gentian

**Q2** 

Second quarter and first half year 2021 results



# Gentian diagnostics

# **Highlights**

Record total revenues of MNOK 31.5 in 2Q21 and MNOK 55.7 for 1H21. EBITDA for 2Q21 was MNOK -0.8 which includes MNOK 3.5 costs related to the transfer of listing to Oslo Børs.

Sales revenue of MNOK 24.6 in 2Q21, a 48 % growth compared to 2Q20. Organic growth was 65%. Sales growth for 1H21 was 35% with corresponding organic growth of 47%.

Development of the SARS COV-2 assay is on track for launch in Q421 and recent market data confirms the need for such high throughput test

The Gentian share was successfully transferred to Oslo Børs on June 25<sup>th</sup>

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.

Today, 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 nanoparticle proprietary 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 31% annual revenue growth in 2017-2020. In addition, GCAL® has been launched and is in market development while NT-proBNP and SARS-COV-2 Ab are in the product development phase – of which the two former have the potential to become blockbuster products. The company also has three undisclosed biomarkers in exploration and 'proof of concept' phases.

Gentian has a long-term ambition to generate an estimated annual revenue of NOK 1 billion in 5-7 years, up from NOK 79 million in 2020. 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 prevention of sepsis and the severity assessment COVID-19 patients



Launch one new product per year; SARS-COV-2 Ab scheduled for Q4 2021 and NT-proBNP for Q1 2022



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

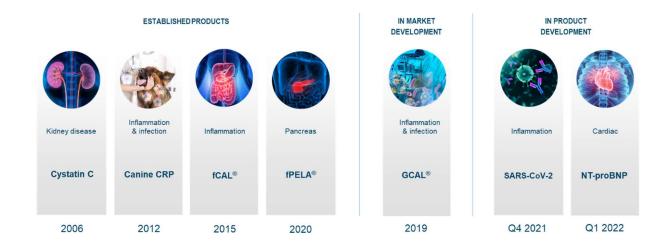


Grow gross margin ~50% in 2021 to 60%+ at volume production through economies of scale



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

# Illustration of product categories



# **Operational summary**

## Sales

Sales revenue grew 65% organically in 2Q21 ending the quarter at MNOK 24.6, a new record level. Reported growth was 48%. Sales for 1H21 was MNOK 44.2, representing an organic growth of 47% from 1H20.

Sales of Cystatin C were MNOK 11.1 for the quarter, an increase of 31 % compared to 2Q20. Growth in Asia was achieved by Gentian's partners in China and Korea with sales being up by 39 % compared to 2Q20, driven by account conversions and higher usage per instrument. The newly established co-operation with a major IVD player in South West Sweden was fully implemented and has driven 40% sales growth for Cystatin C sales in 2Q21 vs 2Q20 in Gentian AB.

Sales of fCAL® turbo have fully recovered after the negative COVID-19 impact in 2Q20. For 2Q21 sales reached MNOK 8.3, with sales more than doubling vs 2Q20 and growth of 82% for 1H21 vs 1H20. Sales growth in 2Q21 was driven by increased demand for both kit and

bulk segments, with positive impact from the Bühlmann/Roche Diagnostics partnership.

Our Swedish distribution subsidiary, Gentian Diagnostics AB (GAB), continues to show a strong positive sales trend for third party products totalling MNOK 3.9 in 1H21, a 32 % increase compared to 1H20. Continued profitable growth is anticipated going forward by extending activities to other Scandinavian countries.

The continuing COVID-19 pandemic impacted Gentian sales performance in a limited manner, with Gentian maintaining both production as well as product supply at levels to fully meet the growing market demand. In person direct contact with both partners and customers has still been very limited, which does have an impact especially on market development efforts. With laboratories heavily burdened by the COVID-19 testing challenges as well as resource limitations, are more reluctant to introduce new products.

# Market development

### **GCAL®**

A multi-center COVID-19 study, performed in collaboration with four hospitals in Spain is being finalized. The study evaluated the value of calprotectin in estimation of disease severity and identification of patients in need for invasive respiratory support. Results from this study, which included 395 COVID-19 patients, have been submitted for publication and will be presented at the Euromedlab meeting in December 2021. Two additional studies, in Norway and in the UK, are close to be finalized.

A prospective study, in collaboration with a university hospital in the United Kingdom, was started in Q2. The aim of the study is to prove the role of calprotectin in early detection of infections and evaluate the performance of GCAL® in prediction of deterioration in severely ill patients.

A paediatric prospective study is initiated in collaboration with a paediatric hospital in Canada with the aim to investigate the performance of GCAL® in detection of severe infections which could result in sepsis in neonates. The study will also provide data about reference values for calprotectin in a healthy paediatric population.

# **Product development**

### NT-proBNP

With the establishment of the NT-proBNP Immunoassay on high-volume clinical chemistry analysers, Gentian will fulfil the need for accurate and faster diagnosis of cardiac diseases. Α proprietary antibody and nanoparticle-based technology has developed for clinical biomarkers that occur in low concentrations in blood, which were previously not possible to quantify turbidimetric analysers. This allows for the development and measurement of NT-proBNP on fast, cost-effective and high-volume clinical analysers. Market sensing has identified the

The prospective study in collaboration with a German research group at one of the large university hospital groups with the aim to prove the ability of calprotectin to detect infections and differentiate between viral and bacterial infections is ongoing according to the study plan.

Gentian has in 2Q21 experienced increased traction for GCAL® due to repeat orders from existing customers and new customers. The assay has been implemented both in hospital settings as well as in specialty testing private lab organisations in Europe.

Gentian continues to advance the discussions with global IVD companies for adopting GCAL® in their portfolios. Furthermore, Gentian entered into co-operation discussions with internationally operating private lab organisations to implement the GCAL® assay, demonstrating innovation driven diagnostic services.

Specific focus for further market implementation is on the validation of additional clinical chemistry platforms by global IVD suppliers to enable further commercial expansion. Within 2021 a minimum of two additional instruments will be validated for GCAL.

lack of harmonisation and standardisation of NT-proBNP assays as a key concern among laboratory managers and clinicians and with this in mind Gentian has expanded the NT-proBNP development scope towards harmonisation and standardisation of NT-proBNP assays.

To enable the harmonisation and standardisation of NT-proBNP assays, Gentian is establishing a reference method and clinical investigations are ongoing to determine the regularity of deviations from existing assays. If these deviations are constant, a conversion factor can be used, and a «plug-and-play»

version of the Gentian assay will be part of the offer to the customer. If a conversion factor cannot be established, the commercial roll-out and potential will likely to be impacted.

# SARS-CoV-2 Total Antibody Immunoassay

The semi-quantitative SARS-CoV-2 Total Antibody Immunoassay captures the full immune response detecting antibodies with high sensitivity and specificity and will be calibrated against the international WHO standard. The test is established on automated, open-access clinical chemistry platforms, increasing both the testing capacity and the laboratory efficiency. The tracking of the total antibody response by the Gentian assay will allow the assessment of the level of protection and this will be the tool to achieve documented protection for individuals and the society. With this SARS-CoV-2 Total Antibody Immunoassay, Gentian will offer a powerful high-throughput test for community management of COVID-19 through long-term monitoring of natural and vaccine-related immune response. The routine laboratory based high-quality test will leverage existing lab infrastructure and will provide accurate test results in a cost-effective manner.

The Norwegian Ministry of Health and Care Services, based on advice from the Norwegian Directorate of Health and the Norwegian Institute of Public Health, has made a change in regulations that allows for the use of antibody tests to assess immunisation levels of vaccinated individuals. This may represent an additional market potential for this test if this change in regulation is followed up with defined levels for when an individual is considered immunised.

The assay is currently in the verification phase and preparations for the transfer into the validation phase are ongoing and launch is planned for 4Q21.

# Regulatory update

As a manufacturer and distributor in Europe, our products are CE marked and subjected to the European IVD 98/79 EC directive Norwegian Medicines Agency the Company's national competent authority. The products are classified as self-declared according to the IVD 98/79 directive with EU Declaration of Conformity and certificate of free sales issued by the national competent authority. The certificate of free sales gives the CE marked IVD medical devices free access to the EU market according to the IVD 98/79 EC. The current IVD 98/79 directive will be replaced by an IVD regulation (EU 2017/217) coming into force from 26 May 2022. The new regulation (IVDR) has a significant impact to the quality management system for manufacturers, importers and distributors as well as to the

required product documentation for each IVD medical device. There is no grandfathering rule with the IVDR, meaning that the quality management system and IVD medical devices available on the market after 26 May 2022 must comply to the IVDR. At Gentian, implementation of the regulation is on track according to the timelines in an established milestone plan, and the Group is on track to complete the IVDR certification by 26th of May 2022 to ensure continued supply of products in accordance with IVDR. Therefore, introduction of the IVDR is expected to have limited impact on established products; for future launches there is a potential for industry wide bottlenecks based on external capacity with notified bodies.

# Long-term outlook

Gentian targets disease groups that account for a Total Addressable Market of USD 7.1bn globally (2020), which is estimated to grow by 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 that contribute 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 USD 1.3bn (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 versus the addressable market is Gentian's selective approach, targeting attractive segments – in particular the early detection of infection, which prevents 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 varies across products but is expected 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 enabling improved treatment decisions and a 3-10x increase in volume throughput which saves costs and makes Gentian's offering an attractive solution to the increasing pressure on laboratory productivity.

Further, Gentian's 5–7-year ambition of NOK 1 billion revenue and a long-term EBITDA margin of 40% is set to be de-risked through several key milestones related to the company's product portfolio in H2 2021 and 2022:

### Established products

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

#### **GCAL**

- Clinical studies confirming relevance for the early detection of infections, which supports the prevention of sepsis and the severity assessment of COVID-19 patients – 6 studies ongoing
- 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 Q4 2021
- Entering commercial partnerships for the Nordics

### NT-proBNP

- Successful verification during 2021
- Publication on the reference method for standardisation
- Successful validation and launch, scheduled for Q1 2022
- Securing endorsements from key opinion leaders and global commercial partnerships

# **Financial performance**

Comparative numbers for Gentian in 2020 in ()

# Revenue, Geographic Split and Product Split

Total operating revenue ended at MNOK 31.5 (MNOK 19.9) for 2Q21. Total operating revenue for 1H21 was MNOK 55.7 (MNOK 39.0), an increase of 43% compared to 1H20.

Sales revenue in 2Q21 ended at a record high of MNOK 24.6 (MNOK 16.6), a 48 % increase compared to 2Q20. Organic growth from 2Q20 was 66 %.

### Geographic split

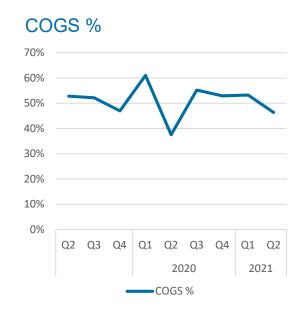
MNOK	2Q21	2Q20	1H21	1H20
US	1.0	1.0	1.4	1.7
Europe	15.7	9.9	29.7	21.1
Asia	7.9	5.7	13.1	10.1
Total	24.6	16.6	44.2	32.9

## **Product Split**

MNOK	2Q21	2Q20	1H21	1H20
Cystatin C	11.1	8.5	18.5	15.0
fCAL®turbo	8.3	3.9	16.7	9.2
Other*	5.2	4.3	9.0	8.7
Total	24.6	16.6	44.2	32.9

<sup>\*&</sup>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 6,9 (MNOK 3,2) for 2Q21, and MNOK 11,5 (MNOK 6,1) for 1H21. The increase in other operating revenues is a result of an increase in spending on Research and Development projects which triggers higher amounts received from associated research grants and tax incentives.



# Consolidated Revenues (MNOK)



### Cost of Goods Sold

We continue to see quarterly variations but expect to see COGS declining as a percentage of sales over time.

## **Total Other Operating Expenses**

Total other operating expenses before capitalization of R&D expenses ended at MNOK 23.3 (MNOK 15.0) in 2Q21. The increase is a result of higher spending on research and development projects related to both NT-proBNP and SARS COV-2 AB and also costs in connection with the transfer of listing of the Company's shares to Oslo Børs which has been charged directly to the profit & loss with MNOK 3.5 in 2Q21.

R&D expenses amounted to 55% (40%) of total other operating expenses before capitalization for 2Q21 and increase of 132 % compared to 2Q20. Capitalization of R&D expenses was MNOK 2.3 (MNOK 0.6) in 2Q21.

Total other operating expenses after capitalization of R&D expenses ended at MNOK 21.0 (MNOK 13.4) in 2Q21.

### **Earnings**

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -0.9 (MNOK 0,2) for 2Q21. Net profit ended at MNOK -3,5 (MNOK -1,4) for 2Q21.

### **Balance Sheet**

Cash and cash equivalents as of 30.06.2021 were MNOK 138,3 (MNOK 161.2). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 30.06.2021 were MNOK 12.2 (MNOK 7.3). Inventory as of 30.06.2021 was MNOK 24.9 (MNOK 19.8).

### Covid-19

At Gentian, the health and safety of our employees, as well as our customers and partners, is our primary concern. Gentian has robust business-continuity plans in place and will be able to maintain production even if the situation would deteriorate. Gentian abides by policies of the health authorities in all countries in which it operates whilst it seeks to continue to seamlessly support our customers. Gentian may be affected by the COVID-19 outbreak by reduced demand for diagnostic services, especially for outpatient markers, and we expect some delays with our R&D programs. The length of potential delays will depend on the duration of the outbreak.

## Corporate

The Company successfully transferred the listing of its shares from Euronext Growth to Oslo Børs on June 25<sup>th</sup>.

# Events after the balance sheet date

There are no events to report after the balance sheet date.

## Declaration by the board and the CEO

We confirm, to the best of our knowledge, that the unaudited interim financial statements for the period 1 January to 30 June 2021 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.

We also declare, 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, 24. August 2021

On behalf of Gentian Diagnostics ASA,

Tomas Settevik Chairperson of the board (sign.)	Espen Tidemann Jørgensen Board member <i>(sign.)</i>
Susanne Stuffers Board member (sign.)	Ingrid Teigland Akay Board member <i>(sign.)</i>
Kari E. Krogstad Board member (sign.)	Runar Vatne Board member <i>(sign.)</i>
Tomas Kramar Board member <i>(sign.)</i>	Hilja Ibert CEO <i>(sign.)</i>

# Statement of Profit and Loss Gentian Group

	Note	2021	2020	2021	2020	2020
(NOK 1000)		Q2	Q2	01.01- 30.06	01.01- 30.06	
Revenue						
Revenue from contracts with customers	3	24 568	16 634	44 210	32 882	63 327
Other operating revenue	4	6 936	3 244	11 496	6 128	15 554
Total revenue		31 504	19 879	55 705	39 010	78 881
Operating expenses						
Cost of goods sold	6	-11 379	-6 250	-21 844	-16 176	-32 586
Employee benefit expenses	7,13	-8 654	-9 443	-18 362	-18 430	-37 231
Depreciation and amortisation		-1 982	-1 566	-3 954	-3 133	-6 630
Impairment		-	-	-	-	-
Other operating expenses		-12 326	-3 947	-18 300	-9 054	-20 258
Total operating expenses		-34 341	-21 206	-62 459	-46 793	-96 705
Operating result		-2 838	-1 327	-6 754	-7 783	-17 824
Finance income		55	175	161	1 328	1 840
Finance cost		-732	-264	-1 843	-496	-1 484
Net financial items		-677	-89	-1 682	832	356
Profit before tax		-3 514	-1 416	-8 436	-6 951	-17 469
Income tax expense		-	-	-	-	-
Profit for the period		-3 514	-1 416	-8 436	-6 951	-17 469
Other comprehensive income						
Exchange differences		46	129	-87	203	68
Total other comprehensive income		46	129	-87	203	68
Total comprehensive income for the period		-3 468	-1 287	-8 523	-6 748	-17 401

2nd quarter Statement of Profit and Loss is not audited

# Statement of Financial Position - Gentian Group

Note	2021	2020	2020
(figures in NOK thousands)	30.06	30.06	31.12
Assets			
Non-Current Assets			
Intangible assets 9	18 267	13 999	15 610
Property, plants and equipment	6 627	4 420	3 865
Right-of-use assets	18 518	1 994	21 689
Other Financial Assets	335	336	337
Total Non-Current Assets	43 746	20 748	41 501
Current Assets	04.050	40.770	00.070
Inventory	24 856	19 772	20 876
Accounts receivables and other receivables	26 795	17 584	15 241
Cash and cash equivalents	138 250	160 885	157 648
Total Currents Assets	189 900	198 241	193 764
Total Assets	233 646	218 989	235 265
Equity and liabilities			
Paid-in equity			
Share capital	1 541	1 540	1 541
Share premium	293 241	292 780	293 241
Other paid-in equity	9 262	5 735	7 309
Total paid-in equity	304 044	300 055	302 091
Retained earning			
Retained earning	-116 036	-96 859	-107 512
Total retained equity	-116 036	-96 859	-107 512
Total equity	188 008	203 196	194 579
Liabilities			
Financial leasing 10	1 107	951	928
Operational leasing (Right-of-Use)		2 170	17 173
Total non-current liabilities	21 760	3 121	18 101
Current liabilities			
Accounts payable and other current liabilities	23 877	12 672	22 585
Total current liabilities	23 877	12 672	22 585
Total liabilities	45 637	15 793	40 686
Total equity and liabilities	233 645	218 989	235 265

# Statement of changes in equity

(figures in NOK thousands)

			Other		
	Share	Share	paid-in	Retained	Total
	capital	premium	capital	earnings	equity
Equity at 31.12.2019	1 540	292 780	4 031	-90 112	208 240
Net result for the year				-6 951	-6 951
Other comprehensive income				-0 931	-0 951
Proceeds from share issue					
Cost of share issue					
Share based payments			1 704		1 704
Other changes in equity			1704	203	203
Equity at 30.06.2020	1 540	292 780	5 735	-96 859	203 196
Equity at 30.06.2020	1 340	292 700	5 / 35	-90 009	203 190
Equity at 01.01.2020	1 540	292 780	4 031	-90 112	208 240
Net result for the year				-17 468	-17 468
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				-8 436	-8 436
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			1 953		1 953
Other changes in equity				-87	-87
Equity at 31.06.2021	1 541	293 241	9 262	-116 036	188 009

2nd quarter Statement of changes in equity is not audited

### **Cash Flow Statement**

	2021	2020	2021	2020	2020
(NOK 1000)	Q2	Q2	01.01- 30.06	01.01- 30.06	01.01 - 31.12
Operating activities					
Net profit (loss)	-3 514	-1 416	-8 436	-6 951	-17 469
Depreciation and amortisation	1 982	1 566	3 954	3 133	6 630
Change Inventory	-3 315	-1 320	-3 980	-1 549	-2 652
Change Accounts Receivables	-4 285	2 610	-4 535	1 177	860
Change Accounts Payables	7 823	-314	6 054	-956	1 202
Accrued cost of options	982	832	1 953	1 704	3 278
Change in other assets and liabilities	-2 563	821	-6 853	-5 154	-4 359
Net cash flow from operating activities	-2 890	2 778	-11 844	-8 595	-12 509
Investing activities					
Payments of property, plant and equipment	-1 645	-634	-2 383	-697	-2 734
Investment in intangible assets	-2 316	-581	-3 804	-958	-3 733
Investments in other companies	-	-	-		6 741
Net cash flow from investing activities	-3 961	-1 215	-6 187	-1 655	274
Financing activities	-	-	-	-	-
New debt	-	-	-	-	497
Loan instalments	-604	-71	-1 187	-142	-2 469
Proceeds from issue of share capital	-	-	-	-	462
Net cash flow from financing activities	-604	-71	-1 187	-142	-1 510
Net change in cash and cash equivalent	-7 455	1 492	-19 218	-10 392	-13 745
Cash and cash equivalents at beginning of period	146 055	161 407	157 985	171 567	171 567
Effect of currency translation of cash and cash equivalents	-16	-15	-182	46	163
Net Cash and cash equivalents at period end	138 585	162 885	138 585	161 221	157 985

2nd quarter Cash Flow Statement is not audited

<sup>\*</sup> Note: Gentian Diagnostics divested its subsidiary PreTect AS in fourth quarter 2020. 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 NOK 6,741 thousand 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 NOK 1,893 thousand. The remaining part of net cash received which amounts to the amount of NOK 4,848 thousand was classified as cash from operating activities.

### **Notes**

#### General Information

Gentian Diagnostics ASA is registered in Norway and listed on the Oslo stock exchange. 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 AS 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 AS.

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

2.2. 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.

#### 2.3. Basis of consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries. As at 30 June 2021, Gentian AS, located in Moss, Norway is a 100% owned and controlled subsidiary.

### 3. Sales and revenue

Revenue by classification	2Q21	2Q20	1H21	1H20	2020
Sales revenue	24 568	16 634	44 210	32 881	63 327
Public grants	6 936	3 244	11 496	6 128	10 512
Revenue from divestiture	-	-	-	-	4 384
Other revenue	-	-	-	-	657
Total	31 504	19 878	55 705	39 009	78 881
Geographical split	2Q21	2Q20	1H21	1H20	2020
Europe	15 654	9 894	29 687	21 103	45 416
Asia	7 899	5 728	13 134	10 072	14 909
USA	1 105	1 012	1 389	1 707	3 002
Total	24 568	16 634	44 210	32 882	63 327
Sales by product	2Q21	2Q20	1H21	1H20	2020
Renal diagnostic products	11 121	8 451	18 485	15 566	25 237
Inflammation diagnostic products	11 648	6 032	22 268	12 501	29 889
Other diagnostic products	1 799	2 152	3 457	4 816	8 201
Total	24 568	16 634	44 210	32 882	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.

	2Q21	2Q20	1H21	1H20	2020
Norwegian Research Council and Eurostars	4 798	1 708	7 637	3 150	7 510
Innovation Norway	345	319	810	669	1 222
SkatteFUNN	1 793	1 217	3 049	1 921	1 780
Total	6 936	3 244	11 496	5 740	10 512

<sup>\*</sup>The subsidiary PreTect AS was divested in 2020.

### 5. Operating expenses by function

	2Q21	2Q20	1H21	1H20	2020
Sales and marketing expenses	3 671	2 976	7 742	6 432	14 193
Administration expenses	8 949	5 968	14 392	11 033	19 408
Research and development expenses	10 676	5 027	18 333	10 665	23 887
Total	23 296	13 971	40 467	28 130	50 488

### 6. Cost of goods sold

	2Q21	2Q20	1H21	1H20	2020
Change in inventory of goods under manufacture and finished goods	-3 315	-1 320	-3 980	-1 549	-2 014
Purchase of goods	9 815	4 775	15 252	9 444	16 309
Production salary	3 590	2 565	8 451	6 519	14 909
Other production expense	1 289	230	2 120	1 762	3 382
Total	11 379	6 250	21 844	16 176	32 586

#### 7. Employee benefit expenses

	2Q21	2Q20	1H21	1H20	2020
Wages and salaries	10 095	9 942	21 445	19 857	40 551
Payroll tax	577	842	2 376	2 500	5 907
Pension costs (mandatory occupational pension)	348	242	715	524	1 416
Share based payments	982	832	1 832	1 704	3 278
Other expenses	243	150	445	364	988
Transfer to COGS	-3 590	-2 565	-8 451	-6 519	-14 909
Total	8 654	9 443	18 362	18 430	37 231

### 8. Research and Development expenses

The Gentian Group has per 30 June 2021 eight 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 one in 2018, and consequently the capitalisation of the costs in these projects was started.

Recognised research and development expenses	2Q21	2Q20	1H21	1H20	2020
Purchase of external services	1 481	1 617	3 378	2 696	8 470
Salary and other operating expenses	11 511	3 991	18 759	8 615	18 839
Capitalised research and development expenses	-2 316	-581	-3 804	-646	-3 421
Total	10 676	5 027	18 333	10 665	23 887

#### 9. Intangible assets

As of 30 June 2021, the recognized intangible assets in the Group amounts to MNOK 18.3. The intangible assets are derived from capitalization 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 2Q21.

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 30.06.2021 according to VPS and disclosures from investors:

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

### 12. Earnings per share

	2Q21	2Q20	2020
Loss for the period	-3 514 417	-1 416 278	-17 468 742
Average number of outstanding shares during			
the period	15 411 889	15 402 718	15 402 718
Earnings/ loss (-) per share - basic and diluted	-0.228	-0.092	-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. As at 30 June 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.

	2Q21	2Q20	2020
Outstanding options at beginning of period	594 916	454 916	454 916
Options granted	-		150 000
Options forfeited	-	-10 000	-10 000
Options exercised	-		-
Options expired	-		-
Outstanding options at end of period	594 916	444 916	594 916

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	269 962
2025-11	62,88	150 000
		594 916

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 (50 %), expected dividend yield (0 %), expected term of 4 years, annual risk-free interest rate (1.1 %). The volatility is based on other comparable companies' stock price volatility. No new options have been granted in 2Q21.

### 14. Transactions with related parties

The Group uses Getica AB as a supplier for one of it's 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 to Getica AB amounted to MNOK 7.1 in 1H 2021 (MNOK 3.1 in 1H 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 30.06.2021 is estimated to NOK 151 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	2Q21	2Q20	1H21	1H20	2020
(NOK 1000)					
Revenue from contracts with customers	24 568	16 634	44 210	32 881	63 327
Revenue growth	7 934	6 463	11 329	12 098	15 372
Impact using exchange rates from last period	2 399	-1 966	2 798	-3 160	-5 025
Impact M&A	405	-	1 422	-	-
Organic revenue growth	10 738	4 497	15 549	8 938	10 347
Organic revenue growth %	65%	44%	47%	43%	22%

# 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	2Q21	2Q20	1H21	1H20	2020
(NOK 1000)					_
Employee benefit expenses	8 654	9 443	18 362	18 430	37 231
Other operating expenses	12 326	3 974	18 300	9 054	20 258
Total other operating expenses after capitalisation of R&D expenses	20 980	13 417	36 662	27 484	57 489
Capitalisation	2 316	581	3 804	646	3 421
Total other operating expenses <b>before</b> capitalisation of R&D expenses	23 296	13 998	40 466	28 130	60 910

Reconciliation	2Q21	2Q20	1H21	1H20	2020
(NOK 1000)					
Other non-salary related operating expenses <b>after</b> capitalisation of R&D expenses	12 326	3 974	18 300	9 054	20 258
Capitalisation	1 650	460	2 510	460	2 814
Other non-salary related operating expenses <b>before</b> capitalisation of R&D expenses	13 976	4 434	20 810	9 514	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	2Q21	2Q20	1H21	1H20	2020
(NOK 1000)					
Total Revenue	31 504	19 879	55 706	39 010	78 881
Total Operating Expenses	-34 341	-21 206	-62 458	-46 793	-96 705
EBIT	-2 837	-1 327	-6 753	-7 783	-17 824
Depreciation and Amortisation	1 982	1 566	3 953	3 133	6 630
EBITDA	-855	239	-2 800	-4 650	-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.

	2Q21	2Q20	1H21	1H20	2020
(NOK 1000)					
Revenue from contracts with customers	24 568	16 634	44 210	32 881	63 327
COGS	11 379	6 250	21 843	16 176	32 586
COGS % of Revenue from contracts with customers	46 %	38 %	49 %	49 %	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.

	2Q21	2Q20	1H21	1H20	2020
(NOK 1000)					
Non-cash shared-based compensation	982	832	1 832	1 704	3 278