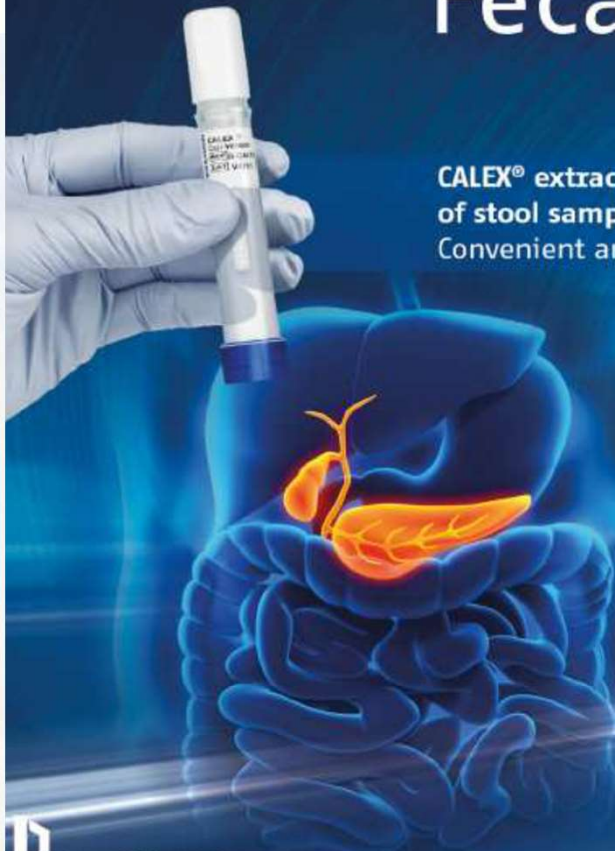


- Strong quarter for fCAL turbo
- Growth driven by addition of new customers converting from other platforms
- First revenues from Bühlmann / Roche agreement expected in Q4
- Revenues from US customers expected in 2020

# Fecal Pancreatic Elastase Assay

CALEX® extraction  
of stool sample  
Convenient and safe

Turbidimetric  
Unique in Speed, Quality  
and Flexibility



**BÜHLMANN**

**BÜHLMANN fPELA® turbo**

***gentian***

# fPELA (Fecal Pancreatic Elastase)

- Marker for pancreatic exocrine insufficiency (PEI)
- Emerging market
- Same sample as fCAL® turbo
- Same end-users as fCAL® turbo
- Launch of fPELA is planned for 2020 by our sales channel partner  
Bühlmann

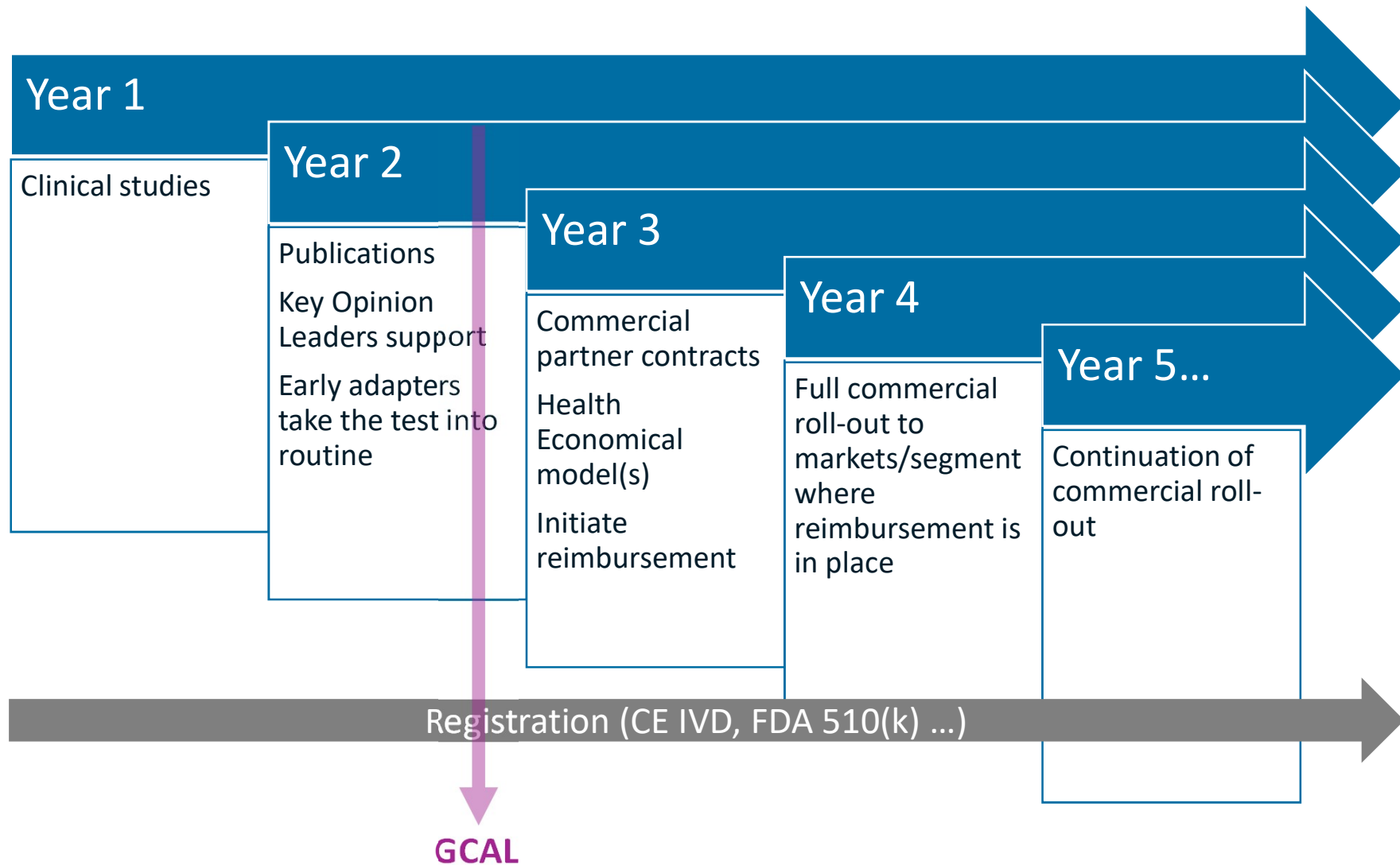
# GCAL<sup>®</sup>

- 
- Novel test for differentiating bacterial from viral infections
  - Potential application for early detection and monitoring of sepsis, other severe infections and rheumatoid arthritis
  - Informed treatment decisions for antibiotic stewardship
  - Reported infectious diseases market value is \$4.0B (BCC, 2018)

**gentian**

# Market development timeline

*Process has to be country specific*



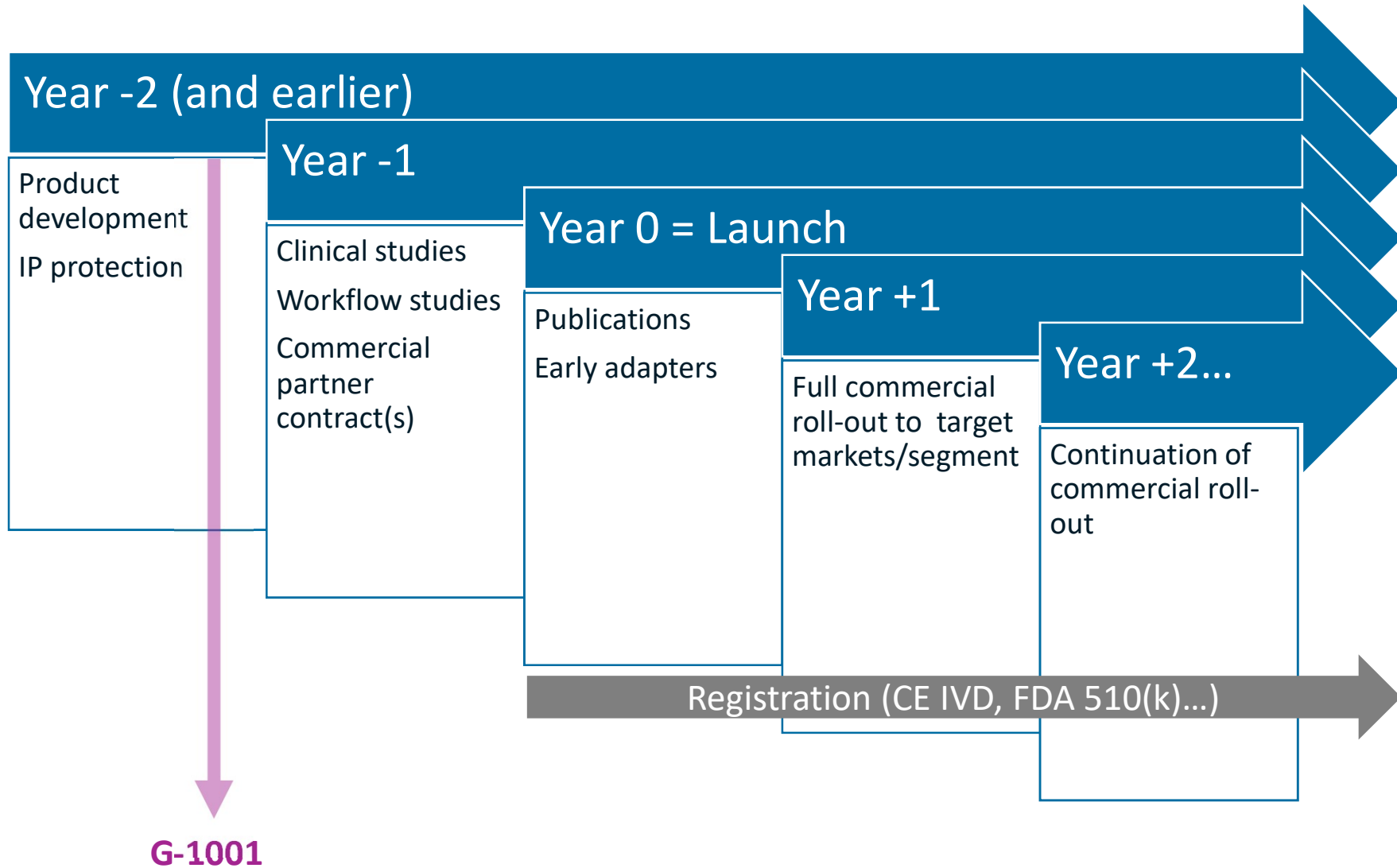
## Study Highlights to date

- Plasma calprotectin is a useful early marker of bacterial infections in critically ill patients, with better predictive characteristics than WBC (white blood cell count), CRP and PCT
- Calprotectin successfully identifies patients with signs of infection in the emergency department
- Calprotectin levels correlates with the severity of the disease
- Prognostic biomarker for ICU admission and mortality
- Better performance than PCT and HBP in differentiation between bacterial and viral infections
- Superior to PCT and HBP in indicating patients with sepsis and differentiation between sepsis and sterile inflammation / trauma

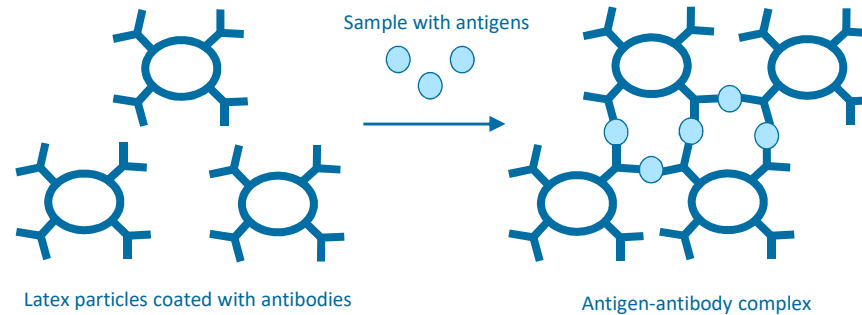
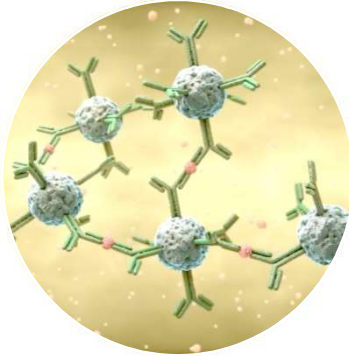
# G-1001

- Cardiac disease marker
- Total cardiac disease marker market value is estimated to be >\$2B
- Launch of G-1001 is planned for 2021
- Go-To-Market via OEM partner(s)
- Short ramp-up time, as it is established in the medical routine

# Launch plan G-1001

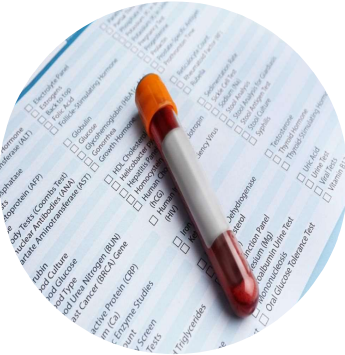


## Particle-enhanced turbidimetric immunoassay (PETIA)



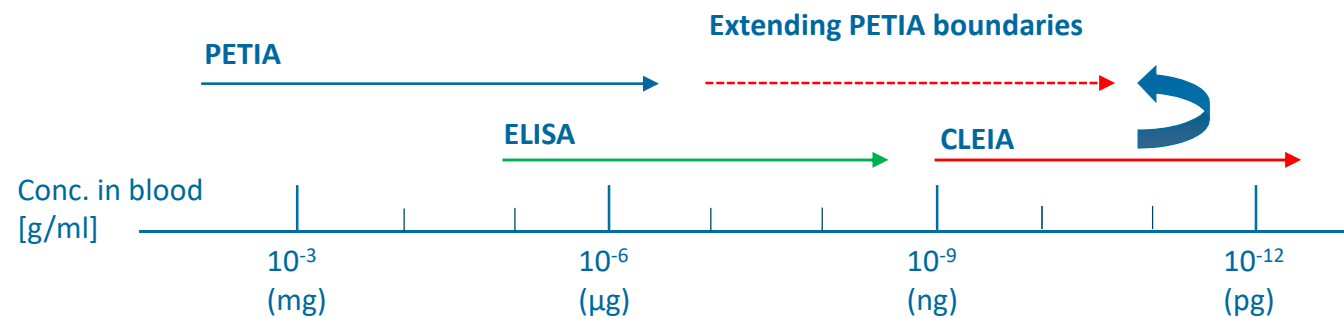
Turbidimetric measurement of antigen-antibody complex

## Detection limits of Gentian PETIA assays (examples)



Product	Limit of quantification [mg/L]	Measuring range [mg/L]
Plasma Calprotectin	$\leq 0.3$	0.5 - 20
Cystatin C	0.28	0.4 - 8.0
Canine CRP	7.0	10 - 300

## Pushing the boundaries for PETIA



# Agenda



**1** Introduction and Highlights

**2** Q3 Financials

**3** Sales, Operations, R&D

**4** Outlook

## Outlook 2019

- The Company expects continued sales growth in 2019 versus 2018 primarily driven by fCAL® turbo.
- The Cystatin C sales in 2H2019 is expected to be to be significantly higher than 1H2019. One contributing factor to this is good sales growth in China. The company expects the total Cystatin C sales in 2019 to be in line with 2018.
- For fCAL® turbo, the company expects continued sales growth in Europe. First customer conversions in the US after the FDA clearance are to be expected early 2020. In addition, the new collaboration with Roche is expected to have a positive effect on sales as of end of 2019.
- For GCAL, new independent publications are in preparations, some of them with anticipated releases in 2019. In addition, the company is continuing to intensify its efforts to engage with Key Opinion Leaders in the field of infectious diseases around the world, as well as selected hospital laboratories and potential commercial partners.
- The Fecal Pancreatic Elastase development is on plan with aim to launch in 2020.
- The G-1001 development is on track with expected launch in 2021.