

# Q1 Presentation 2020 April 24, 2020

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# Agenda



1	Introduction and highlights
2	Q1 Financials
3	Sales, Operations, R&D
4	Outlook



# #DiagnosticEfficiency

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# We innovate diagnostic efficiency - based on deep patent portfolio -



## **Products and pipeline**





\* Pipeline \*\* Not available in the US

# **Highlights for Q1 2020**

- Record sales revenues of MNOK 16.2 in 1Q20, up from MNOK 10.6 in 1Q19.
- Sales growth of 53% is based on strong performance of all product lines. Sales grew by 42% in 1Q20 on a currency neutral basis.
- New publications of clinical study results confirm GCAL as a promising biomarker for earlier detection and better prediction of severity of an infection.



# SARS-CoV-2 / COVID-19

- The health and safety of our employees, as well as our customers and partners, is of primary concern.
- Gentian has robust business-continuity plans in place, so we can maintain our production lines.
- We abide by Norwegian health authority policies whilst continuing to seamlessly support our customers.
- Gentian has offered support to interested site, who would to like to test cystatin C and plasma calprotectin in the context of early detection of the severely affected COVID-19 patients.



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# Financial highlights 1Q 2020

MNOK	1Q 2020	1Q 2019
Sales	16.2	10.6
Other Revenues	2.9	1.5
Total Revenues	19.1	12.1
COGS	9.9	6.6
R&D Costs	5.6	4.1
SG&A	8.6	7.9
Capitalization	-0.1	-0.9
OPEX	24.0	17.7
EBITDA	-4.9	-5.6
EBIT	-6.5	-7.3



# **Sales and revenues**

#### **Revenues and Grants Consolidated (NOK)**



#### Sales revenues - geographic split

MNOK	1Q20	1Q19
US	0.7	0.5
Europe	11.2	7.4
Asia	4.3	2.7
Total	16.2	10.6

#### Sales revenues - product split

MNOK	1Q20	1Q19
Cystatin C	6.6	4.8
fCAL® turbo	5.3	3.9
Other	4.4	1.9
Total	16.2	10.6



# Cost of goods sold



- COGS comprises now both raw material cost and cost of production
- COGS of 61% of sales in Q1 2020 vs 62% in Q1 2019
- COGS measured as a percentage of sales will decline as revenue increases, but with quarterly variations



# **OPEX**





Total OPEX ex COGS before capitalization: 14.2MNOK



# **Cash flow and cash position**

MNOK	1Q20	2019	1Q19
Operating activities	- 9.7	- 23.1	- 6.2
Investing activities	- 0.4	- 4.7	- 1.2
Financing activities	- 0.1	0.7	- 0.0
Changes in cash and cash equivalent	- 10.2	-27.1	- 7.4
Cash and cash equivalent at the beginning of period	171.6	198.6	198.6
Cash and cash equivalent at the end of period	161.4	171.6	191.3



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## **Cystatin C**



# Kidney marker: Cystatin C

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



#### **Partners**



 Beckman Coulter is one of top market share holders in the area of clinical chemistry

#### **Key customers and KOLs**



 Gentian is supplier or sub-supplier to many hospitals on the 'America's Best Hospitals' list \*\*, specifically in the area of kidney disease

\* Publicly available customer information only \*\* https://health.usnews.com/best-hospitals



# **Sales Cystatin C**

Kidney function test, diagnosis and monitoring



- Strong quarter with 40% sales growth versus 1Q19
- Beckman Coulter China shipments were significantly increased
- Beckman Coulter Europe/US shipments are back to double digit growth
- Direct sales efforts in the US resulted in first promising results
- Revenue growth expected in 2020 from all regions with quarterly variations



Reduces the need of colon endoscopic examination







# fCAL<sup>®</sup> turbo

- Support diagnosis of inflammatory bowel disease (IBD)
- Testing of fecal samples on clinical chemistry analysers provide significantly faster results to clinicians
- Estimated market value of >\$50M
- Continued growth due to increasing demand and competitive conversions



### Partners and key customers



Diagnostics

SYNLAB



**業 Unilabs** 



# Sales fCAL® turbo

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



- Continuous strong sales growth of 36% versus 1Q19 is mainly driven by the addition of new customers converting from other platforms
- First revenues from US customers expected in 2020 but with delays due to the COVID-19 outbreak
- Increased quarterly variations expected in 2020



# **Pipeline: fPELA (Fecal Pancreatic Elastase)**

- Marker for pancreatic exocrine insufficiency (PEI)
- Emerging market
- Same sample as fCAL® turbo
- Same treating physicians as fCAL® turbo
- Currently in validation; launch of fPELA is planned in 2020









# **GCAL<sup>®</sup>** Plasma calprotectin immunoassay

www.gentian.com

\* Novel biomarker in market development



# **GCAL: Novel biomarker in market development\***

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

\* not available in the USA

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#### Market development timeline Process has to be country specific



# **Clinical study results on the GCAL performance**

Calprotectin as an early biomarker of bacterial infections in critically ill patients: an exploratory cohort assessment

Jonsson et al., Critical Care and Resuscitation, 2017

Plasma calprotectin appears to be a useful early marker of bacterial infections in critically ill patients, with better predictive characteristics than WBC (white blood cell count) and PCT (procalcitonin). Calprotectin is superior to procalcitonin as a sepsis marker and predictor of 30day mortality in intensive care patients

Larsson et al., Scand J Clin Lab Invest. 2020;80(2):156-161

Calprotectin performed better then Procalcitonin in diagnosis of sepsis and distinguishing between septic and non septic patients.

Calprotectin had also higher predictive ability regarding 30-day mortality then Procalcitonin.

Calprotectin, a new biomarker for diagnosis of acute respiratory infections

Havelka et al., Sci Rep. 2020; 10(1):4208

Calprotectin is a promising biomarker for diagnosis of bacterial infections and differentiation between viral infections and bacterial or Mycoplasma infections.

Rapid determination of calprotectin may improve the management of infections and allow more selective use of antibiotics.



# Clinical study results on the GCAL performance – New since last presentation

Kinetics of calprotectin, procalcitonin and C-reactive protein in healthy volunteers administered intravenous endotoxin

Fullerton et al., Critical Care, Meeting abstracts, ISICEM 2020

Calprotectin is a promising biomarker for rapid diagnosis of bacterial infections. It increases earlier and peaks more rapidly than standard biomarkers procalcitonin and CRP. Plasma-calprotectin compared with routine biomarkers for prediction of early severe event in sepsis

Parke et al., Critical Care, Meeting abstracts ISICEM 2020

In patients with sepsis, level of pcalprotectin was significantly higher in those who subsequently developed severe events. P-calprotectin was superior to traditional biomarkers for prediction of severe events in clinical sepsis.



#### **Study Highlights to date: Early - Differentiation - Prediction**

- Useful early biomarker of bacterial infections in critically ill patients, with better predictive characteristics than WBC (white blood cell count), CRP and PCT
- Increase of calprotectin in the blood is detected several hours before increase of PCT and CRP caused by inflammatory stimuli
- Better performance than PCT and HBP in differentiation between bacterial and viral respiratory infections
- Calprotectin successfully identifies patients with signs of infection and distinguish between infections and other diagnosis in patients presented at an Emergency Department.
- Calprotectin levels correlates with the severity of the disease
- Prognostic biomarker for development of severe complications and mortality
- Superior to PCT in indicating patients with sepsis and differentiation between sepsis and trauma patients



# Pushing the boundaries of PETIA with G-1001 in the product pipeline

#### Cardiac disease marker: G-1001\*



www.gentian.com

\* Launch planned in 2021

# Pipeline: 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



# Agenda







# New management team member as of Q2 2020

VP Global Sales: Markus Jaquemar started on April 1, 2020

- former employments at Beckman Coulter, Agilent, Becton Dickinson, etc.
- Master of Science (Mag. rer. nat.) Biology/Biochemistry, Univ. Vienna



# Outlook

- Gentian may be 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 growth to be driven by increased demand in China and an increased focus on the US market.
- For fCAL® turbo, we may experience reduced demand, at least for a short period of time. This assumption is based on the focus of all health care systems on the COVID-19 management.
- For GCAL, additional and independent clinical publications are in preparations. The company expects to commission prospective clinical studies in Germany and the UK during 1H2020.



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