gentian

Second quarter and first half 2020 results

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We innovate diagnostic efficiency

GENTIAN DIAGNOSTICS

Gentian Diagnostics AS is a medical diagnostics company listed on the Oslo Stock Exchange, Merkur Market. The company performs production, R&D, marketing and distribution of immunoassays at our headquarters in Norway and we are supported globally by our distribution subsidiaries in Sweden, the USA and a representative office in China.

Through in-depth research into Particle-Enhanced Turbidimetric Immunoassays (PETIA), and the development of proprietary antibody and nano-particle technology, Gentian's immunoassays enable users to move assays from low volume immunology platforms to fully automated, high throughput instruments with shorter turnaround times, better workflow and improved cost efficiency.

Gentian serves the immunochemistry segment of the in vitro diagnostics (IVD) market with products which add value to health care suppliers by improving laboratory workflow and clinical outcome. The value propositions of new products will be scientifically proven and promoted by investments into clinical studies, state-of-the art marketing and selective commercial representation in focus countries.

In addition, the subsidiary PreTect AS develops and manufactures molecular diagnostic tests to detect oncogenic activity in cervical samples. The products PreTect SEE and PreTect HPV-Proofer contribute to earlier detection of cervical cancer.

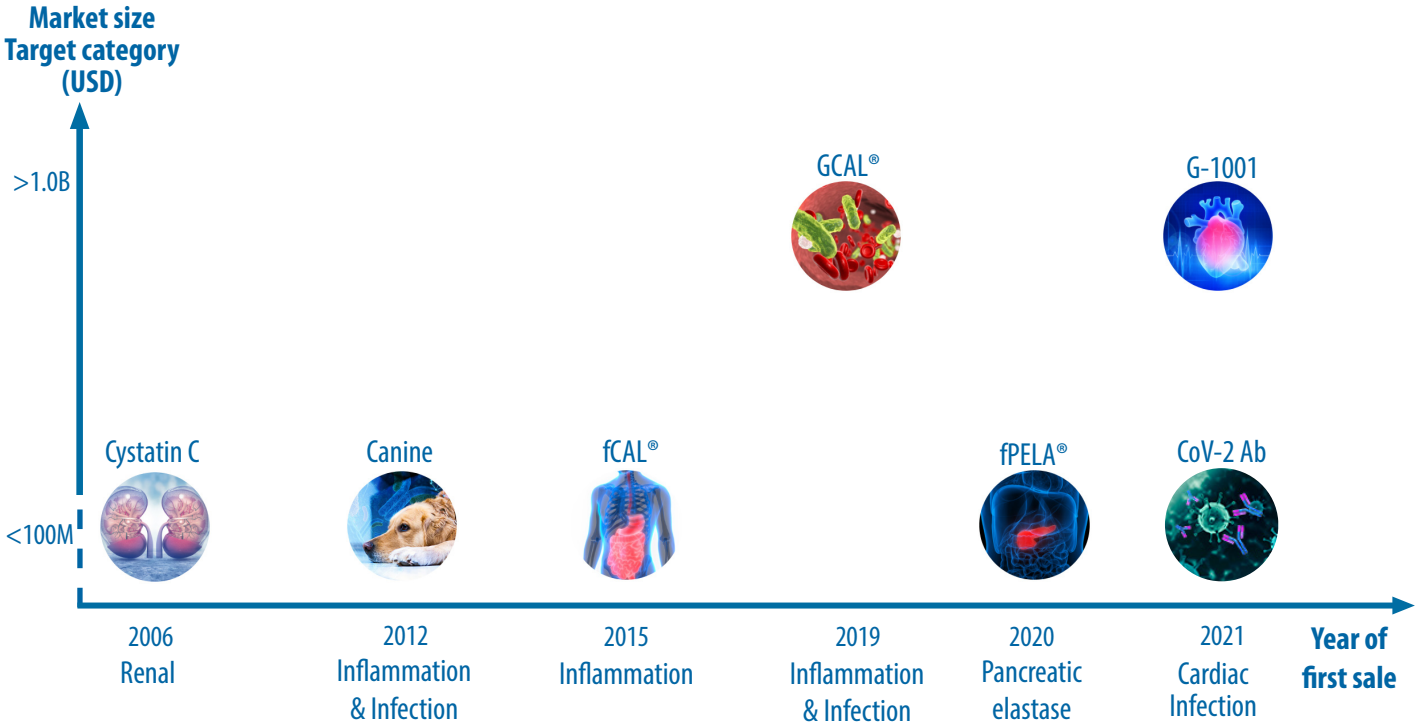
Gentian Diagnostics' PETIA products and product pipeline

Gentian develops and manufactures high quality IVD reagents for a wide range of clinical chemistry analysers. Our product lines of laboratory tests, for diverse diagnostic targets, provide high accuracy and fast results for both human and veterinary healthcare. Current and pipeline products contribute to increased laboratory efficiency and improved outcome for patients with inflammatory/infectious, renal and cardiovascular diseases and cancer.

Gentian's current portfolio includes Cystatin C (CE marked and FDA-510(k) cleared), the calprotectin immunoassay GCAL® (CE marked, US: RUO) and Canine CRP.

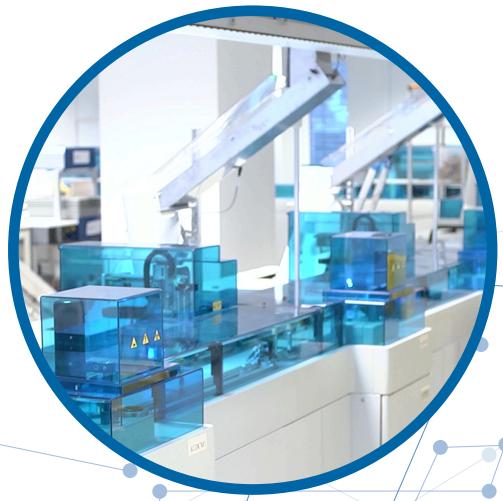
In addition, Gentian is the sole reagent provider and manufacturer for the faecal calprotectin immunoassay fCAL® turbo (CE marked and FDA-510(k) cleared) in addition to the newly launched, pancreatic elastase immunoassay fPELA® turbo (CE marked, FDA Exempt). These immunoassays are sold through Gentian's partner BÜHLMANN.

For 2021, Gentian is preparing the launch of its G-1001 cardiac marker, which is designed specifically for high volume clinical chemistry platforms. Gentian's high throughput turbidimetric SARS-CoV-2 antibody is on a fast track development plan and also expected for launch in 2021.



HIGHLIGHTS

- Record sales revenues of MNOK 16.6 in 2Q20, up from MNOK 10.2 in 2Q19
- Sales growth in 2Q20 of 64 % is especially based on Cystatin C sales in Asia. Sales in the quarter grew by 44 % YoY on a currency neutral basis
- Successful release of fPELA® turbo, which is marketed by our partner BÜHLMANN
- Gentian awarded up to MNOK 8.0 in funding to support the development of a high-throughput SARS-CoV-2 antibody test
- New scientific publications propose calprotectin as a promising biomarker for the management of COVID-19 patients, which represents a new opportunity for our GCAL® assay



OPERATIONAL SUMMARY

Sales

Sales revenue in 2Q20 showed an increase of 64 % compared to 2Q19, ending the quarter at a new record high of MNOK 16.6. For 1H 2020 the sales revenue ended 58 % higher compared to 1H 2019. The increase is based on continued growth and especially a strong performance of Cystatin C sales in Asia where sales in 1H 2020 increased with 119 % compared to 1H 2019.

Due to the COVID-19 outbreak, the company experienced in 2Q20 a strong decline in sales of fCAL turbo compared to 1Q20. There are early indications that sales are now slowly picking up again throughout Europe. Nevertheless, sales compared to 2Q19 increased by 29 %.

Our Swedish distribution subsidiary, Gentian Diagnostics AB, continues to have a positive sales development after securing the rights to distribute more third-party products in Sweden.

In June, the company announced the release of the new CE marked turbidimetric immunoassay for the simplified quantification of human pancreatic elastase, helping to monitor Pancreatic Exocrine Insufficiency (PEI), the BÜHLMANN fPELA® turbo. This immunoassay is sold through Gentian's partner BÜHLMANN and Gentian is the sole reagent provider and manufacturer. For more information see announcement dated 16th of June 2020.

The current outbreak of COVID-19 has had a minor effect on Gentian so far. Gentian has robust business-continuity plans in place, and production has been maintained at normal levels with staff working under enhanced safety conditions. The company has also been able to make deliveries to its customers on time.

Market development

GCAL®

The market development initiatives for the novel biomarker GCAL® have made good progress during the quarter. Only one of the GCAL® clinical studies has experienced some delay due to the COVID-19 situation and is expected to be up and running during fall.

Results from several studies have supported the role of calprotectin in early diagnosis of infection/inflammation as well as in prognosis of deterioration and mortality in severely ill patients. The knowledge and awareness about GCAL® and its clinical use are communicated to potential customers.

During the last few months of the COVID-19 pandemic, several studies have confirmed the critical role of neutrophils in patients infected with SARS-CoV-2 virus. Two studies performed at universities and hospitals in Michigan, Shanghai and Washington have specifically focused on calprotectin as an early biomarker for neutrophil activation and its role in COVID-19 [1-2]. The results from these studies confirms significantly elevated levels of calprotectin in patients hospitalised with COVID-19. Calprotectin levels correlated with the severity of the respiratory failure and need for mechanical ventilation. Elevated levels of calprotectin were also associated with higher mortality risk due to thrombotic complications indicating the use of calprotectin as a prognostic biomarker for severity of the disease and risk of mortality.

Product development

G-1001

The development work during the quarter has resulted in promising performance data coming from additional testing of clinical samples in comparison to established tests in the market. The COVID-19 outbreak related delays of reagent supply represent a confirmed challenge for the company's plan to launch in 2021, which will be addressed during the coming quarters.

SARS-CoV-2 antibody immunoassay

As announced on 3rd of July, Gentian has initiated the development of a SARS-CoV-2 antibody immunoassay in order to address the emerging needs associated with the COVID-19 outbreak to test patient's immune status. The Norwegian Research Council will support this project with up to MNOK 8. For more information see the announcement dated 3rd of July 2020.

References: 1. Shi et al., Neutrophil calprotectin identifies severe pulmonary disease in COVID-19, MedRxiv. May 2020. PMCID: PMC7274221 DOI: 10.1101/2020.05.06.20093070 **2.** Zuo et al., Neutrophil extracellular traps (NETs) as markers of disease severity in COVID-19, MedRxiv. Apr2020. PMCID: PMC7276989 DOI: 10.1101/2020.04.09. 20059626

During Q2, Gentian further strengthened its commercial organisational structure and focused on enhancing and intensifying the discussions with our customer in order to develop successful and long lasting business relationships with market specific initiatives.

Markus Jaquemar, VP Global Sales

A lot of IVD companies have already established SARS-CoV-2 antibody tests, however, these tests use assay technologies which usually result in a lower volume throughput. The Gentian antibody test will be a turbidimetric SARS-CoV-2 assay using the PETIA technology. The PETIA technology offers the benefits of cost-effective open platform testing, with shorter time-to-result and higher through-put compared to other immunoassay systems, perfectly responding to the envisaged testing needs for COVID-19.

Torsten Knüttel, VP R&D

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FINANCIAL PERFORMANCE

Comparative numbers for Gentian 2019 in ()

Sales, Geographic Split and Product Split

Total operating revenue ended at MNOK 19.9 (MNOK 12.1) for 2Q20, and MNOK 39.0 (MNOK 24.2) for 1H 2020.

Sales revenue in 2Q20 ended at MNOK 16.6 (MNOK 10.2), a 64 % increase compared to 2Q19. Sales revenue for 1H 2020 ended at MNOK 32.9 (MNOK 20.8), a 58 % increase compared to 1H 2019. Adjusted for currency effects sales growth was 43 % YTD.

Geographic split:

MNOK	2Q20	2Q19	1H20	1H19
US	1.0	0.6	1.7	1.1
Europe	9.9	7.7	21.1	15.1
Asia	5.7	1.9	10.1	4.6
Total	16.6	10.2	32.9	20.8

Product split:

MNOK	2Q20	2Q19	1H20	1H19
Cystatin C	8.5	3.9	15.0	8.6
fCAL®turbo	3.9	3.0	9.2	6.9
Other	4.3	3.3	8.7	5.3
Total	16.6	10.2	32.9	20.8

Other operating revenue ended at MNOK 3.2 (MNOK 1.9) for 2Q20, and MNOK 6.1 (MNOK 3.4) for 1H 2020.

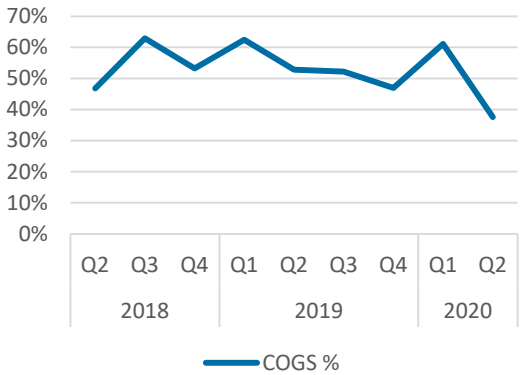
Revenues and Grants Consolidated (NOK)

Cost of Goods Sold

COGS ended at MNOK 6.2 (MNOK 5.4) in 2Q20, which represents 38 % (53 %) of sales revenue. Total COGS for 1H 2020 ended at MNOK 16.1 (MNOK 12.0), which represents 49 % (58 %) of sales revenue.

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

COGS %



Total Other Operating Expenses

Total other operating expenses before capitalization of R&D expenses ended at MNOK 14.0 (MNOK 12.0) in 2Q20, and MNOK 28.1 (MNOK 24.0) for 1H 2020.

Other operating expenses include salary and social expenses of MNOK 9.6 (MNOK 6.0) and other expenses of MNOK 4.4 (MNOK 6.0) for 2Q20. For 1H2020 total salary and social expenses ended at MNOK 18.6 (MNOK 13.6) and other expenses ended at MNOK 9.5 (MNOK 10.4). SG&A also include a share-based compensation of MNOK 1.7 year to date with no cash effect.

Total other operating expenses after capitalization of R&D expenses ended at MNOK 13.4 (MNOK 11.5) in 2Q20 and MNOK 27.5 (MNOK 22.6) for 1H 2020.

R&D Expenses

R&D expenses amounted to 36 % (44 %) of total other operating expenses before capitalization for 2Q20, and 38 % (39 %) for 1H 2020.

Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK 0.2 (MNOK -4.8) for 2Q20, and MNOK -4.6 (MNOK -10.4) for 1H 2020.

Net financial income ended at MNOK -0.1 (MNOK 0.3) for 2Q20, and MNOK 0.8 (MNOK 0.3) for 1H 2020.

Net profit ended at MNOK -1.4 (MNOK -20.3) for 2Q20, and MNOK -7.0 (MNOK -27.6) for 1H 2020.

Balance Sheet

Cash and cash equivalents as of 30.06.2020 were MNOK 161.2 (MNOK 179.3). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 30.06.2020 were MNOK 7.3 (MNOK 8.7).

Inventory as of 30.06.2020 were MNOK 19.8 (MNOK 15.4).

Cash Flow

Cash flow from operating activities ended at MNOK 1.1 (MNOK -11.3) for 2Q20 and MNOK -8,6 (MNOK -17.5) for 1H 2020.

Cash flow from investment activities ended at MNOK -1.2 (MNOK -0.6) for 2Q20, and MNOK -1.7 (MNOK -1.8) for 1H 2020. Capitalization of R&D expenses amounted to MNOK 0.6 (MNOK 0.5) for 2Q20, and MNOK 0.6 (MNOK 1.4) for 1H 2020.

Cash flow from financial activities ended at MNOK -0.1 (MNOK -0.0) for 2Q20, and MNOK -0.1 (MNOK -0.1) for 1H 2020.

OUTLOOK

At Gentian, the health and safety of our employees, as well as our customers and partners, is our primary concern. That continues to be our focus as we manage our response to the COVID-19 outbreak that has proliferated globally. Gentian has robust business-continuity plans in place and expects to maintain production even if the situation deteriorates. Gentian abides by policies of the health authorities in all countries of operation whilst continuing 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 the delays will depend on the duration of the outbreak.

The company estimate continued sales growth in 2020 versus 2019, with expected quarterly variations and so far, unpredictable effects of the COVID-19 outbreak.

For Cystatin C, the company expects reduced orders from Asia in 2H 2020 due to high warehouse levels but continuous growth in the US and Europe. Overall Y/Y growth in 2H 2020 is expected to be lower than in 1H 2020.

For fCAL® turbo, we have experienced reduced growth in 1H 2020. Early indications points to an increase in demand in 3Q 2020 a stabilisation of the situation will depend on the capacity of health systems to process outpatient services under a sustained presence of COVID-19 patients.

For GCAL®, results from several studies are published and additional clinical publications are in preparations. The company will continue its engagement with Key Opinion Leaders in the field of infectious diseases around the world, as well as globally respected hospital laboratories and potential commercial partners. In addition, Gentian has initiated several study collaborations with aim to confirm and further investigate the role of calprotectin in COVID-19, using Gentian GCAL® turbidimetric assay and providing fast and accurate results.

For G-1001; the COVID-19 outbreak has resulted in supply delays of reagents which represents a confirmed challenge for the company's plan to launch in 2021. This will be addressed during the coming quarters.

EVENTS AFTER THE BLANCE SHEET DATE

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

SHAREHOLDER INFORMATION

20 largest shareholders in Gentian Diagnostics AS as of 30.06.2020 according to VPS and disclosures from investors:

Shareholder	No of Shares	%
Vatne Equity AS	2 010 224	13,05 %
Holta Life Sciences AS	1 214 702	7,89 %
Safrino AS	1 100 000	7,14 %
Salix AS	1 022 626	6,64 %
Norron Sicav - Target	713 000	4,63 %
Verdipapirfondet Delphi Nordic	680 000	4,41 %
Norda ASA	649 186	4,21 %
Storebrand Vekst	447 455	2,91 %
Portia AS	433 000	2,81 %
Equinor Pensjon	381 320	2,48 %
Verdipapirfondet DNB SMB	358 623	2,33 %
Bård Sundrehagen	274 768	1,78 %
Silvercoin Industries AS	263 738	1,71 %
Cressida AS	235 000	1,53 %
Vingulmork Predictor AS	224 083	1,45 %
Lioness AS	220 000	1,43 %
Marstal AS	210 542	1,37 %
Mutus AS	210 465	1,37 %
Viola AS	199 990	1,30 %
Borgano AS	186 499	1,21 %
Other Shareholders	4 367 497	28,36 %
Total Shares	**15 402 718**	**100,00 %**

Statement of Comprehensive Income Gentian Group

	2020	2020	2019	2019
(figures in NOK thousands)	**Q2**	**01.01-30.06**	**Q2**	**01.01-30.06**
Operating Revenue				
Sales revenue	16 634	32 882	10 171	20 784
Other operating revenue	3 244	6 128	1 942	3 392
Total Operating Revenue	**19 879**	**39 010**	**12 113**	**24 175**
Operating Expenses/Costs				
Cost of goods sold	-6 250	-16 176	-5 372	-12 002
R&D costs	-5 027	-10 665	-5 223	-9 332
Selling, general & administrative costs	-8 944	-17 465	-6 748	-14 622
Capitalization	581	646	457	1 364
Total Operating Expenses/Costs	**-19 639**	**-43 660**	**-16 886**	**-34 591**
EBITDA	**239**	**-4 650**	**-4 774**	**-10 416**
Depreciation	-1 566	-3 133	-1 722	-3 378
Impairment	-	-	-14 086	-14 086
EBIT	**-1 327**	**-7 783**	**-20 583**	**-27 880**
Financial income/expense	-89	832	302	323
Tax	-	-	-62	-62
Net Profit	**-1 416**	**-6 951**	**-20 343**	**-27 620**

2nd quarter Statement of Comprehensive Income is not audited

Statement of Financial Position Gentian Group

	2020	2019	2019
(figures in NOK thousands)	30.06	31.12	30.06
Assets			
Non-Current Assets			
Property, plants and equipment	4 420	4 714	4 399
Right-of-use asset	1 994	3 062	4 101
Capitalized development costs	13 966	14 076	13 243
Other intangible assets	33	36	38
Financial assets	336	329	326
Total Non-Current Assets	**20 748**	**22 216**	**22 108**
Current Assets			
Inventory	19 772	18 224	15 393
Accounts receivables	7 317	8 493	8 703
Other receivables	10 267	7 012	8 735
Cash and cash equivalents	160 885	171 238	178 950
Total Currents Assets	**198 241**	**204 967**	**211 780**
Total Assets	**218 989**	**227 182**	**233 887**
Equity and Liabilities			
Equity			
Net profit	-6 951	-39 857	-27 620
Other equity	210 147	248 096	246 754
Equity	**203 196**	**208 240**	**219 134**
Non-Current Liabilities			
Interest-bearing loans and dept	951	1 093	619
Lease liability	2 170	3 202	4 192
Total Non-Current Liabilities	**3 121**	**4 295**	**4 811**
Current liabilities			
Accounts payable	3 650	4 606	4 267
Public dept	3 263	2 501	2 188
Accrued expenses	5 760	7 541	3 487
Total Current Liabilities	**12 672**	**14 648**	**9 942**
Total Equity and Liabilities	**218 989**	**227 182**	**233 887**

2nd quarter Statement of Financial Position is not audited

Cash Flow Statement

	2020	2020	2019	2019
(figures in NOK thousands)	Q2	Q1	31.12	30.06
Cash Flow from Operating Activities				
Net profit (loss)	-1 416	-5 535	-39 857	-27 620
	-	-		-
Depreciation	1 566	1 567	6 132	3 378
Impairment	-	-	14 086	14 086
Change Inventory	-1 320	-229	-5 126	-2 295
Change Accounts Receivables	2 610	-1 433	792	582
Change Accounts Payables	-314	-642	1 310	971
Change in other short-term receivables/ liabilities	-11	-3 438	-431	-6 611
Net Cash Flow from Operating Activities	**1 114**	**-9 710**	**-23 093**	**-17 508**
Cash Flows from Investment Activities				
Acquisition of Property, plant and equipment	-634	-63	-1 589	-437
Investment in intangible assets	-581	-377	-3 071	-1 364
Other changes in financial items	-	-	-	-
Net Cash Flow from Investment Activities	**-1 215**	**-440**	**-4 660**	**-1 801**
Cash Flow from Financial Activities				
New debt	-	-	621	-
Downpayment of loans	-71	-70	-226	-79
Cash flows from share issues	-	-	259	-
Dividend payment	-	-	-	-
Net Cash Flow from Financial Activities	**-71**	**-70**	**654**	**-79**
Net Change in Cash and Cash Equivalents	-172	-10 221	-27 099	-19 388
Cash and cash equivalents at beginning of period	161 407	171 567	198 634	198 634
Currency adjustment	-15	62	32	29
Net Cash and Cash Equivalents	**161 221**	**161 407**	**171 567**	**179 275**

2nd quarter Cash Flow Statement is not audited

Statement of Changes in Equity

(figures in NOK thousands)

	Share capital	Share premium	Other paid-in capital	Retained earnings	Total equity
Equity at 01.01.2019	**1 540**	**292 522**	**2 162**	**-50 350**	**245 873**
Net result for the year				-39 857	-39 857
Other comprehensive income					
Proceeds from share issue	1	258			259
Cost of share issue					
Share based payments			1 869		1 869
Other changes in equity				95	95
Equity at 31.12.2019	**1 540**	**292 780**	**4 031**	**-90 112**	**208 240**

Equity at 01.01.2020	**1 540**	**292 780**	**4 031**	**-90 112**	**208 240**
Net result for the year				-6 951	-6 951
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			1 704		1 704
Other changes in equity				203	203
Equity at 30.06.2020	**1 540**	**292 780**	**5 735**	**-96 859**	**203 196**

2nd quarter Statement of Changes in Equity is not audited

NOTES

Accounting Principles

The interim report for Q2 2020 has been prepared in accordance with IAS 34 Interim Reporting. The accounting policies applied in the interim report corresponds to what was used in preparing the annual financial statements for 2019.

Currency

The company uses currency rates given by DNB ASA.

Capitalized R&D

There are currently two projects where the Gentian group is capitalizing R&D expenses.

GENTIAN DIAGNOSTICS AS

SEMI-ANNUAL REPORT AND DECLERATION

2020

Declaration by the Board and the CEO

We declare to the best of our knowledge that the interim financial statements for the period 1 January to 30 June 2020 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 Group's assets, liabilities, financial position and overall results.

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, 20. August 2020

On behalf of Gentian Diagnostics AS:

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