



# Efficient diagnostics for better treatment decisions

www.gentian.com

# **Gentian Diagnostics**

## Third quarter 2022 highlights

- Sales revenue of MNOK 23.1 in 3Q22, an increase of 34% (35% organic growth) vs 3Q21
- Strong growth in the US enabled by recent distribution agreement
- Additional US distribution agreement for Cystatin C announced in August 2022 is expected to support revenue growth from 2023
- IVDR certification achieved, demonstrating Gentian's commitment to deliver safe and effective products
- Good progress made on NT-proBNP, a working prototype has been developed from the new immunoparticle candidate
- GCAL<sup>®</sup> is well received in the market and Siemens collaboration is developing positively

## **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 utilise 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's four established products – Cystatin C, fCAL<sup>®</sup> turbo, Canine CRP and fPELA<sup>®</sup> – contributed to 27% annual revenue growth in 2018-2021. In addition, SARS-CoV-2 Ab and GCAL<sup>®</sup> are in market development while NT-proBNP is in product development, with the two latter having potential to become blockbuster products. Further three undisclosed projects are in exploration and 'proof of concept'.

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 100 million in 2021. 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. NT-proBNP in optimisation with launch date TBD and three projects in exploration and 'proof of concept'.



Secure one new contract with a global commercial partner per year, building on established partnerships with Beckman Coulter for Cystatin C, BÜHLMANN/Roche for fCAL<sup>®</sup> turbo through BÜHLMANN Laboratories and Siemens Healthineers for GCAL<sup>®</sup>.



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 grew 34% in 3Q22 versus 3Q21 to MNOK 23.1. Organic growth was 35% in the period. This contributed to a reported growth of 20% year to date and an organic growth of 20% year to date in 2021. The company considers current demand and the commercial progress made so far this year to be supportive of the overall growth ambition.

3Q22 Cystatin C sales were MNOK 8.7, up 20% compared to 3Q21, with sales year to date of MNOK 30.6, an increase of 19% compared to the same period in 2021. While continued covidrelated regional lockdowns contributed to a negative impact on bulk sales to China, Gentian experienced positive direct and distributor kit sales momentum in the US and Europe. The company also continued to acquire several new customers for Cystatin C in the US during 3Q22. This was enabled by the distribution agreement with a large global IVD company announced on 20 April 2022. The company concluded a distribution agreement with another global IVD company for Cystatin C in August 2022. The agreement covers the US, with a shared ambition of expanding to additional territories globally in the future. The growth in US sales is also supported by direct customer shipments

from a US based warehouse established in the US during 2022, meeting market expectations for product availability.

Sales of fCAL<sup>®</sup> turbo reached MNOK 9.0 in 3Q22, a growth of 66% vs 3Q21, driven by continued kit sales growth and bulk shipments. YTD sales were MNOK 24.6, an increase of 11% versus the same period in 2021. Kit sales remained strong with 28% growth year to date compared to the corresponding period in 2021.

The company's Swedish distribution subsidiary, Gentian Diagnostics AB (GAB), started its commercial activities in Norway and Finland in January 2022. Due to initial orders from the new geographies and continued sales success in Sweden, Gentian AB has grown its third-party product revenues to MNOK 7.7 year to date, up 30% compared to the same period in 2021. For 3Q22 revenues were MNOK 2.2 vs MNOK 2.0 in 3Q21, corresponding to 10% growth. The positive sales trend is expected to continue.

Sales momentum for GCAL<sup>®</sup> continued to develop positively and the commercial rollout through our partner Siemens Healthineers is fully on track, including territory expansion.

## **IVDR** approval

As announced on 28 September, the first products, complying with the European In-Vitro Diagnostic Regulation (IVDR), EU 2017/746 have been certified by TüV SÜD. This certification granted by notified bodies such as TüV SÜD is required for in-vitro diagnostics products to continue being sold in the European Union. The extensive requirements of IVDR were adopted by the European Parliament in 2017 with gradual implementation from 26 May 2022.

Gentian has implemented the EU regulatory requirements in its systems and the associated processes to ensure continuous compliance. In addition, Gentian has made all the necessary preparations to have the first products certified.

The risk classification of products and involvement of a notified body in the regulatory procedures have been one of the major changes with the implementation of the IVDR. Under the 98/79/EC Directive, 80% of the products were classified as self-declared and the majority of these products will end up in a higher risk class under IVDR. This new regulation calls for additional performance assessments based on scientific, clinical and analytical data. It also improves traceability in the supply chain and establishes a proactive monitoring system for the early detection of issues in products already in circulation. Although the introduction of IVDR is a considerable regulatory burden for the industry, it aims to increase the protection of health for patients and users.

## Market development

## **GCAL**<sup>®</sup>

The company's efforts in marketing development of serum and plasma calprotectin, including results from several clinical studies highlighting the benefit of this biomarker, are leading to increased routine use and evolving

interest in the GCAL<sup>®</sup> assay. The number of independently published articles covering serum and plasma calprotectin is increasing.

## SARS-CoV-2 Total Antibody Immunoassay

In an effort to contain the COVID-19 pandemic, serological testing to detect SARS-CoV-2 specific antibodies is likely to aid in disease and community management.

A scientific poster with the title "Platform independent, turbidimetric SARS-CoV-2 total antibody assay" has been presented at the recent Clinical Chemistry meeting in Sweden.

## **Product development**

## NT-proBNP

The optimisation of the Gentian NT-proBNP immunoassay progressed positively during the third quarter. Gentian's NT-proBNP assay aims to be the first turbidimetric in vitro diagnostic test for the quantitative measurement of NTproBNP. An aging population and lifestyle choices increase the cost burden in healthcare systems and thereby drive demand for NTproBNP testing. Gentian's NT-proBNP assay aims to fulfil the need for accurate and rapid diagnosis of congestive heart failure, while allowing for easier standardisation of test results. Making NT-proBNP testing accessible on high volume, clinical chemistry analysers is also expected to increase laboratory productivity.

Investigations during the third quarter showed that the initial results with the lead immunoparticle candidate from the second quarter were reproducible. Consequently, more studies to test the robustness of the lead candidate have been carried out with regards to particle size, coupling process, and particle stability resulting in a working prototype. The prototype has been tested with more clinical samples and the clinical testing will continue to optimise the immunoassay further. In parallel, the work on calibrating the immunoassay towards commercially available products continued.

The establishment of the reference method at the first trial site has been accomplished as planned. The gathering of more clinical reference data is ongoing to support the optimisation of the immunoassay.

If a product in development makes it through optimisation, the following phases are typically characterised by lower risk. Gentian estimates the remaining development period for NTproBNP after completion of optimisation to be 6-9 months. In addition, the product will now fall under the new IVDR regulatory regime which will add another 6-9 months before commercial launch.

Interest from potential partners have been confirmed during 3Q, which indicates significant

commercial value if the assay can make it through the development phase.

In line with established practice, should the current effort of optimisation not prove to be successful the company will consider returning the project to the exploration phase.

### **Pipeline**

The company has currently two projects in the proof-of-concept phase, where one biomarker project has been recently moved from the exploration phase into the early proof-of-concept stage. The existing proof-of-concept project is progressing well, and currently more technical results and market data are gathered.

The exploration phase plays a vital role within Gentian and the company continuously collects information about new biomarker projects to fill the company product pipeline.

# Long-term outlook

Gentian targets disease groups that represent a total addressable market of around BUSD 7.1 globally and an estimated growth rate of 5-6% annually over the next 4-6 years, according to leading market data provider Kalorama (2020). 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 1.3 (2020), with an estimated annual growth rate of 8-9% over the next 5-7 years. The key driver for the higher expected growth rate in the serviceable market is Gentian's selective approach to target attractive segments – particularly detection of severe infections, including sepsis, one of the diagnostic industry's highest growing 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 high value 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 Gentian announced last year, and the long-term EBITDA margin target of 40%, are set to be derisked through several key milestones for the company's product portfolio over the coming twelve months. The revenue ambition is dependent on the timing of NT-proBNP 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 commercial partners, while increasing direct sales
- Bring additional established products to the market, including 3rd party products

# Products in market development GCAL®

- Securing additional global commercial partners and continue EU rollout
- Continue clinical study program confirming relevance for the early detection of infections
- Securing additional endorsements from key opinion leaders

#### SARS-CoV-2 AB

- Initiating rollout in the EU with focus on the Nordics
- Entering commercial partnerships for the Nordics, while initiating direct sales

## New products

#### NT-proBNP

- Progress on remaining challenges in optimisation phase
- Publication on the reference method for standardisation
- Securing endorsements from key opinion leaders and global commercial partners

#### Pipeline

• Finalise proof-of-concept of one new pipeline project

# **Financial performance**

Comparative numbers for Gentian in 2021 in ().

114

1.12

## Revenue, geographic split and product split

Total operating revenue amounted to MNOK 25.1 (MNOK 19.4) for 3Q22. Total operating revenue year to date amounted to MNOK 81.1 (MNOK 75.1).

Sales revenue increased 34% to MNOK 23.1 (MNOK 17.2) in 3Q22, with organic revenue growth of 35%.

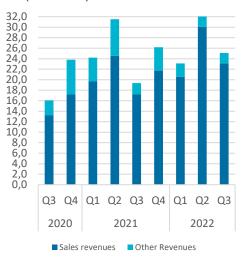
Geogra	aphic sp	olit	Product S			uct Split			
MNOK	3Q22	3Q21	YTD22	YTD21	MNOK	3Q22	3Q21	YTD22	YTD21
Europe	17.3	12.4	52.0	42.0	Cystatin C	8.7	7.3	30.6	25.7
Asia	3.1	4.3	16.3	17.4	fCAL®turbo	9.0	5.4	24.6	22.2
USA	2.6	0.6	5.4	2.0	Other	5.4	4.5	18.6	13.5
Total	23.1	17.2	73.7	61.4	Total	23.1	17.2	73.7	61.4

Other operating revenue ended at MNOK 2.0 (MNOK 2.2) for 3Q22 and MNOK 7.3 (MNOK 13.7) year tom date. Other operating revenue consists of public grants related to the company's R&D projects.



# Consolidated Revenues (MNOK)

· • · · ·



## Cost of goods sold

Cost of goods sold (COGS) was 55% (63%) of sales revenue in 3Q22 and 53% (53%) year to date. With continued sales growth and further optimisation of production processes, Gentian expects COGS as a percentage of sales to decline over time.

### Total other operating expenses

Total other operating expenses before capitalisation of R&D expenses ended at MNOK 19.5 (MNOK 16.7) in 3Q22.

R&D expenses amounted to 46% (50%) of total other operating expenses before capitalisation for 3Q22. Capitalisation of R&D expenses was MNOK 1.2 (MNOK 3.9) in 3Q22.

Total other operating expenses after capitalisation of R&D expenses ended at MNOK 18.4 (MNOK 12.8) in 3Q22.

## Earnings

Operating profit before depreciation and amortisation (EBITDA) ended at MNOK -6.1 (MNOK -4.2) for 3Q22. Net profit ended at MNOK -9.4 (MNOK -6.8).

## **Balance sheet**

Cash and cash equivalents as of 30 September 2022 were MNOK 93.9 (MNOK131.3). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 30 September 2022 were MNOK 4.5 (MNOK 6.1), and inventory MNOK 35.3 (MNOK 26.0). The inventory increase is due to the company taking measures to mitigate potential shortages from a congested supply chain, and an inventory increase in the US in order to serve the increased demand in this region.

The equity ratio was 82.8% as of 30 September 2022.

# Events after the balance sheet date

There are no events after the balance sheet date.

## Statement of Profit and Loss Gentian Group

	Note	2022	2021	2022	2021	2021
(NOK 1000)		Q3	Q3	01.01- 30.09	01.01- 30.09	
Revenue						
Revenue from contracts with customers	3	23 071	17 178	73 725	61 388	83 122
Other operating revenue	4	2 015	2 184	7 328	13 680	16 887
Total revenue		25 086	19 362	81 053	75 067	100 009
Operating expenses						
Cost of goods sold	6	-12 781	-10 774	-38 786	-32 618	-43 176
Employee benefit expenses	7,13	-9 972	-8 896	-30 120	-27 258	-39 539
Depreciation and amortisation		-2 675	-2 376	-7 476	-6 330	-7 351
Other operating expenses		-8 396	-3 884	-23 634	-22 185	-32 790
Total operating expenses	5	-33 823	-25 931	-100 017	-88 390	-122 856
Operating result		- 8 737	-6 569	- 18 964	-13 323	-22 847
Finance income		836	685	4 742	045	2 084
					845	
Finance cost		-1 477	-898	-4 770	-2 740	-4 031
Net financial items		-641	-213	-28	-1 895	-1 947
Profit before tax		- 9 378	-6 782	-18 992	-15 218	-24 794
Income tax expense		-	-	-	-	-
Profit for the period		-9 378	-6 782	- 18 992	-15 218	-24 794
Other comprehensive income						
Exchange differences		-463	-43	-445	-130	-222
Total other comprehensive income		-463	-43	-445	-130	-222
Total comprehensive income for the period		- 9 841	-6 825	-19 437	-15 348	-25 016

3<sup>rd</sup> quarter Statement of Profit and Loss is not audited

## Statement of Financial Position - Group as of 30.09

	Note	2022	2021	2021
(NOK 1000)		30.09	30.09	
Assets				
Non-current assets				
Intangible assets	9	27 442	24 622	25 006
Property, plant and equipment		9 943	3 006	3 363
Right-of-use assets		13 297	17 471	16 125
Total non-current assets		50 682	45 099	44 495
Current assets				
Inventory		35 336	26 039	29 779
Accounts receivables and other receivables		10 643	15 856	22 580
Cash and cash equivalents		93 880	131 315	114 936
Total current assets		139 859	173 210	167 295
Total assets		190 541	218 308	211 790
Equity and Liabilities				
Paid-in equity				
Share capital	11	1 542	1 541	1 542
Share premium		293 810	293 241	293 810
Other paid-in equity		14 400	10 169	11 941
Retained earnings		-151 964	-122 860	-132 528
Total equity		157 788	182 091	174 766
Liabilities				
Lease liabilities	10	13 277	20 914	14 470
Total non-current liabilities		13 277	20 914	14 470
Current liabilities				
Current lease liabilities		3 439	3 218	4 114
Account payables		5 329	4 883	4 975
Public taxes, duties etc.		2 799	1 491	3 598
Other short-term liabilities		7 909	5 711	9 868
Total current liabilities		19 476	15 304	22 554
Total liabilities		32 753	36 217	37 024
Total equity and liabilities		190 541	218 308	211 790

3<sup>rd</sup> quarter Statement of Financial Position is not audited

## Statement of changes in equity

(NOK 1000)

	Share	Share	Other paid-in	Retained	Total
	capital	premium	capital	earnings	Equity
Equity at 01.01.2021	1 541	293 241	7 309	-107 512	194 579
Net result for the period				-15 218	-15 218
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			2 860		2 860
Other changes in equity				-130	-130
Equity at 30.09.2021	1 541	293 241	10 169	-122 860	182 091
Equity at 01.01.2021	1 541	293 241	7 309	-107 512	194 579
Net result for the year				-24 794	-24 794
Other comprehensive income					
Proceeds from share issue	1	569			570
Cost of share issue					
Share based payments			4 633		4 633
Other changes in equity				-222	-222
Equity at 31.12.2021	1 542	293 810	11 941	-132 528	174 766
Equity at 01.01.2022	1 542	293 810	11 941	-132 528	174 766
Net result for the period				-18 992	-19 492
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments					
Other changes in equity			2 459	-445	-445
Equity at 30.09.2022	1 542	293 810	14 400	-151 964	157 788

3<sup>rd</sup> quarter Statement of changes in equity is not audited

## **Cash Flow Statement**

	2022	2021	2022	2021	2021
(NOK 1000)	Q3	Q3	01.01- 30.09	01.01- 30.09	01.01 - 31.12
Operating activities					
Net profit (loss)	- 9 378	-6 782	-18 992	-15 218	-24 794
Depreciation and amortisation	2 674	2 376	7 476	6 330	7 351
Change Inventory	- 779	-1 183	-5 557	-5 163	-8 904
Change Accounts Receivables	10 160	6 114	2 017	1 579	1 120
Change Accounts Payables	-1 776	-6 978	355	-925	-833
Accrued cost of options	1 086	907	2 459	2 860	4 633
Change in other assets and liabilities	2 871	3 475	6 716	-3 378	-5 626
Net cash flow from operating activities	4 859	-2 071	- 5 525	-13 915	-27 053
Investing activities					
Payments of property, plant and equipment	-641	-175	-7 962	-2 558	-1 024
Investment in intangible assets	-2 418	-3 890	-5 702	-7 694	-11 791
Investments in other companies	-	-		-	-
Net cash flow from investing activities	-3 059	-4 065	-13 664	-10 253	-12 815
Financing activities		-		-	-
New debt	454	-	454	-	-
Loan instalments	-439	-1 125	-2 322	-2 312	-3 691
Proceeds from issue of share capital	-	-		-	570
Net cash flow from financing activities	15	-1 125	-1 867	-2 312	-3 121
Net change in cash and cash equivalent	1 816	-7 261	-21 056	-26 479	-42 989
Cash and cash equivalents at beginning of period	92 113	138 585	114 936	157 985	157 985
Effect of currency translation of cash and cash equivalents	-49	-9	1	-191	-60
Net Cash and cash equivalents at period end	93 880	131 315	93 880	131 315	114 936

3rd 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 2021 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 2022.

#### 2.2. Basis of consolidation

The consolidated financial statements comprise the financial statements of the company and its subsidiaries. As at 30 September 2022, Gentian AS, located in Moss, Norway is a 100% owned and controlled subsidiary.

#### 3. Sales and revenue

Revenue by classification	3Q22	3Q21	YTD22	YTD21	2021
Sales revenue	23 071	17 178	73 725	61 388	83 122
Public grants	2 015	2 184	7 328	13 680	16 887
Revenue from divestiture	-	-	-	-	-
Other revenue	-	-	-	-	-
Total	25 086	19 362	81 053	75 067	100 009
Geographical split	3Q22	3Q21	YTD22	YTD21	2021
Europe	17 329	12 357	52 016	42 044	55 676
Asia	3 134	4 255	16 338	17 389	25 008
USA	2 608	566	5 371	1 955	2 438
Total	23 071	17 178	73 725	61 388	83 122
Sales by product category	3Q22	3Q21	YTD22	YTD21	2021
Renal diagnostic products	8 667	7 310	30 550	25 745	36 450
Inflammation diagnostic products	10 684	8 421	29 323	24 741	40 478
Other diagnostic products	3 720	1 446	13 852	10 902	6 194
Total	23 071	17 178	73 725	61 388	83 122

#### 4. Public Grants

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

	3Q22	3Q21	YTD22	YTD21	2021
Norwegian Research Council and Eurostars	1 079	629	4 646	8 266	10 943
Innovation Norway	-	211	-	1 021	1 194
SkatteFUNN	936	1344	2 682	4 393	4 750
Total	2 015	2 184	7 328	13 680	16 887

#### 5. Operating expenses by function

	3Q22	3Q21	YTD22	YTD21	2021
Cost of goods sold	12 781	10 774	38 786	32 618	43 176
Sales and marketing expenses	3 760	3 338	15 166	11 080	15 145
Administration expenses	7 873	5 073	22 184	19 465	32 769
Research and development expenses	6 735	4 369	16 404	18 898	24 416
Depreciation	2 674	2 376	7 476	6 330	7 351
Total	33 823	25 930	100 017	88 391	122 856

#### 6. Cost of goods sold

	3Q22	3Q21	YTD22	YTD21	2021
Change in inventory of goods under manufacture and finished goods	531	-1 183	400	-5 163	3 727
Purchase of goods	5 074	5 817	18 331	21 070	16 086
Production salary	6 571	4 980	15 401	13 431	18 662
Other production expense	605	1 160	4 654	3 280	4 702
Total	12 781	10 774	38 786	32 618	43 176

#### 7. Employee benefit expenses

	3Q22	3Q21	YTD22	YTD21	2021
Wages and salaries	13 313	10 941	36 090	32 385	43 733
Payroll tax	1 068	1 436	4 162	3 812	6 888
Pension costs (mandatory occupational pension)	678	305	1 996	1 020	1 733
Share based payments	1 086	907	2 459	2 739	4 633
Other expenses	397	287	814	732	1 214
Transfer to COGS	-6 571	-4 980	-15 401	-13 431	-18 662
Total	9 972	8 896	30 120	27 258	39 539

#### 8. Research and Development expenses

The Gentian Group has per 30 September 2022 four ongoing R&D projects. Costs related to the projects consist of salary, external procurement of services, and other operating expenses. One of the projects went over in the development phase in 2016 and two others in 2021, and consequently the capitalisation of the costs in these projects was started.

Recognised research and development expenses	3Q22	3Q21	YTD22	YTD21	2021
Purchase of external services	2 406	1 315	5 308	4 693	8 996
Salary and other operating expenses	5 503	6 945	14 784	21 899	27 180
Capitalised research and development expenses	-1 174	-3 890	-4 374	-7 694	-11 658
Total	6 735	4 369	15 718	18 898	24 519

#### 9. Intangible assets

As of 30 September 2022, the recognised intangible assets in the Group amounts to MNOK 27.4. 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 3Q22.

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 September 2022 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 Life Sciences AS	1 214 702	7.88%
Verdipapirfondet Delphi Nordic	970 934	6.29%
Safrino AS	800 000	5.19%
Skandinaviska Enskilda Banken AB	489 000	3.17%
Salix AS	390 689	2.53%
Verdipapirfondet DNB SMB	361 291	2.34%
Verdipapirfondet Storebrand Vekst	344 292	2.23%
Equinor Pensjon	300 047	1.95%
Portia AS	300 000	1.95%
Cressida AS	235 000	1.52%
J.P. Morgan SE	232 922	1.51%
Lioness AS	220 000	1.43%
Marstal AS	212 407	1.38%
Mutus AS	210 465	1.36%
Carpe Diem Afseth AS	208 797	1.35%
Krefting, Johan Henrik	196 400	1.27%
Vingulmork Predictor AS	184 083	1.19%
Silvercoin Industries AS	175 657	1.14%
Other Shareholders	4 642 612	30.10%
Total Shares	15 422 350	100.00%

#### 12. Earnings per share

	3Q22	3Q21	2021
Loss for the period	-9 378 981	-6 781 586	-24 794 000
Average number of outstanding shares during			
the period	15 422 350	15 411 889	15 414 504
Earnings/ loss (-) per share - basic and diluted	-0.61	-0.44	-1.61

Share options issued have a potential dilutive effect on earnings per share. No dilutive effect has been recognised 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 September 2022, eleven 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.

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 (as long as the option holder is still employed). 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 settles 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.

	3Q22	3Q21	2021
Outstanding options at beginning of period	740 590	594 916	594 916
Options granted	-	-	155 674
Options forfeited	-	-	-10 000
Options exercised	-	-	-
Options expired	-	-	-
Outstanding options at end of period	740 590	594 916	740 590

The outstanding options are subject to the following conditions:

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
		740 590

The fair value of the options has been calculated using Black - Scholes - Merton Option Pricing Model. The most important parameters are share price at grant date, exercise prices shown above, volatility (44%), expected dividend yield (0%), expected term of 4 years, annual risk-free interest rate (1.2%). 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. Erling Sundrehagen, Chief Scientific Officer of Gentian Diagnostics ASA, indirectly owns 76% of Getica AB. The amount invoiced from Getica AB was MNOK 4.8 per 30 September 2022 (MNOK 8.6 per 30 September 2021).

#### 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 September 2022 is estimated to approximately MNOK 191. 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	3Q22	3Q21	YTD22	YTD21	2021
(NOK 1000)					
Revenue from contracts with customers	23 071	17 178	73 725	61 388	83 122
Revenue growth	5 893	3 929	12 344	15 257	19 795
Impact using exchange rates from last period	59	300	-496	3 263	4 399
Impact M&A		532		1 954	1 954
Organic revenue growth	5 952	4 760	11 848	20 473	26 148
Organic revenue growth %	35 %	37 %	20%	46 %	43 %

## 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	3Q22	3Q21	YTD22	YTD21	2021
(NOK 1000)					
Employee benefit expenses	9 972	8 896	30 120	27 258	39 539
Other operating expenses	8 396	3 884	23 634	22 185	32 790
Total other operating expenses <b>after</b> capitalisation of R&D expenses	18 368	12 781	53 754	49 443	72 330
Capitalisation	1 174	3 890	4 374	7 694	11 659
Total other operating expenses <b>before</b> capitalisation of R&D expenses	19 542	16 671	58 129	57 137	83 988
Reconciliation	3Q22	3Q21	YTD22	YTD21	2021
(NOK 1000)					
Other non-salary related operating expenses <b>after</b> capitalisation of R&D expenses	8 396	3 884	23 634	22 185	32 790
Capitalisation	423	3 071	1 922	5 581	8 579
Other non-salary related operating expenses <b>before</b> capitalisation of R&D expenses	8 819	6 956	25 556	27 766	41 370

## 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	3Q22	3Q21	YTD22	YTD21	2021
(NOK 1000)					
Total Revenue	25 086	19 362	81 053	75 067	100 009
Total Operating Expenses	-33 823	-25 931	-100 017	-88 390	-122 854
EBIT	-8 738	-6 569	-18 964	-13 323	-22 845
Depreciation and Amortisation	2 675	2 376	7 476	6 330	7 349
EBITDA	-6 062	-4 193	-11 488	-6 993	-15 496

## 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.

	3Q22	3Q21	YTD22	YTD21	2021
(NOK 1000)					
Revenue from contracts with customers	23 071	17 178	73 725	61 388	83 122
COGS	12 781	10 774	38 786	32 618	43 176
COGS % of Revenue from contracts with customers	55 %	63 %	53 %	53 %	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.

	3Q22	3Q21	YTD22	YTD21	2021
(NOK 1000)					
Non-cash shared-based compensation	1 086	907	2 459	2 739	4 633