

First quarter 2020 results



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Gentian Diagnostics AS is a medical diagnostics company listed on the Oslo Stock Exchange, Merkur Market, with the ticker "GENT-ME".

Gentian is headquartered in Moss, Norway, with a representative office in China and distribution subsidiaries in Sweden and USA.

Gentian designs, develops and markets in vitro diagnostic reagents (IVD) based on its proprietary Nanosense™ technology. Through in-depth research into Particle-Enhanced Turbidimetric Immunoassays (PETIA), Gentian developed Nanosense™. Nanosense™ is our proprietary antibody and nanoparticle-based technology. This technology creates highly sensitive Particle-Enhanced Turbidimetric Immunoassays (PETIA) and has been used in most of our products to date. The goal is to offer efficient and accurate reagents within the areas of kidney disease, cardiac disease, inflammation and veterinary medicine. The Nanosense™ technology will 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. 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 cancers.

HIGHLIGHTS

- Record sales revenues of MNOK 16.2 in 1Q20, up from MNOK 10.6 in 1Q19
- Sales growth of 53 % is based on strong performance of all product lines. Sales grew by 42 % YoY on a currency neutral basis
- New publications of clinical study results confirm GCAL as a promising biomarker for earlier detection and better prediction of severity of an infection

FINANCIAL PERFORMANCE

Comparative numbers for Gentian 2019 in ()

Sales, Geographic Split and Product Split

Total operating revenue ended at MNOK 19.1 (MNOK 12.1) for 1Q20.

Sales revenue in 1Q20 ended at MNOK 16.2 (MNOK 10.6), a 53 % increase compared to 1Q19. Adjusted for currency effects sales growth was 42 %.

Geographic split:

MNOK	1Q20	1Q19
US	0.7	0.5
Europe	11.2	7.4
Asia	4.3	2.7
Total	16.2	10.6

Product split:

MNOK	1Q20	1Q19
Cystatin C	6.6	4.7
fCAL®turbo	5.3	3.9
Other	4.4	2.0
Total	16.2	10.6

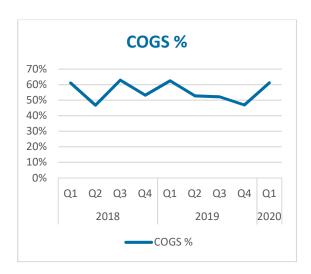
Other operating revenue ended at MNOK 2.9 (MNOK 1.5) for 1Q20.



Cost of Goods Sold

COGS ended at MNOK 9.9 (MNOK 6.6) in 1Q20, which represents 61 % (62 %) of sales revenue.

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



Up until the 3Q19 interim report COGS comprised only of material cost, but as of the 4Q19 report and for the 2019 annual report COGS will also include other production costs. Earlier 2019 numbers in the reports have also been adjusted to be comparable. The main reason behind this change is to bring the company accounts more in line with the reporting made by international peers.

Total Other Operating Expenses

Total other operating expenses before capitalization of R&D expenses ended at MNOK 14.2 (MNOK 12.0) in 1Q20.

Other operating expenses include salary and social expenses of MNOK 9.1 (MNOK 7.6) and other expenses of MNOK 5.1 (MNOK 4.4) for 1Q20. SG&A also include a share-based compensation of MNOK 0.9 year to date with no cash effect.

Total other operating expenses after capitalization of R&D expenses ended at MNOK 14.1 (MNOK 11.1) in 1Q20.

R&D Expenses

R&D expenses amounted to 39 % (34 %) of total other operating expenses before capitalization for 1Q20.

Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -4.9 (MNOK -5.6) for 1Q20.

Net financial income ended at MNOK 0.9 (MNOK 0.0) for 1Q20.

Net profit ended at MNOK -5.5 (MNOK -7.3) for 1Q20.

Balance Sheet

Cash and cash equivalents as of 31.03.2020 were MNOK 161.4 (MNOK 191.3). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 31.03.2020 were MNOK 9.9 (MNOK 6.7).

Inventory as of 31.03.2020 were MNOK 18.5 (MNOK 14.3).

Cash Flow

Cash flow from operating activities ended at MNOK -9.7 (MNOK -6.2) for 1Q20.

Cash flow from investment activities ended at MNOK -0.4 (MNOK -1.2) for 1Q20. Included in investment activities are capitalization of R&D expenses, which amounted to MNOK 0.1 (MNOK 0.9) for 1Q20.

Cash flow from financial activities ended at MNOK -0.1 (MNOK 0.0) for 1Q20.

OPERATIONAL STATUS

Product Sales

Sales revenue in 1Q20 showed an increase of 53 % compared to 1Q19, ending the quarter at a new record high of MNOK 16.2. The increase is based on a strong performance of all products lines.

The continued growth of fCAL® turbo, a marker to detect bowel inflammation is encouraging.

Sales of fCAL turbo increased by 36 % compared to 1Q19.

Our renal function marker, Cystatin C also showed strong development in 1Q20. Sales increased by more than 40 % compared to 1Q19. Sales to China was particularly strong in the quarter.

Our Swedish distribution subsidiary, Gentian Diagnostics AB, had a positive development with securing the rights to distribute more third-party products in Sweden, resulting in increased sales.

The current outbreak of COVID-19 has no effect on Gentian so far. Gentian has robust business-continuity plans in place, and production has been maintained at normal levels. The company has also been able to make deliveries to its customers on time.

R&D

G-1001

The project to develop a cardiac marker is progressing according to plan. The company works with the patent application which will be published towards the end of 2020. In addition, the team continues to work with the assay development and plans for a launch in 2021.

GCAL

The market development initiatives for the novel inflammation marker GCAL has made good progress during the quarter. Results from several clinical studies have been published in scientific journals and as meeting abstracts.

Results of one study support clinical use of calprotectin in diagnosis of respiratory infections and indicate greater performance of calprotectin compared to other biomarkers in distinguishing bacterial and mycoplasma infections from viral infections¹.

¹ Havelka et al., Scientific Reports, (2020) 10:4208

Results from other studies indicate an early increase of calprotectin in infection and inflammation supporting rapid diagnosis of bacterial infections.²

Moreover, it has been shown that calprotectin in plasma can be used in prediction of severe events in septic patients, with better performance than other conventional biomarkers.³

The recent results contribute to the clinical documentation supporting GCAL as an early and promising biomarker for diagnosis and prediction of bacterial infections and sepsis. The knowledge and awareness about GCAL and its clinical use are disseminated in contacts and meetings with potential customers and partners.

fPELA

The company's partner Bühlmann plans for a product launch in 2020. fPELA is a marker that can detect pancreatic exocrine insufficiency which leads to problems in the digestive system. Currently, there is a lack of efficient tests to address this indication and Gentian believe that it will in collaboration with Bühlmann bring a marker with improved efficiency to the market.

CORPORATE

The company has resolved an intent to apply for its shares to be listed on a regulated market. It is expected that the process will start within 12 months, subject to market conditions and the company's ability to meet the formal requirements for such a listing.

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, so we can maintain our production lines. We abide by Norwegian health authority policies whilst continuing to seamlessly support our customers. Gentian may be affected by the COVID-19 outbreak by reduced demand for diagnostic services for outpatients and we expect some delays with our R&D programs and the start of new clinical studies for GCAL. 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 growth to be driven by increased demand in China and an increased focus on the US market.

For fCAL® turbo, we may experience reduced demand, at least for a short period of time. This assumption is based on the focus of all health care systems on the COVID-19 management.

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. The company expects to commission prospective clinical studies in Germany and the UK during 1H2020 with the aim to establish further clinical evidence for GCAL as an early marker for sepsis and other serious infections, and its ability to differentiate between viral and bacterial infections.

² Fullerton et al., Critical Care, Meeting Abstracts from the 40th International Symposium on Intensive Care & Emergency Medicine

³ Parke et al., Critical Care, Meeting Abstracts from the 40th International Symposium on Intensive Care & Emergency Medicine

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 06.04.2020 according to VPS:

Shareholder	No of Shares	%
Holta Life Sciences AS	2 014 702	13,08 %
Vatne Equity AS	2 010 224	13,05 %
Safrino AS	1 100 000	7,14 %
Salix AS	1 068 088	6,93 %
Norron Sicav – Target	687 059	4,46 %
Norda ASA	549 186	3,57 %
Storebrand Vekst	445 823	2,89 %
Portia AS	425 000	2,76 %
Equinor Pensjon	381 320	2,48 %
Verdipapirfondet DNB SMB	358 623	2,33 %
Silvercoin Industries AS	281 644	1,83 %
Bård Sundrehagen	275 906	1,79 %
SEB CMU	257 075	1,67 %
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	4 061 489	26,37 %
Total Shares	15 402 718	100,00 %

Statement of Comprehensive Income Gentian Group

	2020	2019	2019
(figures in NOK thousands)	Q1	Q1	01.01-31.12
Operating Revenue			
Sales revenue	16 247	10 613	47 952
Other operating revenue	2 884	1 450	7 433
Total Operating Revenue	19 131	12 063	55 384
Operating Expenses/Costs			
Cost of goods sold	-9 926	-6 630	-25 449
R&D costs	-5 638	-4 109	-22 283
Selling, general & administrative costs	-8 521	-7 874	-31 746
Capitalization	65	907	3 071
Total Operating Expenses/Costs	-24 021	-17 705	-76 407
EBITDA	-4 889	-5 642	-21 023
Depreciation	-1 567	-1 656	-6 132
Impairment	-	-	-14 086
EBIT	-6 456	-7 298	-41 241
Financial income/expense	921	21	1 447
Tax	-	-	-63
Net Profit	-5 535	-7 277	-39 857

 $^{{\}bf 1}^{\rm st}\,quarter\,{\it Statement}\,of\,{\it Comprehensive}\,{\it Income}\,is\,not\,audited$

Statement of Financial Position Gentian Group

	2020	2019	2019
(figures in NOK thousands)	31.03	31.12	31.03
Assets			
Non-Current Assets			
Property, plants and equipment	4 283	4 714	4 622
Right-of-use asset	2 528	3 062	4 512
Capitalized development costs	13 919	14 076	19 721
Other intangible assets	34	36	7 994
Financial assets	335	329	329
Total Non-Current Assets	21 099	22 216	37 178
Company America			
Current Assets	10.452	10.224	14 202
Inventory	18 453	18 224	14 303
Accounts receivables	9 926	8 493	6 749
Other receivables	9 161	7 012	7 032
Cash and cash equivalents	161 072	171 238	191 012
Total Currents Assets	198 611	204 967	219 096
Total Assets	219 711	227 182	256 274
Equity and Liabilities			
Equity			
Net profit (Loss)	5 535	39 857	7 277
Other equity	-209 186	-248 096	-246 384
Equity	-203 651	-208 240	-239 107
Non-Current Liabilities			
Interest-bearing loans and dept	-1 022	-1 093	-659
Lease liability	-2 686	-3 202	-4 560
Total Non-Current Liabilities	-3 709	-4 295	-5 219
Current liabilities			
Accounts payable	-3 964	-4 606	-3 450
Public dept	-2 342	-2 501	-1379
Accrued expenses	-6 045	-7 541	-7 119
Total Current Liabilities	-12 351	-14 648	-11 948
Total Equity and Liabilities	-219 711	-227 182	-256 274

^{1&}lt;sup>st</sup> quarter Statement of Financial Position is not audited

Cash Flow Statement

	2020	2019	2019
(figures in NOK thousands)	Q1	01.0131.12	Q1
Cash Flow from Operating Activities			
Net profit (loss)	-5 535	-39 857	-7 277
	-		
Depreciation	1 567	6 132	1 656
Impairment	-	14 086	-
Change Inventory	-229	-5 126	-1 205
Change Accounts Receivables	-1 433	792	2 536
Change Accounts Payables	-642	1 310	155
Change in other short-term receivables/liabilities	-3 438	-431	-2 044
Net Cash Flow from Operating Activities	-9 710	-23 093	-6 179
Cash Flows from Investment Activities			
Acquisition of Property, plant and equipment	-63	-1 589	-263
Investment in intangible assets	-377	-3 071	-907
Other changes in financial items	-	-	-
Net Cash Flow from Investment Activities	-440	-4 660	-1 170
Cash Flow from Financial Activities			
New debt	-	621	-
Downpayment of loans	-70	-226	-39
Cash flows from share issues	-	259	-
Dividend payment	-	-	
Net Cash Flow from Financial Activities	-70	654	-39
Net Change in Cash and Cash Equivalents	-10 221	-27 099	-7 388
Cash and cash equivalents at beginning of period	171 567	198 634	198 634
Currency adjustment	62	32	95
Net Cash and Cash Equivalents	161 407	171 567	191 341

^{1&}lt;sup>st</sup> quarter Cash Flow Statement is not audited

Statement of Changes in Equity

(figures in NOK thousands)

	Share capital	Share Ot premium	her 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 Other comprehensive income Proceeds from share issue	1	258		-39 857	-39 857 259
Cost of share issue Share based payments			1 869		1 869
Other changes in equity			1 003	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				-5 535	-5 535
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			872		872
Other changes in equity				74	74
Equity at 31.03.2020	1 540	292 780	4 903	-95 572	203 651

^{1&}lt;sup>st</sup> quarter Statement of Changes in Equity is not audited

NOTES

Accounting Principles

The interim report for Q1 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.