gentian

Q4

Fourth quarter 2021 results

Efficient diagnostics for better treatment decisions

Gentian Diagnostics

Fourth quarter 2021 highlights

- Total operating revenue of MNOK 26.2 in 4Q21, an increase of 10% from 4Q20, and MNOK 101.3 in 2021, up 28% from 2020
- Sales revenue of MNOK 21.7, up 26% from 4Q20, with organic growth of 33%. Full year sales revenue increased 31% to MNOK 83.1, with organic growth of 43%.
- EBITDA was MNOK -8.5 in 4Q21, including costs of MNOK 4.4 related to implementation of a new cloud based ERP system. EBITDA for the full year was MNOK -15.5 including MNOK 3.5 in IPO related costs
- Progressing the NT-proBNP assay optimisation. A revised launch date to be communicated upon completion of the optimisation phase.
- Post quarter, Gentian entered into a global distribution contract for GCAL[®] with Siemens Healthineers, one of the global leaders in clinical diagnostics, and completed development of the SARS COV-2 Antibody assay, with commercial launch planned in 1Q22.

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 – that contributed to 27% annual revenue growth in 2018-2021. In addition, SARS-COV-2 Ab and GCAL® are in market development while NT-proBNP is in the product development phase – with the two latter having potential to become blockbuster products. The company also has three undisclosed biomarkers in exploration and 'proof of concept' phases.

In 2021, Gentian announced a long-term ambition to generate an estimated annual revenue of BNOK 1.0 in 5-7 years, dependent on the timing of NT-proBNP launch yet to be concluded. In comparison, total revenue was MNOK 101 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® for the early detection of severe infections, which supports the avoidance of sepsis and the severity assessment of COVID-19 patients



Launch one new product per year; SARS-COV-2 Ab scheduled for 1Q22, NT-proBNP in optimisation with launch date TBD and three biomarkers in exploration and 'proof of concept'.



Secure one new contract with a global commercial partner every year, building on already established partnerships with Beckman Coulter for Cystatin C, Bühlmann / Roche for fCAL® turbo through Bühlmann Laboratories and Siemens Healthineers for GCAL®



Grow gross margin from \sim 50% to 60%+ at volume production 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 33% organically in 4Q21 versus 4Q20, ending the quarter at MNOK 21.7. Reported growth was 26%. Sales revenue for the full year 2021 was MNOK 83.1, representing organic growth of 43% from 2020. Quarterly variations are expected to continue as sales are affected by the timing of large orders.

Sales of Cystatin C were MNOK 10.5 for the quarter, an increase of 59% compared to 4Q20. Sales in Asia more than doubled vs 4Q2020 mainly driven by strong new customer installations and competitive conversion, executed by Gentian's partners in China and South Korea.

The company sees continued adoption of Cystatin C in Chronic Kidney Disease (CKD) monitoring in both the US and globally. While samples historically have been sent to specialised labs, a number of institutions are now starting to establish Cystatin C in their own labs. Gentian provides direct assistance to these initiatives with scientific and application support from both the US and Norway.

Sales of fCAL® turbo reached MNOK 5.8 in 4Q21, a decline of 6.5% vs 4Q20. Growth for the full year 2021 was 34% to MNOK 28.0, and the underlying commercial development for fCAL® turbo continues to be positive, with a general trend to implement selected stool tests on automated core lab instrumentation.

The company's Swedish distribution subsidiary, Gentian Diagnostics AB (GAB), continues to demonstrate a positive sales trend for third party products with revenue totalling MNOK 8.1 in 2021. This represents an increase of 17% compared to 2020. Continued profitable growth is expected as GAB is expanding its commercial activities to Norway and Finland, starting in January 2022

Market development

GCAL®

In January 2022, Gentian announced the signing of a global distribution agreement for GCAL® with Siemens Healthineers, one of the global leaders in clinical diagnostics.

The GCAL® assay will be offered on the Siemens Healthineers nephelometric platforms BN™ II, BN ProSpec®, and Atellica® NEPH and positioned towards the rheumatoid arthritis market. The Siemens Healthineers BN II platform is a fully automated system with a large installed base, and additional systems from Siemens Healthineers are scheduled to be added at a later stage.

The GCAL® assay will initially be made available in Europe, with launch scheduled for the first half of 2022, and expansion to additional countries or regions depending on regulatory clearance.

GCAL® sales on already established platforms continue to evolve positively from both existing and new routine customers as well as from increased paid study activities.

During the year, Gentian entered into promising commercial collaboration agreements with specialised distributors in several countries.

Documentation of the benefits of GCAL [®] for early detection of infections and inflammations continues to build. Several prospective studies in collaboration with reputable hospitals in Europe and Canada are ongoing and progressing according to plan. The aim of these studies is to prove the ability of GCAL[®] to detect severe infections at an early stage and avoid clinical deterioration and mortality. The studies will also focus on the role of GCAL[®] in the evaluation of disease severity and risk assessment, suggesting the use of the assay as a tool for fast and correct treatment decisions in addition to optimal use of healthcare resources.

The studies will not only provide scientific evidence, but also establish a bridge between research and routine use of the GCAL® assay at the study sites. As an example, after participating in a study, a large university hospital laboratory in Germany recently implemented GCAL® in its routine use.

GCAL® validation was successfully completed on the new mid/high throughput clinical chemistry platform Roche Cobas c503 during 4Q21 and additional platforms are scheduled to be added to the list during 2022.

Product development

NT-proBNP

The development of a platform independent NT-proBNP turbidimetric assay could represent ground-breaking advances in the field of high throughput diagnostics. Gentian Diagnostics aims to push the boundaries regarding measurement of low concentrations, and a successful development of NT-proBNP will represent a significant advance for the PETIA technology.

As communicated on 5 October 2021, the optimisation of the NT-proBNP assay has proven to be more complex than first assumed. The remaining challenges related to particle aggregation, differences in measurement of NT-proBNP in plasma and serum samples and reaching an even lower level of quantification to ensure a competitive product.

The company continued the technical development of the NT-proBNP assay in the optimisation phase during the fourth quarter. The particle coating procedure was improved, resulting in an increased particle stability without particle aggregation. Stability investigations are ongoing to confirm the long-term stability of particles manufactured by the improved coating procedure.

The assay development has advanced during the quarter, and the first measurements now show reproducible results in a controlled environment. Investigations are ongoing to confirm the consistency of turbidimetric measurements at low sample concentrations.

Further testing of clinical plasma material revealed that in a fraction of clinical samples the NT-proBNP molecule is likely influenced by particles in the plasma. This affects the turbidimetric signal and investigations are ongoing to reveal and remove the interference sources so that a stable assay signal is obtained.

The application of the independent reference method has progressed and additional trial sites have been recruited to test the reference method and confirm the results from the first site.

Despite all the progress made in optimisation of the assay during the fourth quarter, the company views the range of probable outcomes to be too wide for it to be able to provide an updated timeline for the remaining optimisation phase. If a product in development makes it through optimisation, the following phases are typically characterized by lower risk. The company estimates the remaining development period for NT-proBNP after completion of the optimisation to be 6-9 months. In additon, the product will now fall under the new IVDR regulatory regime which will add another 6-9 months before commercial launch. Prior to the delays in optimisation Gentian planned to launch NT-proBNP under the regulatory regime where the estimated time was around 1 month.

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 be crucial for disease and community management. Gentian has completed the development of a turbidimetric SARS-CoV-2 Total Antibody Immunoassay in collaboration with University in Tromsø (UiT). The quantitative antibody test captures the full immune response detecting antibodies with high sensitivity and specificity and will be calibrated against the WHO international standard enabling harmonisation between results across laboratories and serological assays. The standardisation allows scientist, health care workers and laboratories to directly compare results, minimising variation and calibration correction. Gentian will bring SARS-CoV-2 serology testing to automated, open-access clinical chemistry platforms, increasing the testing capacity to up to 2,000 tests/hour while positively impacting laboratory efficiency. Since the Gentian assay is platform independent it can be seamlessly integrated in daily laboratory routine without additional infrastructure or workflow cost. The test will follow a standard testing protocol utilising existing logistic structure, from the routine blood test at the GP office to the clinical chemistry platforms with an assay time to result of only 10 minutes. The Gentian assay will provide a tool to assess and document protection status for individuals and society. It will provide a powerful high-throughput test fitted to international standards for community management of COVID-19 through long-term monitoring of natural and vaccine-related immune response.

The technical development of the SARS-CoV-2 Total Antibody Immunoassay has been completed and the application of the turbidimetric assay on clinical material, necessary to fulfill CE-marking requirements, is currently ongoing.

Pipeline

Gentian has made significant progress with one of the projects that are in the exploration phase. From a technical point of view this initiative is now ready to be moved into the proof-of-concept phase. In addition, and given the significance of this project the company will engage external experts to assess the market positioning before announcing the details to the capital markets.

In addition, resources from other early phase projects have been re-allocated to the NT-proBNP assay development.

Regulatory update

Gentian is on track towards IVDR readiness. The company has completed important milestones towards the IVDR certification for our products. The remaining steps towards IVDR certification are a final review and issuing the IVDR certificate by the notified body.

As informed earlier, the new date of application is now May 2027, instead of May 2022. While Gentian has continued to work towards the May 2022 deadline, the notified bodies have depriorities the issue of IVDR certificates to after May 2022, however, without any impact on the products on the market. All new products that will be launched after May 2022 must comply with IVRD

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 5-7 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 — in particular early 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, which is dependent on the timing of NT-proBNP launch, and its long-term EBITDA margin target of 40% are set to be de-risked through several key milestones for the company's product portfolio:

Established products

- Targeting additional large commercial partners
- Additional regulatory approvals, including IVDR

GCAL (in market development)

- Clinical studies confirming relevance for the early detection of infections, which supports the avoidance of sepsis and the severity assessment of COVID-19 patients
- Securing endorsements from key opinion leaders
- Securing global commercial partnerships and initiating EU rollout

New products

SARS-CoV-2 AB

- Initiating rollout of SARS-CoV-2 AB in the EU with focus on the Nordics
- Successful validation and launch, scheduled for 1Q22
- Entering commercial partnerships for the Nordics

NT-proBNP

- Successful optimisation of the assay
- Publication on the reference method for standardisation
- Securing endorsements from key opinion leaders and global commercial partnerships

Pipeline

Finalize proof-of-concept of one new pipeline project

Financial performance

Comparative numbers for Gentian in 2020 in ()

Revenue, geographic split and product split

Total operating revenue amounted to MNOK 26.2 (MNOK 23.8) for 4Q21 and to MNOK 101.3 for the full year 2021 (MNOK 78.9). This represented year-on-year growth of 10% for the quarter and 28% for the full year.

Sales revenue increased 26% to MNOK 21.7 in 4Q21 (MNOK 17.2), with organic revenue growth of 33%. Sales revenue for the full year increased 31% to MNOK 83.1 (MNOK 63.3), with organic revenue growth of 43%.

Geographic split

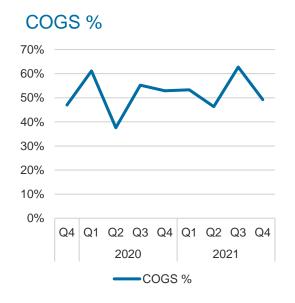
MNOK	4Q21	4Q20	2021	2020
US	0.5	0.7	2.5	3.0
Europe	13.6	13.0	55.6	45.4
Asia	7.6	3.6	25.0	14.9
Total	21.7	17.2	83.1	63.3

Product split

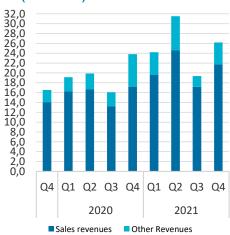
MNOK	4Q21	4Q20	2021	2020
Cystatin C	10.5	6.6	36.2	25.8
fCAL®turbo	5.8	6.2	28.0	20.9
Other*	5.4	4.5	18.9	16.6
Total	21.7	17.2	83.1	63.3

^{*&}quot;Other" under Product Split include sales from the subsidiary Pretect that was successfully divested at the end of 3Q20.

Other operating revenue ended at MNOK 4.5 (MNOK 6.6) for 4Q21, and MNOK 18.1 (MNOK 15.6) for 2021. The increase in other operating revenue for the full year is a result of an increase in spending on Research and Development (R&D) projects which triggers research grants and tax incentives.







Cost of goods sold

Cost of goods sold (COGS) was 49% (53%) of sales revenue in 4Q21, and 52% (51%) in 2021. With continued sales growth and further optimisation of our production processes, Gentian expects COGS to decline as a percentage of sales over time.

Total other operating expenses

Total other operating expenses before capitalisation of R&D expenses ended at MNOK 26.5 (MNOK 18.3) in 4Q21. The increase is a result of an overall higher activity level and a cost of MNOK 4.4 related to the implementation of a new ERP system for the Group.

R&D expenses amounted to 36% (54%) of total other operating expenses before capitalization for 4Q21. Capitalisation of R&D expenses was MNOK 2.5 (MNOK 2.5) in 4Q21.

Total other operating expenses after capitalisation of R&D expenses ended at MNOK 24.0 (MNOK 15.8) in 4Q21.

For the full year 2021 total other operating expenses amounted to MNOK 83.6 (MNOK 60.9) before capitalization of R&D expenses, and MNOK 73.4 (MNOK 57.5) after capitalization.

Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -8.5 (MNOK -1.1) for 4Q21 and MNOK -15.5 (MNOK -11.2) for the full year 2021. Net profit ended at MNOK -9.5 (MNOK -3.5) for 4Q21 and MNOK -24.8 (MNOK -17.5) for 2021.

Balance sheet

Cash and cash equivalents as of 31.12.2021 were MNOK 114.9 (MNOK 158.0). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 31.12.2021 were MNOK 14.3 (MNOK 7.6), and inventory MNOK 29.7 (MNOK 20.9).

The equity ratio was 82.2% as of 31.12.2021.

Events after the balance sheet date

On 31 January 2022 the company announced that it had entered into a global distribution contract for the Gentian Calprotectin Immunoassay GCAL® with Siemens Healthineers, with launch scheduled for the first half of 2022.

The agreement is described in more detail above under the 'Operational Summary'.

Statement of Profit and Loss Gentian Diagnostics Group

	Note	2021	2020	2021	2020
(NOK 1000)		Q4	Q4	01.01- 31.12	01.01- 31.12
Revenue					
Revenue from contracts with customers	3	21 717	17 196	83 105	63 327
Other operating revenue	4	4 475	6 614	18 154	15 554
Total revenue		26 192	23 810	101 259	78 881
Operating expenses					
Cost of goods sold	6	-10 694	-9 097	-43 311	-32 586
Employee benefit expenses	7,13	-11 154	-8 863	-38 412	-37 231
Depreciation and amortisation		-999	-1 958	-7 328	-6 630
Impairment		-	-	-	-
Other operating expenses		-12 828	-6 948	-35 013	-20 258
Total operating expenses		-35 675	-26 866	-124 065	-96 705
Operating result		-9 483	-3 056	-22 806	-17 824
Finance income		1 398	410	2 243	1 840
Finance cost		-1 460	-890	-4 200	-1 484
Net financial items		-62	-480	-1 957	356
Profit before tax		-9 545	-3 536	-24 762	-17 469
Income tax expense		-	-	-	-
Profit for the period		-9 545	-3 536	-24 762	-17 469
Other comprehensive income					
Exchange differences		-26	-149	-156	68
Total other comprehensive income		-26	-149	-156	68
Total comprehensive income for the period		-9 570	-3 686	-24 918	-17 401

^{4&}lt;sup>th</sup> quarter Statement of Profit and Loss is not audited

Statement of Financial Position –Gentian Diagnostics Group

	Note	2021	2020
(figures in NOK thousands)		31.12	31.12
Assets			
Non-Current Assets			
Intangible assets	9	23 761	15 610
Property, plants and equipment		4 235	3 865
Right-of-use assets		15 253	21 689
Total Non-Current Assets		43 250	41 164
Current Assets			
Inventory		29 779	20 876
Accounts receivables and other receivables		24 808	15 241
Cash and cash equivalents		114 936	157 985
Total Currents Assets		169 524	194 101
Total Access		040.774	005 005
Total Assets		212 774	235 265
Equity and liabilities			
Paid-in equity			
Share capital	11	1 542	1 541
Share premium		293 810	293 241
Other paid-in equity		11 941	7 309
Total paid-in equity		307 294	302 091
Retained earning			
Retained earning		-132 551	-107 512
Total retained equity		-132 551	-107 512
Total equity		174 742	194 579
1.0.1.000			
Labilities	40	40.504	40.404
Lease liabilities	10	18 584	18 101
Total non-current liabilities		18 584	18 101
Current liabilities			
Accounts payable and other current liabilities		19 448	22 585
Total current liabilities		19 448	22 585
Total liabilities		38 031	40 686
Total equity and liabilities		212 774	235 265

⁴th quarter Statement of Financial Position is not audited

Statement of changes in equity

(figures in NOK thousands)

	Share	Share	Other	Retained	Total
		0	paid-in		
	capital	premium	capital	earnings	equity
Equity at 01.01.2020	1 540	292 780	4 031	-90 111	208 240
Net result for the year				-17 469	-17 469
Other comprehensive income					
Proceeds from share issue	1	461			462
Cost of share issue					
Share based payments			3 278		3 278
Other changes in equity				68	68
Equity at 31.12.2020	1 541	293 241	7 309	-107 512	194 579
Equity at 01.01.2021	1 541	293 241	7 309	-107 512	194 579
Net result for the year				-24 762	-24 762
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				-277	-277
Equity at 31.12.2021	1 542	293 810	11 941	-132 551	174 742

^{4&}lt;sup>th</sup> quarter Statement of changes in equity is not audited

Cash Flow Statement

	2021	2020	2021	2020
(MOK 1999)	0.4	0.4	01.01-	01.01 -
(NOK 1000)	Q4	Q4	31.12	31.12
Operating activities				
Net profit (loss)	-9 545	-3 197	-24 762	-17 469
Depreciation and amortisation	999	1 958	7 328	6 630
Change Inventory	-3 741	59	-8 904	-2 652
Change Accounts Receivables	-2 454	1 940	-875	860
Change Accounts Payables	1 530	1 723	605	1 202
Accrued cost of options	1 773	821	4 633	3 278
Change in other assets and liabilities	-3 557	-696	-6 936	-4 359
Net cash flow from operating activities	-14 996	2 608	-28 911	-12 509
Investing activities				
Payments of property, plant and equipment	584	-1 996	-1 974	-2 734
Investment in intangible assets	-2 476	-2 520	-10 171	-3 733
Investments in other companies*	-	6 741	-	6 741
Net cash flow from investing activities	-1 892	2 225	-12 145	274
Financing activities	-	-	-	-
New debt	-	497	-	497
Loan instalments	-77	-73	-2 388	-2 469
Proceeds from issue of share capital	570	462	570	462
Net cash flow from financing activities	493	887	-1 818	-1 510
Net change in cash and cash equivalent	-16 394	5 720	-42 873	-13 745
Cash and cash equivalents at beginning of period	131 315	152 265	157 985	171 567
Effect of currency translation of cash and cash equivalents	16	-	-175	163
Net Cash and cash equivalents at period end	114 936	157 985	114 936	157 985

⁴th quarter Cash Flow Statement is not audited

^{*} Note: Gentian Diagnostics divested its subsidiary PreTect AS in 4Q20. The Group has identified an error related to classification of the transaction in the statement of cash flow in the consolidated financial statements for the year ended 31 December 2020. The net cash received in the transaction was TNOK 6,741 and should in its entirety have been classified as cash flow from investing activities, while cash flow from investing activities in the financial statement only contains an amount of TNOK 1,893. The remaining part of net cash received which amounts to the amount of TNOK 4,848 was classified as cash from operating activities.

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 development-based 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 2020 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 given 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 2021.

2.2. Basis of consolidation

The consolidated financial statements comprise the financial statements of the company and its subsidiaries. As at 31 December 2021, Gentian AS, located in Moss, Norway is a 100% owned and controlled subsidiary.

3. Sales and revenue

Revenue by classification	4Q21	4Q20	2021	2020
Sales revenue	21 717	17 196	83 105	63 327
Public grants	4 475	1 572	18 154	10 512
Revenue from divestiture	-	4 384	-	4 384
Other revenue	-	657	-	657
Total	26 192	23 810	101 259	78 881
Geographical split	4Q21	4Q20	2021	2020
Europe	13 607	12 958	55 651	45 416
Asia	7 613	3 551	25 002	14 909
USA	497	687	2 452	3 002
Total	21 717	17 196	83 105	63 327
Sales by product	4Q21	4Q20	2021	2020
Renal diagnostic products	10 489	5 990	36 432	25 237
Inflammation diagnostic products	9 788	9 864	40 478	29 889
Other diagnostic products	1 440	1 342	6 195	8 201
Total	21 717	17 196	83 105	63 327

4. Public Grants

The companies Gentian AS and PreTect AS* receives public grants from the Norwegian Research Council, Innovation Norway, Eurostars and SkatteFUNN.

	4Q21	4Q20	2021	2020
Norwegian Research Council and Eurostars	2 709	2 662	10 943	7 510
Innovation Norway	173	461	1 194	1 222
SkatteFUNN	1 624	-1 551	6 017	1 780
Total	4 475	1 572	18 154	10 512

^{*}The subsidiary PreTect AS was divested in 2020.

5. Operating expenses by function

	4Q21	4Q20	2021	2020
Sales and marketing expenses	4 159	4 640	15 240	14 193
Administration expenses	12 874	3 718	32 339	19 408
Research and development expenses	6 949	7 453	25 847	23 887
Total	23 983	15 811	73 425	57 488

6. Cost of goods sold

	4Q21	4Q20	2021	2020
Change in inventory of goods under manufacture and finished goods	1 586	698	-3 577	-2 014
Purchase of goods	2 613	2 801	23 321	16 309
Production salary	5 334	4 377	18 766	14 909
Other production expense	1 160	1 221	4 801	3 382
Total	10 694	9 097	43 311	32 586

7. Employee benefit expenses

	4Q21	4Q20	2021	2020
Wages and salaries	10 937	10 153	43 323	40 551
Payroll tax	2 317	1 620	6 129	5 907
Pension costs (mandatory occupational pension)	115	621	1 135	1 416
Share based payments	1 773	822	4 633	3 278
Other expenses	444	248	1 176	988
Transfer to COGS	-5 334	-4 377	-18 766	-14 909
Total	10 251	9 086	37 630	37 231

8. Research and Development expenses

The Gentian Group has per 31 December 2021 six 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 the two others in 2021, and consequently the capitalisation of the costs in these projects was started.

Recognised research and development expenses	4Q21	4Q20	2021	2020
Purchase of external services	6 019	4 503	10 712	8 470
Salary and other operating expenses	3 406	5 470	25 305	18 839
Capitalised research and development expenses	-2 476	-2 520	-10 171	-3 421
Total	6 949	7 453	25 847	23 887

9. Intangible assets

As of 31 December 2021, the recognised intangible assets in the Group amounts to MNOK 23.8. 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 4Q21.

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 31 December 2021 according to VPS and disclosures from investors:

Shareholder	No of shares	%
Vatne Equity AS	2 110 224	13.68 %
Norda ASA	1 343 168	8.71 %
Holta Life Sciences AS	1 214 702	7.88 %
Verdipapirfondet Delphi Nordic	868 916	5.63 %
Safrino AS	800 000	5.19 %
Skandinaviska Enskilda Banken AB	546 749	3.55 %
Salix AS	426 745	2.77 %
Kvantia AS	413 200	2.68 %
Verdipapirfondet Storebrand Vekst	375 221	2.43 %
Verdipapirfondet DNB SMB	362 041	2.35 %
Equinor Pensjon	309 820	2.01 %
Portia AS	300 000	1.95 %
Silvercoin Industries AS	240 647	1.56 %
Cressida AS	235 000	1.52 %
Lioness AS	220 000	1.43 %
Marstal AS	212 407	1.38 %
Mutus AS	210 465	1.36 %
Carpe Diem Afseth AS	187 849	1.22 %
Vingulmork Predictor AS	184 083	1.19 %
Verdipapirfondet Delphi Kombinasjon	181 716	1.18 %
Other Shareholders	4 679 397	30.34 %
Total Shares	15 422 350	100.00%

12. Earnings per share

	4Q21	4Q20	2020
Loss for the period	-9 544 711	-3 536 103	-17 468 742
Average number of outstanding shares during the period	15 422 350	15 411 889	15 405 011
Earnings/ loss (-) per share - basic and diluted	-0.619	-0.453	-1.134

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 31 December 2021, 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.

	4Q21	4Q20	2021
Outstanding options at beginning of period	594 916	444 916	594 916
Options granted	155 674	150 000	155 674
Options forfeited	-10 000	-10 000	-10 000
Options exercised	-	-	-
Options expired	-	-	-
Outstanding options at end of period	740 590	584 916	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. 155 674 new options have been granted in 4Q21 and 10 000 options was terminated.

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 11.7 per 31 December 2021 (MNOK 6.1 per 31 December 2020).

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 31 December 2021 is estimated to NOK 166 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	4Q21	4Q20	2021	2020
(NOK 1000)				
Revenue from contracts with customers	21 717	17 196	83 105	63 327
Revenue growth	4 521	3 126	19 778	15 375
Impact using exchange rates from last period	1 094	-874	4 357	-5 025
Impact M&A	-	1 068	1 954	1 068
Organic revenue growth	5 615	3 320	26 088	11 418
Organic revenue growth %	33 %	25 %	43 %	25 %

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	4Q21	4Q20	2021	2020
(NOK 1000)				
Employee benefit expenses	10 251	9 086	37 630	37 231
Other operating expenses	13 731	6 724	35 795	20 258
Total other operating expenses after capitalisation of R&D expenses	23 983	15 811	73 425	57 489
Capitalisation	2 476	2 520	10 171	3 421
Total other operating expenses before capitalisation of R&D expenses	26 459	18 331	83 596	60 910

Reconciliation	4Q21	4Q20	2021	2020
(NOK 1000)				
Other non-salary related operating expenses after capitalisation of R&D expenses	13 731	6 724	35 795	20 258
Capitalisation	1 612	2 138	7 194	2 814
Other non-salary related operating expenses before capitalisation of R&D expenses	15 343	8 862	42 989	23 072

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	4Q21	4Q20	2021	2020
(NOK 1000)				
Total Revenue	26 192	23 810	101 259	78 881
Total Operating Expenses	-35 675	-26 866	-124 065	-96 705
EBIT	-9 483	-3 056	-22 806	-17 824
Depreciation and Amortisation	999	1 958	7 328	6 630
EBITDA	-8 484	-1 098	-15 478	-11 194

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.

	4Q21	4Q20	2021	2020
(NOK 1000)				
Revenue from contracts with customers	21 717	17 196	83 105	63 327
COGS	10 694	9 097	43 311	32 586
COGS % of Revenue from contracts with customers	49 %	53 %	52 %	51 %

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.

	4Q21	4Q20	2021	2020
(NOK 1000)				
Non-cash shared-based compensation	1 773	822	4 633	3 278