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# Innovative and efficient diagnostics

ADDRESSING HIGH-VALUE MARKETS

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# Efficient diagnostics for better treatment decisions



## High-impact diagnostics with global commercial traction

- Gentian is a fast-growing developer and manufacturer of diagnostic tests
- The tests are produced in Moss, Norway, and can • be used on all major clinical chemistry analysers
- They are sold globally, through direct sales and • partnerships with world-leading diagnostic companies
- The end-users are clinical laboratories that leverage • Gentian's tests to make better treatment decisions and save costs
- Gentian currently has 4 established diagnostic tests • being sold worldwide, 2 tests in market development and 1 test in product development
- The company invests in R&D to bring a steady stream of diagnostic tests to the market



#### Founded 2001

Employees

~50

Total revenue 2022 **MNOK 112** 

**OSE: GENT** 

**MNOK ~730** 



## Gentian develops and manufactures innovative and efficient diagnostic tests

#### **IN VITRO DIAGNOSTICS (IVD)**

- Tests done on samples that have been taken from the human body such as blood. IVD can detect diseases, infections or other medical conditions.
- IVD testing is a core component of routine healthcare check-ups for those who are presenting with symptoms or require procedures.
- IVD can be used to monitor a person's overall health to help cure, treat, or prevent diseases – and it influences up to 70% of critical healthcare clinical decision-making.

#### **GENTIAN DIAGNOSTICS**

- Focused on Immunoassay, the largest IVD segment, where an antibody<sup>1</sup> is used to target and detect the presence of certain biomarkers in a sample.
- Industry-leading expertise in developing highly sensitive particle-enhanced turbidimetric immunoassays (PETIA).
- PETIA enables moving immunoassays from low-volume to high-volume clinical analysers.







## Attractive value proposition: fast results at lower cost



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

- Hours from initiation of analysis to results
- Low throughput



Gentian converts existing biomarkers to the most efficient automated, highthroughput analysers

- 10 minutes from initiation of analysis to results
- High throughput



Faster results leading to better treatment decisions

3-10x higher throughput, improving laboratory productivity and cost-efficiency



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



#### 7\* tests contributing to saving costs and protecting life

USD 1.8bn serviceable market with 5-10% annual growth



## Industry-leading team and knowhow

Team with proven trackrecord and industry expertise from market leading IVD companies



#### Entered partnerships with 5 major global IVD companies

Long-term ambition of NOK 1bn revenue and 40% EBITDA margin\*\*



#### ~28% average annual sales growth 2019-22

2 'blockbuster' tests in market and product development



### **Dedicated and experienced management team**



CEO Dr. Hilja Ibert



**Consulting Founder** Dr. Erling Sundrehagen



CCO Markus Jaquemar



Dr. Alexandra Havelka







VP BD Jack Andreassen

Njaal Kind

CFO & COO



Dr. Torsten Knüttel

VP QA & RA Anne-Mette Horsrud Akre

20+ years of relevant industry experience across management positions

CSO

Track record from leading global diagnostics companies in across all phases

















## 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



## Positioned for strong value creation: high growth and scalability

Enabling 40% long-term EBITDA margin

#### Monthly sales revenue 2Q19-2Q23 LTM, NOKm



#### **Commercial traction** As per 1Q23

- Commercial interest for Gentian NT-proBNP in optimisation
- Two potential projects in 'proof of concept' phase
- Clinical studies confirm value of the product
- First agreements with global IVD companies concluded

 Delivered >25% sales CAGR since 2019-2022

• Targeting 20%+ sales growth 2022-2028



#### Pipeline products NOK 0-400m

**GCAL** NOK 100-300m

#### Established products NOK 250-300m

Note: Established products include 3<sup>rd</sup> party products sold through Gentian AB. Pipeline products include NT-proBNP currently in product development and two undisclosed projects in 'proof of concept' phase. In 2023, Gentian upgraded its lab facilities to provide increased efficiency and production capacity in line with the 5-6 year sales potential.



## **Delivered 28% sales growth last four years**



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

SIEMENS ... Healthineers

Global distribution agreement for GCAL<sup>®</sup>, initial roll-out in Europe



Long-standing commercial partnership for Cystatin C



Partnership for fCAL<sup>®</sup>turbo initiated through Bühlmann Laboratories



## Significant progress towards profitability

#### 2Q23 financials and key milestones

<b>Sales</b>	Gross margin
<b>MNOK 34.2</b>	56%
+13% vs 2Q22	52% in 2Q22
EBITDA	Several updated
MNOK 3.6	guidelines for
MNOK -1.2 in 2Q22	Cystatin C

#### **EBITDA positive in 2Q23 and 1H23**

#### Highlights

- Record sales of MNOK 34.2 in 2Q23, up 13% vs 2Q22. Revenue of MNOK 65.6 in 1H23 up 30% vs 1H22. Organic growth for the quarter was 2% in 2Q23 vs 2Q22 and 17% in 1H23 vs 1H22
- EBITDA of NOK 3.6 million in 2Q23 and NOK 3.1 million for 1H23, compared to EBITDA of NOK -1.2 million in 2Q22 and NOK -5.4 million 1H22
- Third Party product sales increased by 112% in Q2 and 68% for H1, driven by the new fCAL<sup>®</sup> turbo contracts in Sweden and Norway
- Increased use of Cystatin C recommended in updated guidelines for clinical use, of which the proposed update from KDIGO\* is the most recent one, resulting in further expansion of the global market
- Confirmed value, validated by clinical trial, of GCAL for early detection of severe infections and prediction of clinical deterioration in an emergency setting
- Acquisition of Getica AB (Gothenburg, Sweden) to secure unique R&D capabilities and to gain control of critical production competence with estimated operational gains of approximately NOK 2.0 million from 2024



## On track for profitability: operational leverage, long-term contracts and comfortable cash position





## Long-term ambitions rooted in recent progress

Four established products with potential to grow 20%+ annually

Prove clinical relevance of GCAL and bring NT-proBNP to market

Bring a steady stream of high-impact diagnostic tests to market

Secure one new contract with a global commercial partner per year

Grow gross margin from ~50% in 2021 to 60%+ at volume production

#### Long-term EBITDA margins of 40%







Unrisked revenue potential of NOK 1bn\*









\* Dependent on timing of NT-proBNP launch







## Appendix

## 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 costefficiency

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



## Strong demand growth: USD1.8bn market growing 5-10% annually

	Total Addressable Market, USDm	Total Serviceable Market, USDm	Target market share, unrisked	Gentian's revenue take	Serviceable Market annual growth rate, next 4-6 years
Established products	2,200	220	~25%	30-50%	5-10%
GCAL infection (sepsis)	1,000	440	~15%	30-50%	7%
GCAL inflammation	1,250	250	Under evaluation	30-50%	Under evaluation
NT-proBNP	1,700	900	~15%	30-50%	5-10%
Total	6,100	1,810	>15%	30-50%	5-10%

#### IVD market is driven by a growing and ageing population

In 2030, there will be 400 million more people over 60 years than in 2020 – driving demand for diagnostics

Sources: Kalorama 2022, WHO 2022, company estimates. Note: Key risks to target market shares include market adoption rates for GCAL, and successful launch of NT-proBNP. Upside potential from product candidates in exploration and 'proof of concept' phases not included.



## Several de-risking milestones expected next 12-18 months

	ESTABLISHED PRODUCTS	GCAL	PIPELINE PRODUCTS
IES	Targeting additional large and medium size commercial partners globally Achieve additional regulatory approvals	Clinical studies confirming patient outcomes and relevance for the early detection of infections, which supports the avoidance of sepsis as well as diagnosis of inflammatory diseases	Successful optimisation of NT-proBNP Securing endorsements of the assay from key opinion leaders
MILESTONES		Securing endorsements from key opinion leaders and inclusion in clinical guidelines Securing further global commercial partnerships with phased regional rollout	Obtain progress on global commercial partnerships Finalise proof of concept of two new projects Identify and confirm opportunities in exploration phase

Aiming to bring a steady stream of high-impact diagnostic tests to the market and all the way to commercial success



## **P&L** highlights

MNOK	2Q23	2Q22	1H23	1H22
Sales	34.2	30.1	65.6	50.7
Other revenues	2.0	2.8	4.1	5.3
Total revenues	36.2	32.9	69.8	56.0
COGS	-14.9	-14.4	-29.9	-26.0
Employee benefit expenses	-10.7	-11.6	-22.5	-20.1
D&A	-2.4	-2.7	-4.8	-4.8
Other OPEX	-4.6	-5.4	-9.5	-10.5
EBITDA	3.6	-1.2	3.1	-5.4
EBIT	1.2	-4.0	-1.7	-10.2



## **Cash flow highlights**

MNOK	2Q23	2Q22	1H23	1H22
Operating activities	7.1	1.0	3.8	-10.4
Investing activities	-1.1	-8.4	-2.2	-10.6
Financing activities	-1.2	-0.8	-2.3	-1.9
Changes in cash and cash equivalent	4.8	-8.1	-0.7	-22.9
Cash and cash equivalent at the beginning of period	76.0	100.2	81.6	114.9
Cash and cash equivalent at the end of period	80.7	92.1	80.7	92.1



## **Board of directors**

Tomas Settevik	Espen T. Jørgensen	Kari E. Krogstad	Kjersti Grimsrud	Fredrik Thoresen	Monika Neuman	Frank Frantzen
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, a large shareholder in Gentian Diagnostics. 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.	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.	Kjersti Grimsrud is currently President and COO of Infusion care at Convatec plc, where she has spent the last 5 years. She has over 30 years' experience in MedTech and IVD companies with roles in science, operations and commercial in Axis- Shield ASA and Alere Inc./Abbott, where she last held the position of VP Commercial EME (Europe Middle East) and International (APAC). Ms Grimsrud served as a board member of Biotec Pharmacon (now ArcticZymes technologies) from 2011 to 2015. Ms. Grimsrud holds a master's degree in biotechnology Norwegian University of Science and Technology	Fredrik Thoresen is a partner in Andenaes- gruppen where he joined in 2021. Mr. Thoresen has previous buy- and sell-side experience from Storebrand, SEB, DNB and Sector Asset Management. Mr. Thoresen has an MBA in International Business from Middlebury Institute of International Studies, Monterey, California and a bachelor's degree in Computer Science and Economics from Augustana University, Sioux Falls, South Dakota	Monika Neuman has 20 years of experience from the diagnostics industry and is currently Managing Director for Sarstedt Group in the Nordics. During the past 4 years, Ms. Neuman has been working at Siemens Healthineers Laboratory Diagnostics HQ in Tarrytown, NY, to set a successful strategy for launch and implementation of a new product portfolio on the global IVD market. Ms. Neuman holds a MSc degree in Biochemistry and a PhD degree in Clinical Bacteriology from Medical Faculty at Göteborg University in Sweden.	Frank Frantzen has more than 35 years of experience from the diagnostic industry. He has served as principal scientist and has directed larger R&D units in international IVD companies Axis-Shield, Alere and Abbott. Mr. Frantzen left his Senior Director R&D position at Abbott in 2021 and is currently serving as Chief Technology Officer in CardiNor AS. Mr. Frantzen holds a master's degree in chemistry and a PhD, both from the Norwegian University of Science and Technology in Trondheim.

in Trondheim.



## **Top 20 shareholders**

Shareholder	No of shares	%
Vatne Equity AS	2 110 224	13.68 %
Kvantia AS	1 623 368	10.53 %
Holta Invest AS	1 228 502	7.97 %
Verdipapirfondet Delphi Nordic	987 104	6.40 %
Safrino AS	749 700	4.86 %
Carpe Diem Afseth AS	536 589	3.48 %
Skandinaviska Enskilda Banken AB	497 273	3.22 %
Verdipapirfondet DNB SMB	361 291	2.34 %
Verdipapirfondet Storebrand Vekst	331 220	2.15 %
J.P. Morgan SE	325 000	2.11 %
Portia AS	300 000	1.95 %
Intertrade Shipping AS	257 716	1.67 %
Cressida AS	235 000	1.52 %
Krefting, Johan Henrik	229 900	1.49 %
Verdipapirfondet Equinor Aksjer NO	227 880	1.48 %
Lioness AS	220 000	1.43 %
Marstal AS	212 407	1.38 %
Mutus AS	210 465	1.36 %
Salix AS	208 954	1.35 %
Vingulmork Predictor AS	184 083	1.19 %
Other Shareholders	4 485 674	28.44 %
Total shares	15 422 350	100 %

