

## H1 & Q2 21 Presentation

August 25th, 2021

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## **Today's presenters**



Hilja Ibert

CEO



Njaal Kind CFO & COO





## Introduction and Q2 highlights

## **Gentian's value proposition**





The growing diagnostic market puts increasing pressure on laboratories. Still, many of the existing, clinically relevant biomarkers are only available on slow and inefficient platforms.

By converting biomarkers to the most efficient automated, high-throughput analysers, Gentian contributes to saving costs and protecting life.



## Portfolio of high-impact tests provides solid growth opportunity



7\* tests contributing to saving costs and protecting life



Revenue ambition of NOK 1bn in 5-7 years



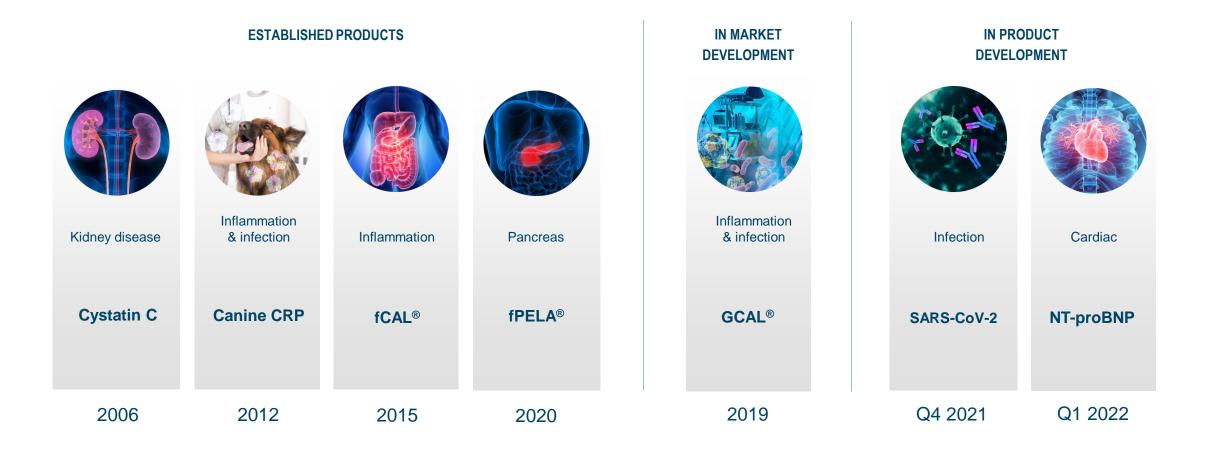


Delivered ~30% annual revenue growth 2017-20



\* 5 launched, further 2 in development.

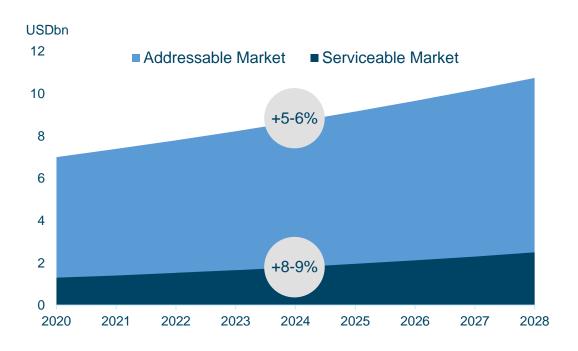
## 7 diagnostic tests, including two potential blockbusters





## Ageing and growing population driving diagnostics demand

#### Market outlook



#### Key drivers

#### **Addressable market**

 Increasing average age and population growth drives increase in chronic diseases and infectious diseases globally

#### Serviceable market

- Gentian's selective approach, targeting attractive segments
- GCAL<sup>®</sup> addressing severe infections and inflammations, providing exposure to one of the diagnostic industry's highest growing segments

#### **Gentian market share**

- High-value biomarkers offering clinical benefits
- Attractive solution to improve laboratory productivity

Addressable Market: Total demand within targeted markets 2020 (Kalorama 2020). Serviceable Market: The segment of the TAM targeted by Gentian's products (company estimates). Gentian's target market share is ~15-20%. Share of revenues net of partner take is 30-50% on average with product variations. Market growth rates = CAGR.



## Ambitions for impact, high growth and value creation

#### Market opportunity and long-term ambitions

5-7 year revenue ambition

NOK 1bn

Gross margin at volume production

60%+

Long-term EBITDA margins

40%

#### **Strategic pillars**

- Grow annual revenue from established products through additional commercial partners and regulatory approvals
- Prove clinical relevance of GCAL<sup>®</sup> for the early detection of severe infections, which supports the avoidance of sepsis and the severity assessment of COVID-19 patients
- Launch one new product per year; SARS-COV-2 Ab scheduled for Q4 2021 and NT-proBNP for Q1 2022
- Secure one new contract with a global commercial partner per year, building on established partnerships
- Grow gross margin through economies of scale
- Deliver healthy long-term EBITDA margins through operational leverage and cost discipline



## Q2 2021 highlights

Sales	<b>EBITDA</b>
NOK 25m	<b>NOK -1m</b>
+48% vs Q2'20	NOK -1m vs Q2'20
Cash NOK 139m NOK -22m vs Q2'20	Profitable pre-R&D based on current revenue from four established products

- Record total revenues of NOK 31.5m in Q2 21 and NOK 55.7m for H1 21
- EBITDA for 2Q21 was MNOK -0.8 including MNOK 3.5 of costs related to the transfer of listing to Oslo Børs
- Sales revenue of NOK 24.6m in Q2 21, a 48% growth compared to Q2 20. Organic growth was 65%\*. Sales growth for H1 21 was 35% with corresponding organic growth of 47%
- Development of the SARS COV-2 assay is on track for launch in Q4 21 and recent market data confirm the need for a high throughput test
- The Gentian share was successfully transferred to Oslo Børs on June 25th

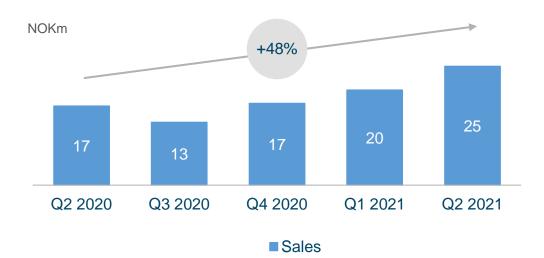






## **Operational review and growth opportunities**

# Sales growth driven by broad-based progress with commercial partners



- 48% sales growth (65% organic) driven by strong development for all products capturing shares in Europe and Asia
- Established products Cystatin C, fCAL<sup>®</sup> turbo, c-CRP and fPELA addressing serviceable market of ~USD 200m, estimated to grow by 5-10% annually
  - Significant room to expand market access through additional commercial partners
  - Targeting 20%+ annual growth from the established products



## **GCAL<sup>®</sup>** market development efforts focusing on validation



#### About GCAL®

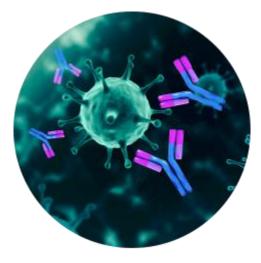
The early inflammation and infection biomarker GCAL<sup>®</sup> is the first calprotectin test available on high-throughput analysers, with first sales realized in 2019. Clinical studies confirm the potential of GCAL<sup>®</sup> for the early detection and prediction of severe infectious diseases. Sepsis kills 11 million people each year, and fast results provided by GCAL<sup>®</sup> could save lives and significantly reduce healthcare costs.

- New biomarker, requiring adoption by key opinion leaders, public and private laboratories
  - Serviceable market of ~USD 300m, estimated to grow by 15% annually
- 6 ongoing studies to confirm GCAL's clinical relevance for supporting the avoidance of sepsis and the severity assessment of COVID-19 patients
  - At least 2 publications expected during H2 21
  - In addition, results from COVID-19 study with four hospitals in Spain to be presented at Euromedlab meeting in Dec 21
- Validation of additional clinical chemistry platforms to drive further the commercial roll-out; 2 additional instruments expected in H2 21
- Ongoing dialogue with potential global commercial partners





## Upcoming product launches progressing as planned





#### About SARS-CoV-2 Ab

The aim with SARS-CoV-2 Ab, measuring COVID-19 immunity, is to offer the first such test for high-throughput analysers with focus on commercialisation in the Nordic markets.

#### About NT-proBNP

Gentian's NT-proBNP is the first test to support diagnosis of congestive heart failure available on high-throughput analysers – contributing to better diagnosis, monitoring and treatment.

- On track for launch of SARS-COV-2 Ab in Q4 21
  - Preparations for transfer into validation phase ongoing
  - Serviceable market of USD 20m in the Nordics
  - The Norwegian Ministry of Health and Care Services, has made a change in regulations that allows for the use of antibody tests to assess immunisation levels of vaccinated individuals
- NT-proBNP scheduled for launch Q1 22
  - Conclusion on reference method for standardisation on track for Q3 21
  - Outcome of reference method will impact rollout
  - Serviceable market of USD 800m, estimated to grow by 5-8% annually
- Limited contingency included in project plans
- Further 3 biomarkers addressing inflammations and infections, and cancer, currently in exploration and 'proof of concept'



## **Regulatory update: IVDR being introduced in 2022**

- The market Gentian operates in is highly regulated and the company must at all times comply with current legislation
- A new legislation is being introduced in Europe from May 2022
  - The current in vitro diagnostic directive will be replaced by a new in vitro diagnostic regulation (IVDR)
  - The regulatory environment in Europe will be tightened, increasing the regulatory responsibilities of in vitro diagnostic manufacturers
  - Gentian's implementation of the regulation is on track according to the timeline in an established milestone plan, and the company expects to complete the IVDR certification by 26th of May 2022 to ensure continued supply of products in accordance with IVDR
- The introduction of IVDR is expected to have limited impact on established products as Gentian is well prepared for the new regulation; for future launches there is a potential for industry wide bottlenecks based on external capacity with notified bodies



## On track for one new global commercial partnership per year

#### Partnerships prove viability of go-to-market model



Long-standing commercial partnership for Cystatin C



Partnership for fCAL initiated through Bühlmann Laboratories

- Gentian's main strategy is to secure broad roll-out through partnerships with global diagnostics companies
  - Adding one new resource to strengthen partner efforts
- Dialogue to extend existing partnership for one additional product ongoing
- Ongoing dialogue with 6 potential new global partnerships
  - On track for closing one new global partner for one Gentian product per year



Collaboration agreement for Canine CRP

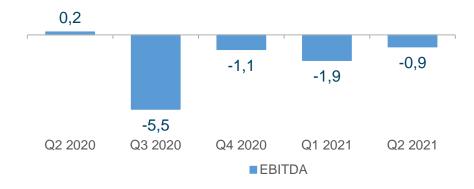


## Stable gross margin expected next 18 months



NOKm

NOKm



- Ambition for 60% gross margin at volume production
  - Expect COGS in % of sales to decline over time as sales grow and new products at higher margin increases as percentage of total sales
  - Stable gross margin levels expected in 2021 and 2022 with quarterly variations driven by customer and product mix
- Ambition for 40% long-term EBITDA margin
  - Plan to continue to increase investments throughout 2021 and 2022 to commercialize GCAL<sup>®</sup> and NT-proBNP





# Financial review

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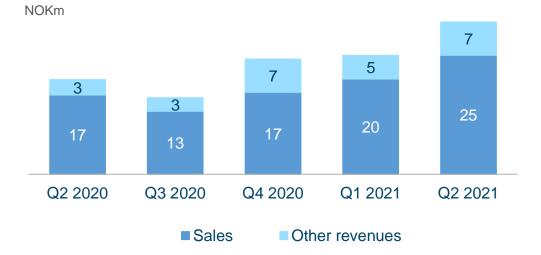
## **Financial highlights**

NOKm	Q2 2021	Q2 2020	H1 2021	H1 2020
Sales	24.6	16.6	44.2	32.9
Other revenues	6.9	3.2	11.5	6.1
Total revenues	31.5	19.9	55.7	39.0
COGS	11.4	6.3	21.8	16.2
Employee benefit expenses	8.7	9.4	18.4	18.4
D&A	2.0	1.6	4.0	3.1
Other OPEX	12.3	3.9	18.3	9.1
EBITDA	-0.9	0.2	-2.8	-4.7
EBIT	-2.8	-1.3	-6.8	-7.8



## Sales and other revenues

- Total revenue of NOK 31.5m in the quarter, up 58% vs Q2 20
- 65% organic sales (48% reported) growth driven by broad-based progress with commercial partners across product portfolio
  - Established products Cystatin C and fCAL<sup>®</sup> turbo experienced strong demand growth in Asia and Europe
- Other revenue growth driven by increased investments in R&D, boosting amounts received from grants and tax incentives



#### Sales - geographic split

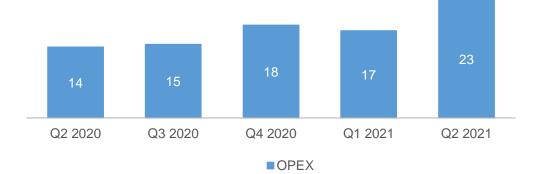
NOKm	Q2 21	Q2 20	H1 21	H1 20
US	1.0	1.0	1.4	1.7
Europe	15.7	9.9	29.7	21.1
Asia	7.9	5.7	13.1	10.1
Total	24.6	16.6	44.2	32.9

#### Sales - product split

NOKm	Q2 21	Q2 20	H1 21	H1 20
Cystatin C	11.1	8.5	18.5	15.0
fCAL® turbo	8.3	3.9	16.7	9.2
Other	5.2	4.3	9.0	8.7
Total	24.6	16.6	44.2	32.9



## **Operating expenditures in the quarter**



NOKm	Q2 21	Q2 20	H1 21	H1 20
Sales and marketing expenses	3.7	3.0	7.8	6.4
Administration expenses	8.9	6.0	14.4	11.0
Research and development expenses	10.7	5.0	18.3	10.7
Total	23.3	14.0	40.5	28.1

- OPEX increased by NOK 9.3 million vs Q2 20
  - Listing cost estimated to NOK 3.5 million booked in Q2
  - Increase in R&D spend primarily driven by development of SARS COV-2 and NT-proBNP assays
    - Partially offset by NOK 3.7 million increase in other revenue



## Strong cash position; fully financed business plan

NOKm	Q2 21	Q2 20	H1 21	H1 20
Operating activities	-2.9	1.1	-11.8	-8.6
Investing activities	-4.0	-1.2	-6.2	-1.7
Financing activities	-0.6	-0.1	-1.2	-0.1
Changes in cash and cash equivalent	-7.5	-0.2	-19.2	-10.4
Cash and cash equivalent at the beginning of period	146.1	161.4	158.0	171.6
Cash and cash equivalent at the end of period	138.6	161.2	138.6	161.2





## Summary and outlook

## Several de-risking milestones next ~18 months

	ESTABLISHED PRODUCTS	GCAL®	SARS-COV-2 AB	NT-PROBNP
2021-2022 MILESTONES	Targeting additional large commercial partners Additional regulatory approvals, including IVDR*	Clinical studies confirming relevance for early detection of infections and with this the support to avoid sepsis and the severity assessment of COVID- 19 patients – 6 ongoing Securing endorsements from key opinion leaders Securing global commercial partnerships and continuation of EU rollout	Successful validation and launch, scheduled for Q4 2021 Entering commercial partnerships for the Nordics	<ul> <li>Successful verification during 2021</li> <li>Publication on the reference method for standardisation</li> <li>Successful validation and launch, scheduled for Q1 2022</li> <li>Securing endorsements from key opinion leaders and global commercial partnerships</li> </ul>

Further potential milestones in pipeline with 3 biomarkers currently in exploration and 'proof of concept'

\* IVDR: A new regulation coming into force 26 May 2022, requiring extensive documentation of the safety, performance and quality of each diagnostic test from manufacturers through several studies on both analytical and clinical performance.





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## Q&A



## Appendix

# Gentian Diagnostics develops and supplies innovative and efficient reagents for the clinical diagnostics market

- Gentian serves the global market for human and veterinary clinical diagnostic tests
- Expertise and focus within immunochemistry, specifically in the disease areas infection, inflammation, kidney failure and congestive heart failure
- Gentian's innovative and efficient reagents can be used on all major clinical chemistry analysers, meaning no extra investments is required by the customer
- Sales mainly through global commercial partners, which are serving the laboratories being the end users
- 5 products launched to date and two further launches scheduled for Q4 2021 and Q1 2022, respectively
- Preparing to scale with a fully funded business plan



## Founded **2001**

Employees

~50

Revenue 2020 **NOK 79m** Up 32% Oslo listing **OSE: GENT** 

Market cap ~NOK 0.9bn



# How Gentian contributes to efficient diagnostics for better treatment decisions



### The industry challenge



A growing diagnostics market puts increasing pressure on clinical laboratory efficiency

Many of the existing, but clinically relevant biomarkers are available only on slow and inefficient platforms

Hours from initiation of analysis to results



### Gentian's solution



Particle-enhanced turbidimetric immunoassays (PETIA) based on proprietary nanoparticle technology and knowhow

Converting existing biomarkers to the most efficient automated, high-throughput analysers

10 minutes from initiation of analysis to results





3-10x higher throughput significantly improves laboratory productivity and cost-efficiency

Early disease detection and faster availability of clinically relevant information leads to better treatment decisions



## **Products targeting large and growing disease groups**

DISEASE GROUP	PRODUCT	APPLICATION	ATTRACTIVE CLINICAL BENEFITS
<ul> <li>Kidney disease</li> </ul>	Cystatin C	Early detection of reduced kidney function	Preventing severe kidney failure
<ul> <li>Inflammation &amp; infection</li> </ul>	fCAL	Fast diagnosis of inflammatory bowel disease	Reducing time-consuming and costly colonoscopy
	GCAL	Early detection of severe infections, including sepsis	Reducing chance of fatality and treatment costs
	SARS-CoV-2 Ab	Measuring COVID-19 immunity	Supporting community management
	Canine CRP	Early detection and diagnosis of inflammation in dogs	High relevance of results due to dog specific CRP
• Cardiac	NT-proBNP	Diagnosis, monitoring and assessment of congestive heart failure	Contributing to standardization of NT-proBNP assays
Pancreas	fPELA	Diagnosis of pancreatic elastase insufficiency in combination with fCAL	Reducing time-consuming and costly colonoscopy



# USD 1.3bn global serviceable market estimated to grow by 8-9% annually next 5-7 years

	Total Addressable Market, USDbn	Total Serviceable Market, USDm	Target market share, unrisked	Gentian's revenue take	Serviceable Market annual growth rate, next 5-7 years
Established products	1.5	180	~25%	30-50%	5-10%
GCAL	2.0	300	~15%	30-50%	15%
NT-proBNP	1.6	800	~15%	30-50%	5-8%
SARS-CoV-2 Ab	2.0	20	~25%	50%	n.m.
Total	7.1	1,300	15-20%	30-50%	8-9%

Key risks include market adoption rates for GCAL, and successful launch of NT-proBNP



# Combining avian antibodies and PETIA enables fast results and improved lab productivity

#### **Avian antibodies**

Avoiding interference enables conversion to PETIA

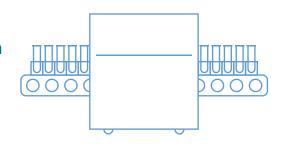
**Antibodies:** Proteins used by the immune system to identify bacteria and viruses

Avian antibodies: Extracted from hen eggs. Avoids interference due to lack of complement system binding antibodies and molecules, enabling analysis at lower concentrations than mammalian antibodies and conversion of existing biomarkers to PETIA

Advantages: Gentian uses avian antibodies when applicable and believes extraction from eggs rather than puncturing animals contributes to better animal welfare while also offering a cost advantage at scale

#### **PETIA**

Removing separation steps increases throughput and reduces cost



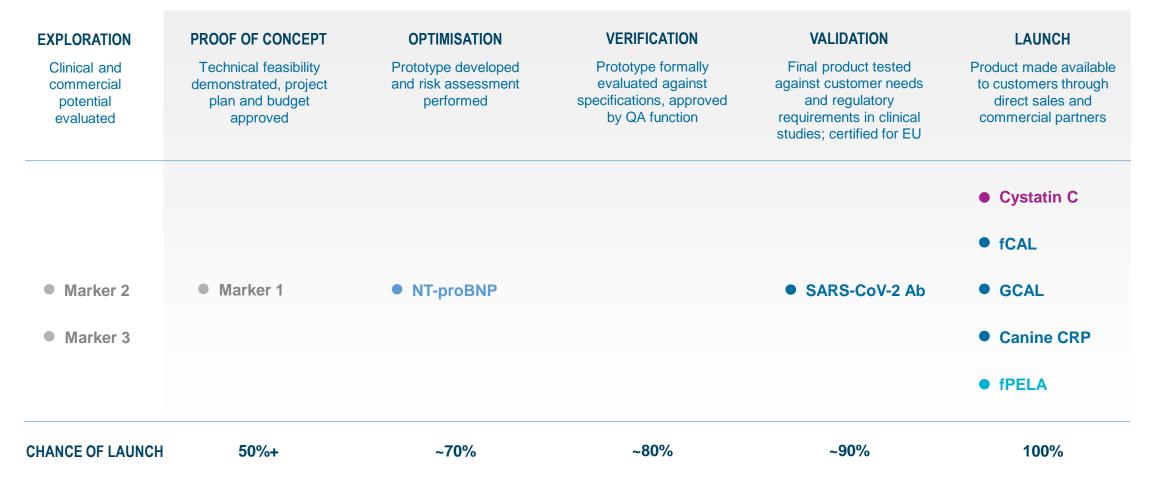
**Immunoassays:** Biochemical tests measuring molecule presence or concentration in human cells using an antibody

**Particle-enhanced turbidimetric immunoassays:** Enables moving immunoassays from low-volume to high-volume clinical analysers

Advantages: Moving immunoassays to PETIA enables removing separation steps, which increases throughput and laboratory efficiency compared to the traditional ELISA and other methods



## Structured approach to product development





# Diversified sales model to ensure broad market access and maximize penetration



#### **Global diagnostics companies**

- Gentian's main strategy to secure broad roll-out and acceptance of product
- Beckman Coulter and Bühlmann/Roche
   Diagnostics are current partners falling into this
   category
- Ambition to secure one new contract with global commercial partner per year



#### Specialized/local distributors

- Accelerating time to revenue and awareness
- Distribution agreements in several European countries and South Korea for GCAL, Cystatin C and Canine CRP



#### **Healthcare providers**

- Direct sales to select end-users and key opinion leaders, including laboratory and hospitals
- Sales representatives in US, Sweden and HQ in Norway
- Sales office in Sweden distributes Gentian and Bühlmann Laboratories complimentary products



### Gentian management



CEO Hilja lbert

25+ years' experience from the international diagnostic industry, including VP International Diagnostic Solutions at Hologic and senior positions within Becton Dickinson and bioMerieux. She was previously the CEO for miDiagnostics in Belgium. Dr. Ibert holds a PhD degree in Nutrition Science from the University of Bonn, Germany.



CSO Erling Sundrehagen

Erling Sundrehagen, cofounder of Gentian, holds 25 int. patents. He has headed the development of a dozen diagnostic products, creating businesses with NOK 1bn+ revenue. Dr. Sundrehagen held management positions in Axis-Shield. Axis Biochemicals and Axis Research, and is dr.med. & cand.real from University of Oslo. Norway.



CFO & COO

20+ years experience and

financial management and

governance and Investor

Manganese, France, and

Tinfos. Kind holds a MSc

Investment Director in

Relations. Mr. Kind has

served as the CFO for

in Eramet Comilog

from BI Norwegian

Business School.

reporting, corporate

Njaal

Kind

VP R&D Torsten Knüttel

18+ years' experience from extensive track-record from the diagnostic industry and commercial supply chain. His background includes OEM/B2B business development at Thermo Fisher Scientific and TiZir, UK, Business Analyst development and production at GE Healthcare. He holds a PhD in Chemistry from the Leibniz University Hannover, Germany.



Havelka

**VP Clinical Affairs** Alexandra

Extensive experience in laboratory medicine. She was previously Biochemist and Unit Manager at Karolinska University Laboratory, with research focusing on biomarkers for inflammation and infection. Dr Havelka holds a PhD in Experimental Oncology from Karolinska Institute in Stockholm, Sweden.



**VP Global Sales** Markus Jaquemar

30+ years experience in life science and diagnostics commercialisation and marketing. He held marketing, sales and business management positions at Beckman Coulter, Agilent Technologies and Becton Dickinson. He holds a Master's degree in Biology from Vienna University, Austria.



VP QA & RA Anne-Mette Horsrud Akre

20+ years of pharma industry experience, including production of pharmaceuticals and medical devices, quality management and assurance and management positions at GE Healthcare and Fresenius Kabi, She holds a Msc in Biotechnology from the Technical University of Trondheim, Norway.



VP BD Jack Andreassen

20+ years of experience from sales, market and business development from the global diagnostics industry. He was previously Associate Director, Global Market Development for OEM at Thermo Fisher. He holds a Msc in Chemistry. Biochemistry/Molecular Biology from the University of Oslo, Norway.

GE Healthcare



**Thermo Fisher** SCIENTIFIC











### **Gentian board**

Tomas Settevik	Espen Tidemann Jørgensen	Ingrid Teigland Akay	Kari E. Krogstad	Susanne Stuffers	Runar Vatne	Tomas Kramar
Chair of the Board	Board member	Board member	Board member	Board member	Board member	Board member
Tomas Settevik has experience in both life sciences and retail and is currently an independent investor and non-exec director in several companies. He was previously CEO of Stokke, and CEO of Pronova BioPharma after serving as Vice President Pharmaceuticals and Manufacturing. Mr. Settevik has also held several senior positions – VP Northern Europe, VP Marketing and R&D, and Managing Director UK/Nordic – at Tyco Healthcare EMEA. Mr. Settevik holds a degree from Copenhagen Business School.	Espen Tidemann Jørgensen is currently Portfolio Manager of Holta Invest and Managing Director of Holta Life Sciences. He has 18 years of financial markets experience as equity analyst at DNB Markets and investor. Mr. Jørgensen was previously member of the Board of Directors at Weifa and Cortendo, and is currently board member at Decisions. Mr. Jørgensen holds a Msc in Economics and has completed 3 years of Medicine studies at the University of Oslo.	Ingrid Teigland Akay is a life science investor and medical doctor. She has previously served as a Senior Investment Manager at Inventages. Ms. Akay has broad clinical experience in internal medicine and surgery at Scandinavian and UK hospitals. Today she is Managing Partner of Hadean Ventures, a life science investment firm with focus on the Nordics. Ms. Akay holds a medical degree from Medizinische Hochschule Hannover and an MBA in Finance from London Business School.	Kari Krogstad has more than 25 years of experience from the biomedical industry, from commercial leadership roles within the pharma, biotech and medtech sectors. Ms. Krogstad has held her current role as President and CEO at Medistim ASA since 2009. She was previously General Manager at Invitrogen Dynal. Ms. Krogstad holds a Cand. Scient. degree in Molecular Biology from the University of Oslo as well as a Business degree from IHM Business School.	Susanne Stuffers is currently managing partner of P53 Invest AS. Previously she was an equity analyst with Arctic Securities covering the healthcare sector, and management consultant at EY. Ms. Suffers has held medical and commercial roles at Novartis and has had clinical practice as a resident in oncology at OUS Ullevál. Ms. Stuffers holds an M.D. degree from the Erasmus University Rotterdam and a Ph.D. degree in cancer biomedicine from the Norwegian Radium Hospital.	Mr. Vatne is the principal and owner of Vatne Capital, a family office investing in financial assets and real estate. He is co-founder of Søylen Eiendom, a leading Oslo based real estate company, and was previously partner and stock broker in Pareto Securities. Mr. Vatne also serves as board member of listed companies Solon Eiendom ASA and Self Storage Group ASA. Vatne and associated companies currently own 14.49% of the outstanding shares in Gentian Diagnostics AS.	Mr. Kramar has more than 40 years of experience from the diagnostic industry including Siemens, Abbott and Roche Diagnostics. Mr. Kramar has held several senior positions like Global Business Manager, Business Director and CEO, as well as being a founding partner in the Kramar Group. In addition, Mr. Kramar has held several board positions over the years. Mr. Kramar holds an MSc degree in Chemistry from the Faculty of Engineering at Lund University in Sweden.



## **Top 20 shareholders**

Shareholder	No of Shares	%
Vatne Equity AS	2 010 224	13,04 %
Norda ASA	1 250 068	8,11 %
Holta Life Sciences AS	1 188 702	7,71 %
Safrino AS	1 050 000	6,81 %
Verdipapirfondet Delphi Nordic	817 045	5,30 %
Salix AS	786 903	5,11 %
Skandinaviska Enskilda Banken AB	783 903	5,09 %
Verdipapirfondet Storebrand Vekst	425 572	2,76 %
Verdipapirfondet DNB SMB	377 682	2,45 %
Equinor Pensjon	337 320	2,19 %
Portia AS	300 000	1,95 %
Cressida AS	235 000	1,52 %
Lioness AS	220 000	1,43 %
Silvercoin Industries AS	214 692	1,39 %
Marstal AS	212 407	1,38 %
Mutus AS	210 465	1,37 %
Vingulmork Predictor AS	184 083	1,19 %
Bård Sundrehagen	181 645	1,18 %
OM Holding AS	179 000	1,16 %
Viola AS	170 916	1,11 %
Other Shareholders	4 276 262	27,75 %
Total Shares	15 411 889	100.00%

