

# Second quarter and first half year 2023 results

# Efficient diagnostics for better treatment decisions

www.gentian.com

# **Gentian Diagnostics**

# Second quarter 2023 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, mainly driven by the new fCAL® turbo contracts in Sweden and Norway
- Increased use of Cystatin C recommended in updated guidelines, of which KDIGO is the most recent one, resulting in further expansion of the global market
- Confirmed value of GCAL, validated by clinical trial, for early detection of severe infections and prediction of clinical deterioration in an emergency setting. In addition, the cost-saving impact of GCAL was proven in a health economic model based on a study performed in an ICU 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

# **About Gentian Diagnostics**

Gentian Diagnostics (OSE: GENT), founded in 2001, develops and manufactures high-quality, in vitro diagnostic reagents. Gentian's expertise and focus lies within immunochemistry, specifically infections, inflammations, kidney failures and congestive heart failures. By converting existing and clinically relevant biomarkers to the most efficient automated, high-throughput analysers, the company contributes to saving costs and protecting life. Gentian is based in Moss, Norway, serving the global human and veterinary diagnostics markets through sales and representative offices in Sweden, USA and China. For more information, please visit www.gentian.com.

# Gentian's strategy for long-term growth and value creation

Gentian Diagnostic's purpose is to deliver efficient diagnostics for better treatment decisions.

The growing diagnostics market puts increasing pressure on clinical laboratory efficiency. However, many of the existing, clinically relevant biomarkers are available only on slow and inefficient platforms. Gentian's solution is to utilize PETIA (particle-enhanced turbidimetric immunoassays), based on proprietary nanoparticle technology and knowhow, to convert existing biomarkers to the most efficient automated, high-throughput analysers.

Gentian's portfolio of high-impact diagnostic tests targets several large and growing disease areas such as infections and inflammation, kidney failure and congestive heart failure. The company has four established products – Cystatin C, fCAL® turbo, Canine CRP and fPELA turbo – that contributed to 28% annual revenue growth in 2019-2022. In addition, SARS-CoV-2 Ab and GCAL® have been launched and are in market development while NT-proBNP is in the product development phase – with the two latter having potential to become growth accelerators. The company also has three undisclosed projects in exploration and 'proof of concept' phases.

In 2021, Gentian announced a long-term ambition to generate an estimated annual revenue of NOK 1.0 billion in 5-7 years, dependent on the timing of NT-proBNP launch yet to be concluded. In comparison, total revenue was NOK 111 million in 2022. The company's roadmap for long-term growth and value creation is founded on six strategic pillars:



Grow annual revenue from the company's four established products by 20%+ annually – by expanding market access through additional commercial partners and regulatory approvals.



Demonstrate clinical relevance of GCAL<sup>®</sup> for the early detection of severe infections.



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



Secure one new contract with a global commercial partner every year, building on already established partnerships with major diagnostic companies across products.



Grow gross margin from ~50% to 60%+ through economies of scale.



Deliver long-term EBITDA margins of 40% through operational leverage and cost discipline.

# Illustration of product categories



# **Operational summary**

# Sales

Sales revenue grew 30% in 1H23 versus 1H22, and 13% in 2Q23 versus 2Q22. The organic growth was 17% for the first half year and 2% for the quarter. With 30% growth after 6 months the sales momentum continues with a positive development. In 1H23, the revenue growth contribution was once more achieved by all products, and through all sales channels; from direct sales to distribution partners and global IVD (in vitro diagnostics) partners.

Sales of Cystatin C, which supports early detection of reduced kidney function, were MNOK 25.9 for 1H23 versus MNOK 21.4 in 1H22, an increase of 18%. Sales for the quarter were MNOK 12.3 versus MNOK 14.4 in 2Q22, corresponding to a 15% decrease. In the US the company's direct activities as well as sales through its recently established distribution partners continue to provide significant growth. Further Cystatin C testing adoption should be enabled by the recently proposed recommendations by KDIGO and others not only in the US, but also globally<sup>1</sup>. Continued commercial efforts by Gentian's partner Beckman Coulter also resulted in securing new customers in the US and Europe.

In 2023, orders have repeatably followed a more regular pattern, surpassing even the record levels of 2Q22. It is worth noting that the 2Q22 high increase was primarily due to precautionary stocking orders in response to reintroduced COVID restrictions in China last year. While variations between quarters can occur due to the shifting of larger order deliveries, it is now evident that the market in China has normalized.

Sales of fCAL<sup>®</sup> turbo, which supports fast diagnosis of inflammatory bowel disease, reached MNOK 21.5 for the first half year in 2023 compared to MNOK 15.6 for the same period last year, recording a 38% increase in sales in the period. The 2Q23 sales also display strong growth, with MNOK 12.0, a 35% increase vs 2Q22. The significant growth in 2Q and 1H is due to continued higher adoption of fecal testing in routine laboratories combined with regional expansion of commercial activities by

<sup>&</sup>lt;sup>1</sup> KDIGO is a global organization developing and implementing evidence-based clinical practice guidelines in kidney disease.

Bühlmann Laboratories and its channel partners, including Roche Diagnostics.

The company's Swedish distribution subsidiary, Gentian Diagnostics AB (GAB), continued to demonstrate a positive sales trend for thirdparty products and for the Gentian portfolio. Revenue from third-party distribution amounted to MNOK 9.3 in 1H23 versus MNOK 5.5 in 1H22 and MNOK 5.7 in 2Q23 representing an increase of 112% compared to 2Q22. The sales growth is the result of recently acquired large customers in Norway and Sweden and their routine implementation of products offered by GAB.

# **Market development**

## **GCAL**<sup>®</sup>

The GCAL® immunoassay, for the quantification of calprotectin in serum and plasma, has demonstrated to improve patient outcomes and contribute to early detection of infections, supporting the avoidance of sepsis as well as diagnosis of inflammatory diseases.

Data from the CASCADE study (Calprotectin in Acute Infections and Sepsis for Prognosis, Characterization and Diagnosis in the Emergency Department), in collaboration with Charite University Hospital and Labor Berlin were presented at the European Congress of Microbiology and Infectious Diseases (ECCMID) in April 2023. The data were presented by the principal investigator of the study, Dr. Wolfgang Bauer, who confirmed the value of GCAL in early detection of bacterial infections, estimation of disease severity and prediction of clinical deterioration. Results from this study support use of calprotectin in the Emergency Department, for early diagnosis of infections and optimal treatment decisions.

The market development of GCAL® continued to develop positively, driven by a growing body of scientific evidence supporting the relevance

A differentiating element contributing to the company's sales growth in Europe is the early achievement of the IVDR<sup>2</sup> registration of its major products (GCAL<sup>®</sup>, Cystatin C, fCAL<sup>®</sup> turbo) during 2022 as well as the achievement of UK registration and MDSAP<sup>3</sup>.

It demonstrates Gentian's commitment to providing quality products to the market, which continues to contribute to strengthening customer relations.

Quarterly variations to sales are expected to continue as sales are affected by the timing of large orders

of the immunoassay and initial traction with global partners.

GCAL<sup>®</sup> sales from direct and partner efforts continue to evolve positively with recurring sales from both existing and new routine customers.

GCAL<sup>®</sup> validation on additional clinical chemistry platforms continues, including the Beckman Coulter DXC700 AU platform, introduced in 2022, and for the recently introduced DXC500AU validation is expected to be established in 2H 2023.

Health economic analysis has been performed supporting that early diagnosis of bacterial infections and earlier start of antibiotic treatment in critically ill patients are beneficial, not only from the clinical, but also from a cost-saving perspective. A health economic model, developed for use of GCAL® in ICU (Intensive Care Unit) has confirmed that the use of GCAL® for early detection of infection saves costs, reduces the duration of patient care in the ICU and in the general ward, and reduces in-hospital mortality in those patients. Compared to other biomarkers, routinely used calprotectin, analysed by GCAL® Calprotectin

<sup>&</sup>lt;sup>2</sup> In Vitro Diagnostics Regulation which came into force on May 26, 2022

<sup>&</sup>lt;sup>3</sup> Medical Device Single Audit Programme

Immunoassay, has shown to reduce total costs by approximately 11 000 – 15 000 EUR per patient, overall mortality rate by 0.11, and mean length of stay in an ICU and general ward by 1.3 – 2 days and 6.9 - 7.8 days, respectively. The model supports previous findings that early detection of severe infections and sepsis has both cost-saving and life-saving impact in the ICU setting. This health economic study has been accepted for publication and is published in Biomedicines 2023, 11(8), 2156.

# **Product development**

# NT-proBNP

Gentian's NT-proBNP assay is currently in the optimization phase of development and aims to be the first turbidimetric in vitro diagnostic test for the quantitative measurement of NTproBNP. The goal is to make NT-proBNP testing more accessible on high-volume clinical chemistry analyzers, which should increase laboratory productivity and reduce overall costs. The growing cost burden in healthcare systems due to an aging population and lifestyle choices is driving the demand for NT-proBNP testing.

During the second quarter, the prototype stability has been extended and the performance of the assay has been tested with material from healthy volunteers. The results from these investigations enable further progress in the preparations to study the capacity of the prototype assay in a cohort of clinical patient material.

In parallel, the measurements and quantifications of the impact of glycosylation on the NT-proBNP molecule have continued, which is of importance for the calibration of the assay.

Despite continuous progress, the company is still unable to provide a specific timeline for the completion of the remaining optimization phase. However, if the product successfully completes this phase, subsequent phases are typically characterized by lower risk. We estimate that the development period for NT-proBNP after completion of optimization will be between 6 and 9 months.

It is important to note that the product will now fall under the new IVDR regulatory regime, which will add an additional 6-9 months before commercial launch. As per our established practice, if the current optimization efforts do not prove successful, we will consider returning the project to the exploration phase.

## **Pipeline**

The company continues to have two projects in the proof-of-concept phase. Market research was conducted in 2022 for one of these projects, which is addressing an alternative IVD market, confirmed a significant commercial potential for this project. The company continues to make investments into exploration projects to ensure future additions to the project pipeline. In addition, Gentian continuously utilizes its network with global IVD companies to evaluate exploratory projects to strengthen the project pipeline.

Gentian is also considering possibilities related to insourcing of products developed by partners which could be manufactured and sold by Gentian.

# Long-term outlook

Gentian targets disease groups that represent a total addressable market of around BUSD 6.1 globally and an estimated growth rate of 4-5% annually over the next 4-6 years, according to leading market data provider Kalorama (2022). From a macro perspective, key growth drivers include a growing and ageing population contributing to an increase in chronic and infectious diseases globally.

The specific segments targeted by Gentian's products add up to a total serviceable market of BUSD 1.8 (2022), with an estimated annual growth rate of 5-10% over the next 4-6 years. The key driver for the higher expected growth rate in the serviceable market is Gentian's selective approach to target attractive segments.

Overall, Gentian targets a market share of 15-20% for its product portfolio which is offered through commercial partners. With a commercial strategy to serve the market through OEM and distribution agreements it is expected that the revenue take will vary across products but remain within the 30-50% range for the product portfolio as a whole.

The company's strategy for growing its market share is founded on innovative biomarkers based on PETIA technology and proprietary know-how offering clinically relevant benefits, supported by an effective go-to-market strategy. The benefits include early diagnostic results that enable improved treatment decisions and a 3-10x increase in volume throughput that saves costs and makes Gentian's offering an attractive solution to the increasing pressure on laboratory productivity.

The 5–7-year revenue ambition of NOK 1 billion, which Gentian announced in 2021, and the long-term EBITDA margin target of 40%, are set to be de-risked through several key milestones for the company's product portfolio over the coming 12 months. The revenue ambition is dependent on the timing of NTproBNP launch, which was estimated to contribute with MNOK 200-400 five to seven years after the product has been launched.

The key milestones are:

# **Established products**

- Targeting additional large and medium size commercial partners globally.
- Additional regulatory approvals to allow for geographical expansion.

# GCAL® (in market development)

- Clinical studies confirming improved patient outcomes and relevance for the early detection of infections, which supports the avoidance of sepsis as well as diagnosis of inflammatory diseases.
- Securing endorsements from key opinion leaders and inclusion in clinical guidelines.
- Securing global commercial partnerships with phased regional rollout.

# New products

## NT-proBNP

- Successful optimization of the assay.
- Securing endorsements from key opinion leaders.
- Obtain progress on global commercial partnerships.

#### Pipeline

• Finalize proof-of-concept for two new pipeline projects.

# **Risks and uncertainty**

As described in the Annual Report for 2022, the company has a structured approach to identifying and mitigating risks. Some of these risks are outside of Gentian's control, including increased risks related to cost inflation, potential supply chain issues, currency volatility and access to growth capital given the recently observed impact on general investor sentiment and investors' required rate of return.

As a response to the Russian invasion of Ukraine in February 2022, many governments imposed targeted sanctions and restrictive export control measures to Russia and regions of Ukraine. Gentian has not supplied products and services to targeted areas, nor scoured any raw materials from these areas. At the time of publication of this report, there is no indication of notable impact to revenue nor raw material supply. The company continues to monitor the situation to early detect possible causes for concern going forward. Gentian has experienced limited impact from increased inflation, but the company expects some inflationary effects on its cost base to materialise in the coming quarters although at a moderate level. There is a risk that increased costs cannot be fully transferred to customers in the form of higher prices without negatively impacting demand.

The Group has experienced increased fluctuations in exchange rates which affects the group's cash flow and financial condition. The group undertakes various transactions in foreign currencies and is consequently exposed to fluctuations in exchange rates. The exposure arises largely from sale of diagnostic products. The group currently does not hedge against foreign currency risk and is mainly exposed to fluctuations in EUR, USD, CHF and RMB. The group monitors movements in the main currencies which it is exposed to and may put in place hedges if deemed necessary.

# **Financial performance**

Comparative numbers for Gentian in 2022 in ().

# Revenue, geographic split and product split

Total operating revenue amounted to MNOK 36.2 (MNOK 32.9) for 2Q23. Total operating revenue for 1H23 amounted to MNOK 69.8 (MNOK 56.0).

Sales revenue increased by 13% to MNOK 34.2 in 2Q23 (MNOK 30.1), with organic revenue growth of 2%. Sales revenue for 1H23 increased 30% with organic revenue growth of 17%.

Revenues from the US market were MNOK 2.8 for 2Q23 (MNOK 1.5), and MNOK 4.8 for 1H23 (MNOK 2.8) representing a growth of 92% and 73% respectively. Europe also experienced strong growth with revenues increasing 33% to MNOK 25.5 in the quarter (MNOK 19.2) and 38% or MNOK 47.6 (MNOK 34.3) in the first half year of 2023. Business in Asia is stabilizing. While 1H sales in Asia are essentially flat, 2Q23 was negatively impacted by a seasonal order shift from 2Q to 3Q and COVID restriction related stocking in 2Q22. Strong growth was recorded in Europe and the US with 33% and 92%, respectively, compared to 2Q22.

MNOK	2Q23	2Q22	1H23	1H22
US	2.8	1.5	4.8	2.8
Europe	25.5	19.2	47.6	34.3
Asia	5.9	9.4	13.3	13.5
Total	34.2	30.1	65.6	50.7

# Geographic split

During 1H23 the group has recorded sales growth for all products compared to 1H22. The sales of Cystatin C grew by 18% in the first half of 2023, while the sales in 2Q23 was slightly lower than the particularly strong sales experienced in 2Q22. This was due to the previously mentioned single order shift from 2Q to 3Q and stocking in 2Q22. Sales of fCAL turbo continued to develop positively with sales increasing 35% in 2Q23 compared to 2Q22. The distribution of third-party products conducted by the Swedish subsidiary Gentian Diagnostics AB (GAB), continues to expand its activities in the Nordic region. Sales increased by 112% in 2Q23 compared to 2Q22.

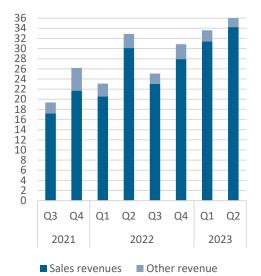
# Product split

MNOK	2Q23	2Q22	1H23	1H22
Cystatin C	12.3	14.4	25.9	21.9
fCAL <sup>®</sup> turbo	12.0	8.8	21.5	15.6
Third party products	5.7	2.7	9.3	5.5
Other	4.2	4.2	9.0	7.7
Total	34.2	30.1	65.6	50.7

Approximately 73% (83%) of the sales revenue in the quarter come from long-term contracts with established customers.



# Consolidated Revenues (MNOK)



Other operating revenue ended at MNOK 2.0 (MNOK 2.8) for 2Q23 and consists of public grants related to the company's R&D projects.

# Cost of goods sold

Cost of goods sold (COGS) was 44% (48%) of sales revenue in 2Q23. Gentian experienced a positive effect related to the high activity in the quarter which more than absorbed higher prices on raw materials. The positive development is also due to the current favourable foreign exchange rates. Considering recent macroeconomic data, Gentian expects further increases in raw material prices and labour cost during 2023, but maintains its ambition that over time, COGS as a percentage of sales revenue will decline with increasing sales.

## Total other operating expenses

Total other operating expenses before capitalisation of R&D expenses ended at MNOK 18.4 (MNOK 20.7) in 2Q23.

R&D expenses amounted to 35% (30%) of total other operating expenses before capitalization in 2Q23. Capitalisation of R&D expenses was MNOK 0.7 (MNOK 1.0) in the quarter. Total other operating expenses after capitalisation of R&D expenses was MNOK 17.7 (MNOK 19.7) in 2Q23.

# Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK 3.6 (MNOK -1.2) for 2Q23. Net profit was MNOK 0.9 (MNOK -3.0).

## **Balance sheet**

Cash and cash equivalents as of 30 June 2023 were MNOK 80.7 (MNOK 92.1). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 30 June 2023 were MNOK 11.0 (MNOK 14.7), and inventory MNOK 42.4 (MNOK 34.6). The inventory increase is partly a result of increased activity and partly due to the company's measures to mitigate potential shortages from a congested supply chain.

The equity ratio was 81.8% as of 30 June 2023.

# Corporate

As announced on 15 June 2023, Gentian Diagnostics ASA entered into an agreement to acquire Getica AB from Erling Sundrehagen. Getica AB, located in Gothenburg Sweden, is currently offering antibody purification services exclusively to Gentian Diagnostics and is also a provider of diagnostics research & development services.

With this acquisition, Gentian Diagnostics will secure critical production competence in an essential step in the manufacturing process and realize operational gains estimated to be approximately NOK 2.0 million from 2024. In addition, Gentian Diagnostics will gain access to unique R&D capabilities.

# Events after the balance sheet date

The acquisition of Getica AB was successfully closed on 3 July 2023 and the final purchase price was SEK 2.8 million.

# **Responsibility statement**

We confirm, to the best of our knowledge, that the unaudited interim financial statements for the period 1 January to 30 June 2023 have been prepared in accordance with IAS 34 - Interim Financial Reporting and that the disclosures in the accounts provide a true and fair view of the company's and the Group's assets, liabilities, financial position and overall results, and that the half-year report provides a fair overview of the information specified in section 5-6, fourth paragraph, of the Norwegian Securities Trading Act.

To the best of our knowledge, that the interim report provides a true and fair overview of key events in the accounting period and their influence on the interim financial statements, the most important risk and uncertainty factors the Group faces during the next accounting period and significant transactions with closely related parties.

Moss, 23. August 2023

On behalf of Gentian Diagnostics ASA,

Tomas Settevik Chair of the board (sign.)

Kjersti Grimsrud Board member *(sign.)* 

Fredrik Thoresen Board member (sign.)

Frank Frantzen Board member (sign.) Espen Tidemann Jørgensen Board member (sign.)

> Kari E. Krogstad Board member (sign.)

> Monica Neuman Board member (sign.)

> > Hilja Ibert CEO *(sign.)*

# Statement of Profit and Loss – Gentian Diagnostics Group

	Note	2023	2022	2023	2022	2022
(NOK 1000)		Q2	Q2	01.01- 30.06	01.01- 30.06	01.01- 31.12
Revenue						
Revenue from contracts with customers	3	34 179	30 095	65 616	50 653	101 636
Other operating revenue	4	1 981	2 781	4 144	5 313	10 287
Total revenue		36 159	32 876	69 760	55 966	111 922
Operating expenses						
Cost of goods sold	6	-14 894	-14 392	-29 910	-26 005	-52 635
Employee benefit expenses	7,13	-10 669	-11 606	-22 485	-20 148	-40 910
Depreciation and amortisation		-2 414	-2 740	-4 772	-4 802	-10 243
Other operating expenses		-7 003	-8 119	-14 287	-15 239	-31 369
Total operating expenses	5	-34 979	-36 857	-71 455	-66 193	-135 158
Operating result		1 180	-3 981	-1 695	-10 227	-23 235
Finance income		993	2 835	3 509	3 906	3 831
Finance cost		-1 266	-1 844	-1 564	-3 294	-4 213
Net financial items		-272	991	1 946	612	-382
Profit before tax		908	-2 990	251	-9 615	-23 618
Income tax expense		-	-	-	-	-
Profit for the period		908	-2 990	251	-9 615	-23 618
Other comprehensive income						
Exchange differences		-97	-2	-180	18	-331
Total other comprehensive income		811	-2	71	18	-331
Total comprehensive income for the period		811	-2 992	71	-9 597	-23 949

2<sup>nd</sup> quarter Statement of Profit and Loss is not audited

# Statement of Financial Position – Gentian Diagnostics Group

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No	ote	2023	2022	2022
(Figures in NOK thousands)		30.6	30.6	31.12
Assets				
Non-Current Assets				
Intangible assets	9	27 117	26 415	26 820
Property, plants and equipment		9 645	10 160	9 251
Right-of-use assets		10 972	13 760	12 386
Total Non-Current Assets	_	47 734	50 335	48 458
Current Assets				
Inventory		42 379	34 558	38 544
Accounts receivables and other receivables		19 562	24 673	19 188
Cash and cash equivalents		80 727	92 113	81 599
Total Currents Assets		142 669	151 344	139 332
		400,400	004 679	407 700
Total Assets	-	190 403	201 678	187 790
Equity and liabilities				
Paid-in equity				
Share capital	11	1 542	1 542	1 542
Share premium		293 810	293 810	293 810
Other paid-in equity		16 808	13 315	15 294
Total paid-in equity	_	312 160	308 667	310 646
Retained earning				
Retained earning		-156 406	-142 125	-156 477
Total retained equity		-156 406	-142 125	-156 477
Total equity		155 754	166 543	154 170
Liabilities	10		10.070	44.004
	10	11 011 <b>11 011</b>	12 273	11 624
Total non-current liabilities	-	11 011	12 273	11 624
Current liabilities				
Accounts payable and other current liabilities		23 638	22 862	21 996
Total current liabilities	_	23 638	22 862	21 996
Total liabilities		34 649	35 135	33 620
Total equity and liabilities		190 403	201 678	187 790

2<sup>nd</sup> quarter Statement of Financial Position is not audited

# Statement of changes in equity

(figures in NOK thousands)

		01	Other	<b>D</b>	<b>T</b> ( )
	Share	Share	paid-in	Retained	Total
Equity at 04 04 2022	capital	premium	capital	earnings	equity
Equity at 01.01.2022	1 542	293 810	11 941	-132 528	174 766
Net result for the year				-9 615	-9 615
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			1 374		1 374
Other changes in equity				18	18
Equity at 30.06.2022	1 542	293 810	13 315	-142 125	166 543
Equity at 01.01.2022	1 542	293 810	11 941	-132 528	174 766
Net result for the year				-23 618	-23 618
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			3 353		3 353
Other changes in equity				-331	-331
Equity at 31.12.2022	1 542	293 810	15 294	-156 477	154 170
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Equity at 01.01.2023	1 542	293 810	15 294	-156 477	154 170
Net result for the year				251	251
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			1 514		1 514
Other changes in equity				-180	-180
Equity at 30.06.2023	1 542	293 810	16 808	-156 406	155 754

2<sup>nd</sup> quarter Statement of changes in equity is not audited

# **Cash Flow Statement**

	2023	2022	2023	2022	2022
(NOK 1000)	Q2	Q2	01.01- 30.06	01.01- 30.06	01.01- 31.12
Operating activities					
Net profit (loss)	908	-2 990	251	-9 617	-23 618
Depreciation and amortisation	2 414	2 739	4 772	4 802	10 243
Change Inventory	-3 248	-3 110	-3 835	-4 778	-8 765
Change Accounts Receivables	4 430	-4 347	-979	-8 143	-3 550
Change Accounts Payables	5 300	5 639	3 677	2 130	-532
Accrued cost of options	761	1 130	1 514	1 374	3 353
Change in other assets and liabilities	-3 478	1 945	-1 595	3 847	8 917
Net cash flow from operating activities	7 086	1 006	3 805	-10 386	-13 952
Investing activities					
Payments of property, plant and equipment	-423	-7 321	-694	-7 321	-8 637
Investment in intangible assets	-695	- 1 054	-1 485	-3 284	-6 029
Net cash flow from investing activities	-1 118	-8 375	-2 179	-10 605	-14 666
Financing activities	-	-	-	-	-
New debt		-	-	-	-
Lease payments	-1 176	-755	-2 324	-1 882	-4 325
Proceeds from issue of share capital	-	-	-	-	-
Net cash flow from financing activities	-1 176	-755	-2 324	-1 882	-4 325
Net change in cash and cash equivalent	4 791	-8 124	-698	-22 873	-32 943
Cash and cash equivalents at beginning of period	76 017	100 237	81 599	114 936	114 936
Effect of currency translation of cash and cash equivalents	-81		-174	50	-395
Net Cash and cash equivalents at period end	80 727	92 113	80 727	92 113	81 599

2<sup>nd</sup> quarter Cash Flow Statement is not audited

# Notes

#### 1. General information

Gentian Diagnostics ASA is registered in Norway and listed on the Euronext Oslo Børs. The company's headquarters are in Bjørnåsveien 5, 1596 Moss, Norway. The company is a research and developmentbased company that develops and manufactures biochemical reagents for use in medical diagnostics and research. The customers are medical laboratories and universities worldwide. The group consists of the parent company Gentian Diagnostics ASA and the subsidiary Gentian AS.

In addition, Gentian AS has a wholly owned subsidiary, registered in Florida, USA, named Gentian USA Inc, and a wholly owned subsidiary in Sweden, Gentian Diagnostics AB.

#### 2. Accounting principles

The interim condensed consolidated financial statements for the group are prepared using the same accounting principles and calculation methods as used for the annual financial statements 2022 for Gentian Diagnostics ASA.

The accounting principles used have been consistently applied in all periods presented, unless otherwise stated.

Amounts are in thousand Norwegian kroner unless stated otherwise. The groups presentation currency is NOK (Norwegian kroner). This is also the parent company's functional currency. The company uses currency rates published by DNB ASA.

#### 2.1. Basis of preparation

The quarterly financial statements of the group have been prepared in accordance with IAS 34 Interim Financial Reporting Standards and interpretations in issue but not yet adopted.

No new accounting standards and interpretations have been published that have been assessed to be of material impact for the group in 2023.

#### 2.2. Basis of consolidation

The consolidated financial statements comprise the financial statements of the company and its subsidiaries. As of 30 June 2023, Gentian AS, located in Moss, Norway is a 100% owned and controlled subsidiary.

#### 3. Sales and revenue

Revenue by classification	2Q23	2Q22	1H23	1H22	2022
Sales revenue	34 179	30 095	65 616	50 653	101 636
Public grants	1 981	2 781	4 144	5 313	10 287
Other revenue	-	-	-	-	-
Total	36 159	32 876	69 760	55 966	111 922
•					
Sales revenue Geographical split	2Q23	2Q22	1H23	1H22	2022
Europe	25 473	19 205	47 557	34 345	71 571
Asia	5 904	9 433	13 243	13 509	23 609
USA	2 803	1 457	4 817	2 800	6 456
Total	34 179	30 095	65 616	50 653	101 636
Sales revenue by product category	2Q23	2Q22	1H23	1H22	2022
Renal diagnostic products	12 253	14 417	25 861	21 927	39 966
Inflammation diagnostic products	14 203	10 716	25 549	21 455	42 886
Other diagnostic products	7 723	4 962	14 206	7 271	18 784
Total	34 179	30 095	65 616	50 653	101 636

#### 4. Public Grants

Gentian has recognised public grants from the Norwegian Research Council, Innovation Norway, Eurostars and SkatteFUNN.

	2Q23	2Q22	1H23	1H22	2022
Norwegian Research Council and Eurostars	1 200	1 977	2 675	3 567	6 298
Innovation Norway	-	-	-	-	-
SkatteFUNN	781	804	1 468	1 746	3 989
Total	1 981	2 781	4 144	5 313	10 287

#### 5. Operating expenses by function

	2Q23	2Q22	1H23	1H22	2022
Cost of goods sold	14 894	14 392	29 910	26 005	52 635
Sales and marketing expenses	5 892	6 812	11 196	11 406	21 490
Administration expenses	6 032	7 611	13 185	14 311	27 973
Research and development expenses	5 747	5 302	12 391	9 670	22 817
Depreciation	2 414	2 740	4 772	4 801	10 243
Total	34 979	36 857	71 455	66 193	135 158

#### 6. Cost of goods sold

	2Q23	2Q22	1H23	1H22	2022
Change in inventory of goods under manufacture and finished goods	403	-2 764	-388	-132	1 368
Purchase of goods	8 725	10 893	17 644	13 257	24 412
Production salary	4 499	3 683	10 185	8 830	20 978
Other production expense	1 267	2 581	2 468	4 049	5 877
Total	14 894	14 392	29 910	26 005	52 635

#### 7. Employee benefit expenses

	2Q23	2Q22	1H23	1H22	2022
Wages and salaries	11 481	11 434	24 914	22 777	48 456
Payroll tax	1 999	1 572	3 821	3 093	5 876
Pension costs (mandatory occupational pension)	678	930	1 537	1 318	3 171
Share based payments	761	1 130	1 514	1 374	3 353
Other expenses	250	223	884	417	1 032
Transfer to COGS	-4 499	-3 683	-10 185	-8 830	-20 978
Total	10 669	11 606	22 485	20 148	40 910

#### 8. Research and Development expenses

The Gentian Group has per 30 June 2023 four ongoing R&D projects. Costs related to the projects consist of salary, external procurement of services, and other operating expenses. One project went over in the development phase in 2016 and one additional in 2021, and consequently the capitalisation of the costs in these projects was started.

Recognised research and development expenses	2Q23	2Q22	1H23	1H22	2022
Purchase of external services	1 934	1 027	3 467	2 903	7 972
Salary and other operating expenses	4 509	5 245	10 409	9 967	20 873
Capitalised research and development expenses	-695	-970	-1 485	-3 200	-6 029
Total	5 747	5 302	12 391	9 670	22 817

#### 9. Intangible assets

As of 30 June 2023, the recognised intangible assets in the Group amounts to MNOK 27.1. The intangible assets are derived from capitalisation of R&D expenses.

Intangible assets are tested for impairment at least annually, or when there are indications of impairment.

The impairment test is based on an approach of discounted cash flows. The valuation is sensitive to several assumptions and uncertainties, and the result from the valuation is thus limited to ensure sufficient certainty for the recognised amount in the financial statement.

#### 10. Interest bearing debt

Loan and loan expenses is recorded in the balance sheet and expensed in the Statement of Profit and Loss at amortised cost. If a loan and loan expenses is related to an asset, and the real value of the asset is lower, the asset is written down to its real value. There was no value adjustment of assets in 2Q23.

Interest bearing debt for Gentian is relating to instrument leases and calculated leases based on contracts according to IFRS 16.

#### 11. Share capital and number of shares

20 largest shareholders in Gentian Diagnostics ASA as of 30 June 2023 according to VPS and disclosures from investors:

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	4 385 674	28.44 %
Total Shares	15 422 350	100.00%

#### 12. Earnings per share

	2Q23	2Q22	2022
Earnings/ loss (-) for the period	907 652	-2 992 303	-23 617 809
Average number of outstanding shares during			
the period	15 422 350	15 422 350	15 422 350
Earnings/ loss (-) per share - basic and diluted	0.06	-0.19	-1.53

Share options issued have a potential dilutive effect on earnings per share. No dilutive effect has been recognized as potential ordinary shares only shall be treated as dilutive if their conversion to ordinary shares would decrease earnings per share or increase loss per share from continuing operations. As the group is currently loss-making, an increase in the average number of shares would have anti-dilutive effects.

#### 13. Share-based compensation

The company has a share option program covering certain key employees. Per 30 June 2023, fifteen employees were included in the option program.

The share option program for key personnel is settled in shares, however, the company may resolve settlement in cash. The fair value of the issued options is expensed over the vesting period:

For options issued from 2018 and up to 2021,1/3 of the options will vest 24 months after the day of grant, 1/3 will vest 36 months after the day of grant and 1/3 will vest 48 months. For options issued from 2022, 1/2 of the options will vest after 36 months and 1/2 of the options will vest after 48 months. Unvested options will be cancelled if the holder terminates its employment with the group.

The cost of the employee share-based transaction is expensed over the average vesting period. The value of the issued options of the transactions that are settled with equity instruments (settled with the company's own shares) is recognised as salary and personnel cost in profit and loss and in other paid-in capital.

The value of the issued options of the programs that are settled in cash (cash-based programs) is recognised as salary and personnel cost in profit and loss and as a liability in the balance sheet. The liability is measured at fair value at each balance sheet date until settlement, and changes in the fair value are recognised in profit and loss.

Social security tax on options is recorded as a liability and is recognised over the estimated vesting period.

	2Q23	2Q22	2022
Outstanding options at beginning of period	960 586	740 590	740 590
Options granted	-	-	219 996
Options forfeited	-	-	-
Options exercised	-	-	-
Options expired	-	-	-
Outstanding options at end of period	960 586	740 590	960 586

Expiry date	Average strike price	Number of share options
2023-8	65.24	174 954
2024-11	47.51	259 962
2025-11	62.88	150 000
2026-11	72.60	155 674
2027-12	46.67	219 996
		960 586

The outstanding options are subject to the following conditions:

The fair value of the options has been calculated using Black - Scholes - Merton Option Pricing Model. The most important parameters are share price at the grant date, exercise prices shown above, volatility (42.74%), expected dividend yield (0%), an expected term of 5 years, and annual risk-free interest rate (2.87%). The volatility is based on other comparable companies' stock price volatility.

#### 14. Transactions with related parties

The group uses Getica AB as a supplier for one of its production steps and has outsourced some R&D project elements to the same supplier. The supplier is owned by Erling Sundrehagen, who also is the sole owner of Vingulmork Predictor AS. The amount invoiced from Getica AB was MNOK 2.2 per 30 June 2023 (MNOK 3.2 per 30 June 2022). Gentian Diagnostics ASA acquired 100 % of the shares in Getica AB on 3 July 2023. The new subsidiary will be consolidated with the group from third quarter 2023.

#### 15. Tax

The Group has carried forward losses which are not capitalised as it is uncertain when the Group will be in a tax position. The loss carried forward per 30 June 2023 is estimated to NOK 206.2 million. The Group will continuously assess the probability of when it will be in a tax position and when to consider a capitalisation of the loss carried forward.

# Alternative performance measures

Non-IFRS financial measures / alternative performance measures

In this quarterly report, the Group presents certain alternative performance measures ("APMs"). An APM is defined as a financial measure of historical or future financial performance, financial position, or cash flows, other than a financial measure defined or specific in the applicable financial reporting framework (IFRS). The APMs presented herein are not measurements of financial performance or liquidity under IFRS or other generally accepted accounting principles, are not audited and investors should not consider any such measures to be an alternative to (a) operating revenues or operating profit (as determined in accordance with generally accepted accounting principles), (b) as a measure of the Group's operating performance; or (c) any other measures of performance under generally accepted accounting principles. The APMs presented herein may not be indicative of the Group's historical operating results, nor are such measures meant to be predictive of the Group's future results.

The company uses APMs to measure operating performance and is of the view that the APMs provide investors with relevant and specific operating figures which may enhance their understanding of the Group's performance. Because companies calculate APMs differently, the APMs presented herein may not be comparable to similarly titled measures used by other companies.

Below is an overview of APMs presented, including an overview of reconciliation and calculation of the relevant APMs.

# Organic revenue growth

Organic revenue growth is defined as revenue adjusted for currency effects and effects from M&A. Organic revenue growth measurement provides useful information to investors and other stakeholders on underlying growth of the business without the effect of certain factors unrelated to its operating performance.

Reconciliation	2Q23	2Q22	1H23	1H22	2022
(NOK 1000)					
Revenue from contracts with customers	34 179	30 095	65 616	50 653	101 636
Revenue growth	4 084	5 534	14 963	6 451	18 538
Impact using exchange rates from last period	-3 474	-821	-6 219	-555	-1 750
Impact M&A	-	-	-	-	-
Organic revenue growth	610	4 713	8 744	5 896	16 788
Organic revenue growth %	2 %	19 %	17 %	13 %	20 %

# Total other operating expenses

Total other operating expenses is a key financial parameter for the Group and consists of salaries and personnel costs and other operating expenses. Total other operating expenses before capitalisation of R&D expenses consists of Employee benefit expenses and other non-salary related operating expenses before capitalisation of R&D expenses. The performance indicator is provided for the purpose of monitoring the evolution of non-production related costs without the effect of capitalisation of costs.

Reconciliation	2Q23	2Q22	1H23	1H22	2022
(NOK 1000)					
Employee benefit expenses	10 669	11 606	22 485	20 148	40 910
Other operating expenses	7 003	8 119	14 287	15 239	31 369
Total other operating expenses <b>after</b> capitalisation of R&D expenses	17 672	19 725	36 772	35 387	72 279
Capitalisation	695	970	1 485	3 200	6 029
Total other operating expenses <b>before</b> capitalisation of R&D expenses	18 367	20 695	38 257	38 587	78 308

Reconciliation	2Q23	2Q22	1H23	1H22	2022
(NOK 1000)					
Other non-salary related operating expenses <b>after</b> capitalisation of R&D expenses	7 003	8 119	14 287	15 238	31 369
Capitalisation	297	479	630	1 499	2 336
Other non-salary related operating expenses <b>before</b> capitalisation of R&D expenses	7 300	8 597	14 918	16 737	33 705

# EBITDA/EBIT

EBITDA is a measurement of operating earnings before depreciation and amortisation of tangible and intangible assets and impairment charges, and EBIT is the operating result. EBITDA and EBIT are used for providing information of operating performance which is relative to other companies and frequently used by other stakeholders.

Reconciliation	2Q23	2Q22	1H23	1H22	2022
(NOK 1000)					
Total Revenue	36 159	32 876	69 760	55 966	111 922
Total Operating Expenses	-34 979	-36 857	-71 455	-66 193	-135 158
EBIT	1 180	-3 981	-1 695	-10 227	-23 235
Depreciation and Amortisation	2 414	2 740	4 772	4 802	10 243
EBITDA	3 593	-1 241	3 077	-5 425	-12 992

# COGS

Cost of goods sold (COGS) refers to the total cost of producing goods for product sales. The key figure COGS % is calculated in relation to revenue from contracts with customers. COGS % is used for providing consistent information of performance related to the production of goods which is relative to other companies and frequently used by other stakeholders.

	2Q23	2Q22	1H23	1H22	2022
(NOK 1000)					
Revenue from contracts with customers	34 179	30 095	65 616	50 653	101 636
COGS	14 894	14 392	29 910	26 005	52 635
COGS % of Revenue from contracts with customers	44 %	48 %	46 %	51 %	52 %

# Non-cash share-based compensation

Non-cash share-based compensation expense is the share-based compensation recognised in the income statement (employee benefit expenses). Information on the non-cash share-based compensation expense is provided to give information on the no-cash components of the employee benefit expenses.

	2Q23	2Q22	1H23	1H22	2022
(NOK 1000)					
Non-cash shared-based compensation	761	1 130	1 514	1 374	3 353