

# **Q3 Presentation 2020**

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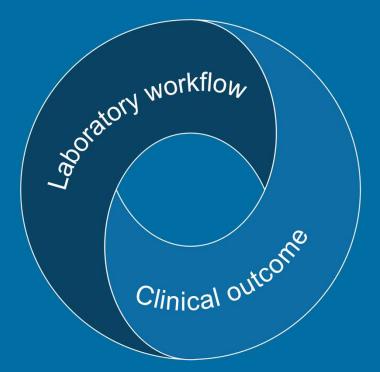
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- **1. Introduction and highlights**
- 2. Q3 Financials
- 3. Growth opportunities
- 4. Outlook





# We innovate diagnostic efficiency

#### **Efficiency gains for immunoassays**

**GENTIAN PLAY** 9.1BUSD Clinical chemist 17.5B USD Immunoassay 51.1BUSD POC, MDX, microbiology, gentian

Moving immunoassays to clinical chemistry: Making them available for high-throughput, fast and cost effective instruments

IVD Reagent Market 2018 65B USD/2023 78B USD CAGR : 4% Source: Kalorama, 2018

## **Highlights for Q3 2020**

- Sales revenue for the first nine months of MNOK 46.1 representing 36 % growth (24 % adjusted for currency effects) compared to the same period last year
- Gentian's Swedish distribution subsidiary, Gentian Diagnostics AB, has had a sales growth from third party products of 52 % YTD 2020 compared to the same period last year
- Gentian is on track with its development of the NT-proBNP immunoassay, previously referred to as G-1001, and is pleased to announce the establishment of a Scientific Advisory Board
- A new study confirms significantly elevated levels of calprotectin in patients with severe COVID-19, which is an opportunity for our GCAL® assay



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### Financial highlights 3Q 2020

MNOK	3Q 2020	3Q 2019
Sales	13.2	13.1
Other Revenues	2.8	1.6
Total Revenues	16.1	14.7
COGS	7.3	6.8
R&D Costs	6.7	5.4
SG&A	7.8	7.4
Capitalization	-0.3	-0.5
OPEX	21.5	19.1
EBITDA	-5.5	-4.5
EBIT	-7.0	-5.8



#### Financial highlights per 3Q 2020

MNOK	YTD 2020	YTD 2019
Sales	46.1	33.9
Other Revenues	8.9	5.0
Total Revenues	55.1	38.9
COGS	23.5	18.8
R&D Costs	17.3	14.7
SG&A	25.2	22.1
Capitalization	-0.9	-1.9
OPEX	65.2	53.7
EBITDA	-10.1	-14.9
EBIT	-14.8	-33.7



#### **Sales and revenues**

**Revenues and Grants Consolidated (NOK)** 



Sales revenues Other Revenues



#### Sales revenues - geographic split

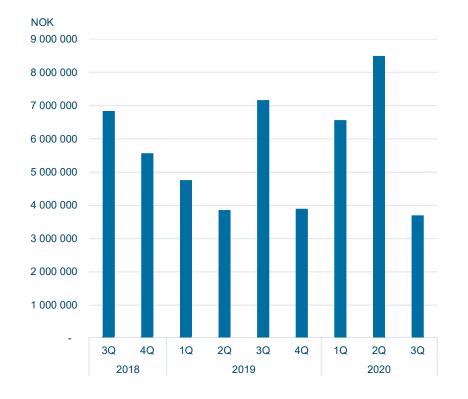
MNOK	3Q20	3Q19	YTD 20	YTD 19
US	0.6	0.3	2.3	1.4
Europe	11.4	7.7	32.5	22.8
Asia	1.3	5.0	11.4	9.6
Total	13.2	13.1	46.1	33.9

#### Sales revenues - product split

MNOK	3Q20	3Q19	YTD 20	YTD 19
Cystatin C	3.7	7.2	18.7	15.8
fCAL® turbo	5.6	3.6	14.8	10.5
Other	4.0	2.4	12.8	7.6
Total	13.2	13.1	46.1	33.9

#### **Sales Cystatin C**

Kidney function test, diagnosis and monitoring

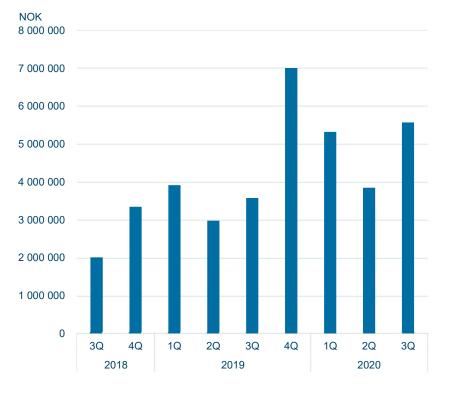




- Decrease of 49 % compared to 3Q19, increase of 19 % YTD
- The high sales activity in 1H20 was partly due to stock building from some of our Asian customers, in relation to the COVID-19 situation
- Revenue growth for 2H2020 expected to be lower than in 1H2020

#### Sales fCAL® turbo

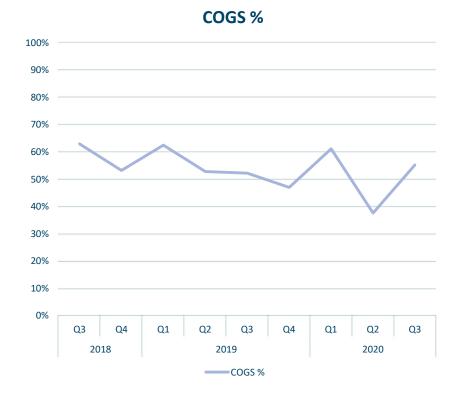
#### Test for inflammatory bowel disease (IBD), diagnosis and monitoring

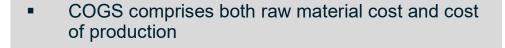


- Sales growth in 3Q20 was 56 % compared to 3Q19 and 41 % YTD
- Sales of fCAL® turbo continues to recover from the low levels seen in 2Q20 due to the COVID-19 situation
- Increased quarterly variations expected in 2020



#### Cost of goods sold



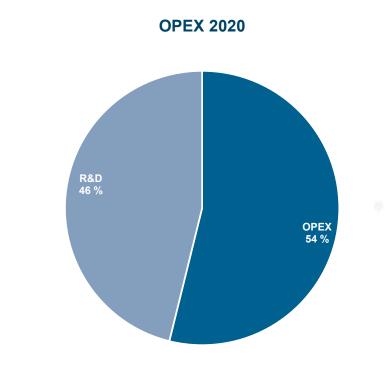


- COGS of 55 % of sales in Q3 2020 vs 52 % in Q3 2019
- COGS measured as a percentage of sales will decline as revenue increases, but with quarterly variations



#### **OPEX**





Total OPEX ex COGS before capitalization (3Q20): MNOK14.5



#### **Cash flow and cash position**

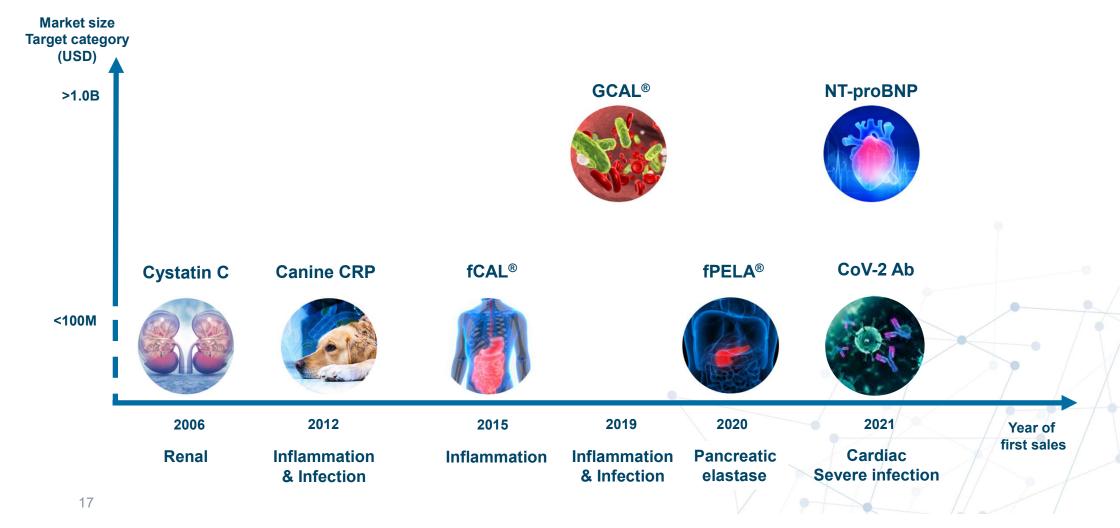
MNOK	3Q20	2Q20	1Q20	2019
Operating activities	- 8.6	1.1	- 9.7	- 23.1
Investing activities	- 0.3	- 1.2	- 0.4	- 4.7
Financing activities	- 0.1	- 0.1	- 0.1	0.7
Changes in cash and cash equivalent	- 9.0	- 0.2	- 10.2	-27.1
Cash and cash equivalent at the beginning of period	161.2	161.4	171.6	198.6
Cash and cash equivalent at the end of period	152.3	161.2	161.4	171.6



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#### Products and pipeline: 1 new product per year



## GCAL<sup>®</sup> Calprotectin immunoassay

Early detection of severe bacterial infections, sepsis and inflammation





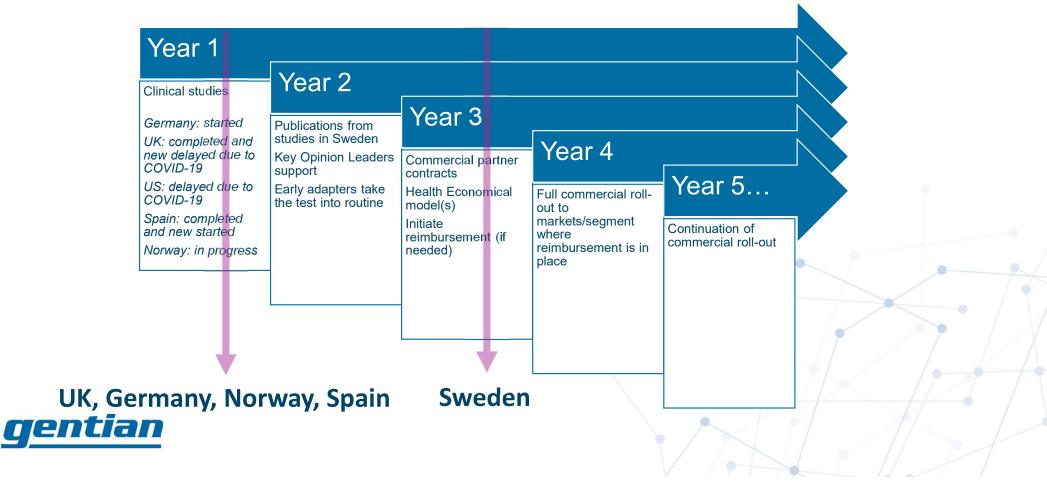
## **GCAL<sup>®</sup> : Novel biomarker in market development**

- Potential biomarker for early detection, prognosis of disease severity and mortality of sepsis and other severe infections
- Scientific studies show increased levels of calprotectin in COVID-19 patients and indicating the prognostic value of calprotectin in estimation of disease severity, organ damage and mortality
- Biomarker for detection and monitoring of inflammation in Rheumatoid Arthritis
- Reported infectious diseases market value is \$4.0B (BCC, 2018); the target category is estimated to represent about \$1.0B



#### **GCAL<sup>®</sup>** market development timeline and progress

Assessment of clinical relevance for COVID-19-patient management has been added to several studies



### **GCAL<sup>®</sup>** in the context of COVID-19

General calprotectin publications [1-3]:

- Scientific publications have shown that calprotectin may be a promising biomarker for assessment of the disease severity and prediction of mortality in COVID-19 patients
- The studies have reported increased levels of calprotectin in patients with severe SARS-Cov-2 infections.

GCAL<sup>®</sup> related data:

- Gentian has, in collaboration with Santa Lucia University Hospital (Cartagena, Spain) and Akademiska University Hospital (Uppsala, Sweden) confirmed increased levels of calprotectin by using the GCAL® assay in patients with severe COVID-19
- Circulating levels of calprotectin were significantly higher in COVID-19 patients who required mechanical ventilation and/or who died, indicating the role of the biomarker in the prognosis and assessment of the disease severity.
- Some of the study results are published in the scientific journal "Journal of Infection" in August 2020 [4]
- Additional results will be presented as posters at the conference of the American Association of Clinical Chemistry (AACC) in December.



References: 1. Shi H, et al. (2020) Neutrophil calprotectin identifies severe pulmonary disease in COVID-19 doi: doi.org/10.1101/2020.05.06.20093070. Preprint PMID: 32511540 2. Zuo Y, et al. (2020) Neutrophil extracellular traps and thrombosis in COVID-19. doi: doi.org/10.1101/2020.04.30.20086736. Preprint. PMID: 32511553 3. Silvin et al. (2020) Elevated calprotectin and abnormal myeloid cell subsets discriminate severe from mild COVID-19 Cell, doi: doi.org/10.1016/j. cell.2020.08.002 4. de Guadiana Romualdo L.G. et al. (2020) Circulating levels of GDF-15 and calprotectin for prediction of in-hospital mortality in COVID-19 patients: a case series. Journal of Infection, doi: doi.org/10.1016/j.jinf.2020.08.010

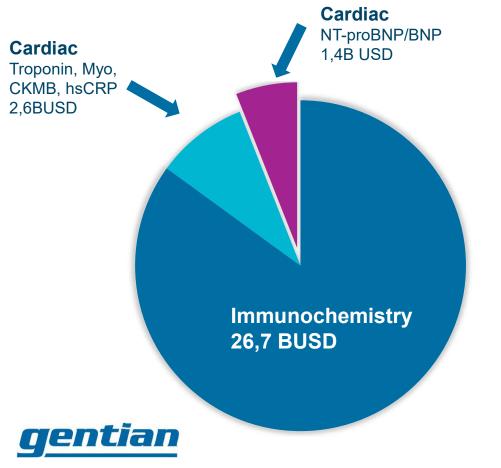
#### **NT-proBNP** (earlier referred to as G-1001)

First cardiovascular test for high-throughput clinical chemistry analysers





#### **IVD Cardiac Marker Market\***



Cardiac Markers: NT-proBNP, BNP Troponin T, I CKMB Myoglobin hsCRP

Major IVD Players for Cardiac Markers: Roche Diagnostics\*\* Abbott Diagnostics Siemens Healthineers Beckman Coulter Ortho Diagnostics

\*\* Market leader

\* Future Market Insights, 2018; BCC Research, 2018; Kalorama IVD Report, 2016

### **Scientific Advisory Board established**

To strengthen the development of the PETIA NT-proBNP immunoassay, Gentian has established a Scientific Advisory Board to provide the company with additional technology expertise, clinical knowhow and strategic input.

The Advisory Board consist of key opinion leaders from industry and academia and it will be utilized by Gentian for the development and commercialization of the PETIA NT-proBNP immunoassay.

Members of the PETIA NT-proBNP Advisory Board:

Marie Buchmann Medical Director at Fürst Medisinsk Laboratorium, Oslo

Anders Olof Larsson Professor at Department of Medical Sciences, Clinical Chemistry, Uppsala University

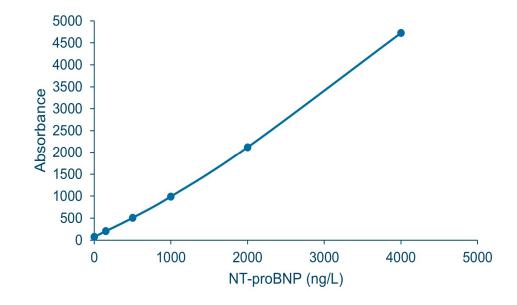
**Erling Sundrehagen** Founder and CSO at Gentian, Moss

Additional members may be appointed in the future.



#### **Development status**

The PETIA NT-proBNP assay is measuring within clinically relevant ranges

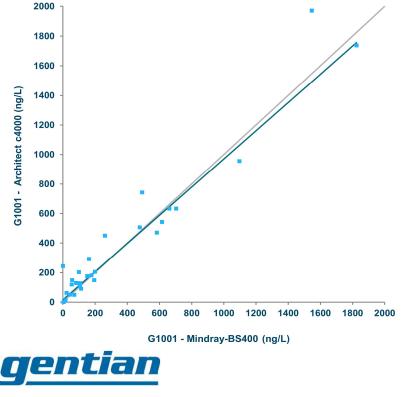


The results show that the Gentian antibodies on the immunoparticles are capable of reacting with varying concentrations of NT-proBNP in a linear fashion, ranging from clinically relevant high NTproBNP concentrations (4000 ng/L) to low NTproBNP concentrations (150 ng/L).



#### **Development status**

The PETIA NT-proBNP assay reproduces results on 2 different analysers with good correlation



The results show the correlation for the same patient samples measured on the Mindray BS400 and Abbott Architect c4000 clinical analysers (same reagents and calibrators used on both instruments)

#### Gentian Turbidimetric NT-proBNP Assay Main benefit

For use on clinical chemistry analysers, which will <u>improve the</u> <u>laboratory efficiency based on the higher throughput</u> in comparison to the currently used immunoassay analysers.



### **Milestones until end of 2021**

- Final product development steps, which are planned to be finalised by the end of 2021
- Continuous work on IP protection
- Accomplished market research for the final positioning of the assay
- Initial clinical studies for regulatory and scientific purposes completed
- Start of OEM partnership negotiations
- Regular updates will be provided in the coming months



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### Outlook

- Gentian may be further affected by the COVID-19 outbreak by reduced demand for diagnostic services for outpatients and we expect some delays with our clinical studies and R&D programs
- The company estimates continued sales growth in 2020 versus 2019, with expected quarterly variations and so far, unpredictable effects of the COVID-19 outbreak
- For Cystatin C, the company expects reduced orders from Asia in the remaining months of 2020 due to high warehouse levels and stable growth in the US and Europe
- For fCAL<sup>®</sup> turbo, we see an increase in demand in 2H20 versus 1H20, but the growth momentum will depend on the capacity of health systems to process outpatient services under COVID- 19 conditions
- For GCAL<sup>®</sup>, we have focused on studies and collaborations related to COVID-19 and the role of calprotectin in prognosis and differentiation between mild and severe form of the disease. Some results will be presented at the world leading diagnostic congress AACC in December 2020.



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