Second quarter and first half 2019 results



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Gentian Diagnostics AS is a medical diagnostics company listed on Merkur Market, Oslo Stock Exchange 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

- 16 % growth in sales revenue in 2Q19 compared to 2Q18
- Total sales revenues of MNOK 10.2 in 2Q19, up from MNOK 8.8 in 2Q18
- FDA 510(k) clearance for the BÜHLMANN fCAL® turbo and with this access to the US market
- In July, Beckman Coulter, one of the top 5 global diagnostics companies, and Gentian have prolongated the trusted partnership agreement by another 6 years
- In August, Gentian announced the sales channel agreement for fCAL® turbo between Roche Diagnostics and Gentian's sales partner Bühlmann Laboratories AG

FINANCIAL PERFORMANCE

Comparative numbers for Gentian 2018 in ()

Sales, Geographic Split and Product Split

Total operating revenue ended at MNOK 12.1 (MNOK 10.9) for 2Q19, and MNOK 24.2 (MNOK 22.2) for 1H 2019.

Sales revenue in 2Q19 ended at MNOK 10.2 (MNOK 8.8), a 16 % increase compared to 2Q18. Sales revenue for 1H 2019 ended at MNOK 20.8 (MNOK 18.4), a 13 % increase compared to 1H 2018.

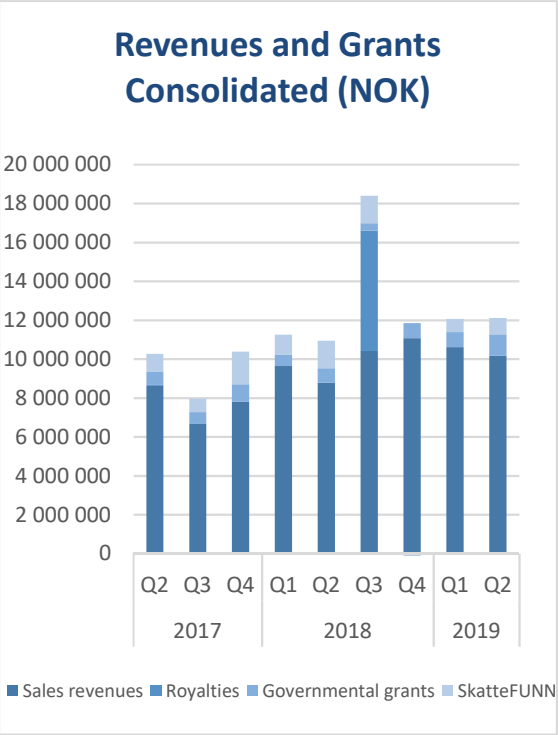
Geographic split:

MNOK	2Q19	2Q18	1H19	1H18
US	0,6	0,6	1,1	1,0
Europe	7,7	7,4	15,1	13,5
Asia	1,9	0,8	4,6	3,9
Total	10,2	8,8	20,8	18,4

Product split:

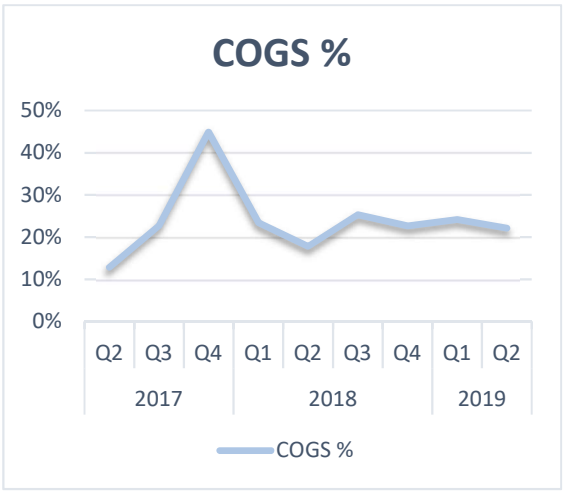
MNOK	2Q19	2Q18	1H19	1H18
Cystatin C	3,9	3,9	8,6	9,3
fCAL®turbo	3,0	2,5	6,9	4,6
Other	3,3	2,4	5,3	4,5
Total	10,2	8,8	20,8	18,4

Other operating revenue ended at MNOK 1.1 (MNOK 0.7) for 2Q19. SkatteFUNN funding ended at MNOK 0.8 (MNOK 1.4) for 2Q19.



Cost of Goods Sold

COGS ended at MNOK 2.3 (MNOK 1.6) in 2Q19, which represents 22 % (18 %) of sales revenue. Total COGS for 1H 2019 ended at MNOK 4.8 (MNOK 3.8), which represents 23 % (21 %) of sales revenue.



Total Operating Expenses

Total operating expenses before capitalization of R&D expenses ended at MNOK 15.1 (MNOK 12.0) in 2Q19, and MNOK 31.1 (MNOK 24.7) for 1H 2019.

Operating expenses include total salary and social expenses of MNOK 8.3 (MNOK 5.7) and other expenses of MNOK 6.8 (MNOK 6.3) for 2Q19. For 1H 2019 total salary and social expenses ended at MNOK 19.3 (MNOK 14.2) and other expenses ended at MNOK 11.9 (MNOK 10.6). SG&A also include a share-based compensation of MNOK 0.8 for 1H 2019 with no cash effect.

Total operating expenses after capitalization of R&D expenses ended at MNOK 14.6 (MNOK 10.8) in 2Q19, and MNOK 29.8 (MNOK 22.9) for 1H 2019.

R&D Expenses

R&D expenses amounted to 35 % (40 %) of total operating expenses before capitalization for 2Q19, and 30 % (35 %) for 1H 2019.

Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -4.8 (MNOK -1.5) for 2Q19, and MNOK -10.4 (MNOK -4.5) for 1H 2019.

After careful review and optimization of the product and R&D portfolios, Gentian has

decided to discontinue specific activities in order to be in alignment of current strategy of allocating resources and capacity to more high impact tests.

The company has decided to terminate the CD Card /CD4 project. During the spring of 2019, the first clinical trial with 50 patients being treated and monitored at Oslo University Hospital was performed. The trial revealed that the number of CD4 receptors per cell varied more in patients than in healthy volunteer donors. Neither Gentian nor its scientific advisors were aware of this biological variance between HIV infected patients and healthy donors. Although the CD Card can successfully measure the number of CD4 receptors, the product will not have clinical value due to the lack of correlation between CD4 receptors and the number of CD4 cells.

As a result of the above mentioned termination and a decision to discontinue the sales of our NGAL product, the company has decided to write down the intangible assets with MNOK 14.1.

These impairments do not have any cash effect.

Net financial income ended at MNOK 0.3 (MNOK 0.2) for 2Q19, and MNOK 0.3 (MNOK 0.3) for 1H 2019.

Net profit ended at MNOK -20.3 (MNOK -2.3) for 2Q19, and MNOK -27.6 (MNOK -6.2) for 1H 2019.

Balance Sheet

Cash and cash equivalents as of 30.06.2019 were MNOK 179.3 (MNOK 201.4). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 30.06.2019 were MNOK 8.7 (MNOK 8.3).

Inventory as of 30.06.2019 were MNOK 15.4 (MNOK 12.6).

Cash Flow

Cash flow from operating activities ended at MNOK -17.5 (MNOK -11.7) for 1H 2019, and MNOK -11.3 (MNOK -6.2) for 2Q19.

Cash flow from investment activities ended at MNOK -1.8 (MNOK -2.6) for 1H 2019, and MNOK -0.6 (MNOK -1.8) for 2Q19. Included in investment activities are capitalization of R&D expenses, which amounted to MNOK 1.4 (MNOK 1.9) for 1H 2019, and MNOK 0.5 (MNOK 1.2) for 2Q19.

Cash flow from financial activities ended at MNOK -0.1 (MNOK 68.8) for 1H 2019, and MNOK -0.0 (MNOK 68.9) for 2Q19.

OPERATIONAL STATUS

Product Sales

Sales in 2Q19 showed an increase of 16 % compared to 2Q18, ending the quarter with a sales revenue of MNOK 10.2.

The increase is driven by strong sales of cCRP, in addition to continued increase in fCAL® turbo sales compared to 2Q18.

The company hosted a successful educational workshop called: “Plasma Calprotectin: a promising early biomarker for diagnosis of bacterial infections and sepsis.”, at the EuroMedLab (European Congress of Clinical Chemistry and Laboratory Medicine) in Barcelona, Spain, on 21st of May 2019. The talks in the workshop discussed calprotectin and other biomarkers’ role in diagnosis of severe infections and sepsis. The presentations showed studies and results supporting the ability of calprotectin to discriminate patients with acute infections from patients with other states of inflammatory responses. For more information see stock exchange announcement dated 24th of May 2019.

The company was pleased to announce on 28th of June 2019, that BÜHLMANN had received 510(k) clearance) from the FDA in the US for the BÜHLMANN fCAL® turbo assay. BÜHLMANN is Gentian's exclusive commercial partner for the fecal calprotectin products worldwide.

In July, Gentian signed a 6-year extension to the global reagent supply agreement with Beckman Coulter for the Gentian Cystatin C Immunoassay. The companies have provided this test together globally for 10 years, with consistent sales growth. For more information see the announcement dated 3rd of July 2019.

In August, Gentian announced an agreement as sole reagent supplier in a sales channel agreement between Roche Diagnostics and Gentian's sales partner Bühlmann Laboratories AG. Gentian will deliver the fCAL® turbo immunoassay reagents to the Roche/Bühlmann co-branded test-kit. With this agreement fCAL® turbo will be available to Roche´s laboratory customers globally. For more information see the announcement dated 13th of August 2019.

R&D

The new Gentian Fecal Pancreatic Elastase[1] product has successfully been transferred into the last development phase before market release. With this, the project is on track for CE-marking and launch in 2020.

The clinical studies of the performance of our GCAL product for diagnosis and monitoring of sepsis and severe infections are progressing according to plan. We expect to enable clinical improvement of diagnosis and treatment of infectious diseases.

The development of G-1001 is on track with expected launch in 2021.

OUTLOOK

The company expects continued sales growth in 2019 versus 2018, with normal quarterly variations.

For Cystatin C, the company expects sales growth to be driven by increased demand in China and increased focus on the US market. As a result of good market growth and low inventories at our distributors, we expect higher sales of Cystatin C in 2H2019 vs. 1H2019.

For fCAL® turbo, the company expects continued sales growth in Europe. First customer conversions in the US after the FDA clearance are to be expected early 2020. In addition, the new collaboration with Roche is expected to have a positive effect on sales as of 2020.

For GCAL, new independent publications are in preparations with anticipated releases in 2019. In addition, the company is continuing to intensify its efforts to engage with Key Opinion Leaders in the field of infectious diseases around the world, as well as selected hospital laboratories and potential market partners.

EVENTS AFTER THE BALANCE SHEET DATE

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

[1] The test to be developed from this concept is a measure of Pancreatic Exocrine Insufficiency (PEI) associated with various health conditions, e.g. chronic pancreatitis, cystic fibrosis, celiac disease, diabetes, post-pancreatic surgery, gastrectomy etc. Ref. Stock exchange release dated 22.06.2018.

SHAREHOLDER INFORMATION

20 largest shareholders in Gentian Diagnostics AS as of 28.06.2019 according to VPS:

Shareholder	No of Shares	%
Holta Life Sciences AS	2 014 702	13,09 %
Vatne Equity AS	1 910 340	12,41 %
Safrino AS	1 300 000	8,44 %
Salix AS	1 132 040	7,35 %
Norron Sicav - Target	617 500	4,01 %
Vingulmork Predictor AS	535 710	3,48 %
Storebrand Vekst	493 864	3,21 %
Norda ASA	455 082	2,96 %
Portia AS	425 000	2,76 %
Statoil Pensjon	392 690	2,55 %
Verdipapirfondet DNB SMB	376 630	2,45 %
Silvercoin Industries AS	330 809	2,15 %
Bård Sundrehagen	307 010	1,99 %
Cressida AS	235 000	1,53 %
Marstal AS	202 500	1,32 %
Strawberry Capital AS	200 300	1,30 %
Spar Kapital Investor AS	192 291	1,25 %
Mutus AS	187 210	1,22 %
OM Holding AS	179 000	1,16 %
Lioness AS	150 000	0,97 %
Other Shareholders	3 758 243	24,41 %
Total Shares	**15 395 921**	**100,00 %**

Statement of Comprehensive Income Gentian Group

	2019	2019	2018	2018
(figures in NOK thousands)	**Q2**	**01.01-30.06**	**Q2**	**01.01-30.06**
Operating Revenue				
Sales revenue	10 171	20 784	8 795	18 439
Other operating revenue	1 942	3 392	2 146	3 750
Total Operating Revenue	**12 113**	**24 175**	**10 940**	**22 189**
Operating Expenses/Costs				
Cost of goods sold	-2 251	-4 821	-1 567	-3 830
Production costs	-3 121	-7 181	-2 546	-6 173
R&D costs	-5 223	-9 332	-4 795	-8 726
Selling, general & administrative costs	-6 748	-14 622	-4 690	-9 834
Capitalization	457	1 364	1 199	1 860
Total Operating Expenses/Costs	**-16 886**	**-34 591**	**-12 399**	**-26 703**
EBITDA	**-4 774**	**-10 416**	**-1 459**	**-4 514**
Depreciation	-1 722	-3 378	-1 005	-1 951
Impairment	-14 086	-14 086	-	-
EBIT	**-20 583**	**-27 880**	**-2 464**	**-6 465**
Financial income/expense	302	323	165	286
Tax	-62	-62	-	-
Net Profit	**-20 343**	**-27 620**	-2 299	-6 179

2nd quarter Statement of Comprehensive Income is not audited

Statement of Financial Position Gentian Group

	2019	2018	2018
(figures in NOK thousands)	30.06	31.12	30.06
Assets			
Non-Current Assets			
Property, plants and equipment	4 399	4 736	5 106
Right-of-use asset	4 101	-	-
Capitalized development costs	13 243	18 691	16 991
Other intangible assets	38	8 883	13 398
Financial assets	326	329	362
Total Non-Current Assets	**22 108**	**32 640**	**35 858**
Current Assets			
Inventory	15 393	13 098	12 572
Accounts receivables	8 703	9 285	8 308
Other receivables	8 735	4 652	9 649
Cash and cash equivalents	178 950	198 305	201 047
Total Currents Assets	**211 780**	**225 340**	**231 576**
Total Assets	**233 887**	**257 980**	**267 434**
Equity and Liabilities			
Equity			
Net profit (Loss)	27 620	19 798	6 179
Other equity	-246 754	-265 671	-264 695
Equity	**-219 134**	**-245 873**	**-258 516**
Non-Current Liabilities			
Interest-bearing loans and dept	-619	-698	-776
Lease liability	-4 192	-	-
Total Non-Current Liabilities	**-4 811**	**-698**	**-776**
Current liabilities			
Accounts payable	-4 267	-3 295	-3 295
Public dept	-2 188	-2 176	-2 735
Accrued expenses	-3 487	-5 937	-2 111
Total Current Liabilities	**-9 942**	**-11 409**	**-8 142**
Total Equity and Liabilities	**-233 887**	**-257 980**	**-267 434**

2nd quarter Statement of Financial Position is not audited

Cash Flow Statement

	2019	2019	2018	2018
(figures in NOK thousands)	Q2	Q1	31.12	30.06
Cash Flow from Operating Activities				
Net profit (loss)	-20 343	-7 277	-19 798	-6 179
Depreciation	1 722	1 656	3 897	1 951
Impairment	14 086	-	5 040	-
Change Inventory	-1 089	-1 205	-2 006	-1 480
Change Accounts Receivables	-1 954	2 536	-2 476	-1 499
Change Accounts Payables	816	155	-253	-253
Change in other short-term receivables/ liabilities	-4 568	-2 044	4 700	-4 259
Net Cash Flow from Operating Activities	**-11 328**	**-6 179**	**-10 897**	**-11 720**
Cash Flows from Investment Activities				
Acquisition of Property, plant and equipment	-174	-263	-989	-731
Investment in intangible assets	-457	-907	-5 165	-1 860
Other changes in financial items	-	-	-	-
Net Cash Flow from Investment Activities	**-632**	**-1 170**	**-6 153**	**-2 591**
Cash Flow from Financial Activities				
New debt	-	-	379	379
Downpayment of loans	-40	-39	-147	-69
Cash flows from share issues	-	-	68 519	68 519
Dividend payment	-	-	-	-
Net Cash Flow from Financial Activities	**-40**	**-39**	**68 751**	**68 829**
Net Change in Cash and Cash Equivalents	-12 000	-7 388	51 701	54 518
Cash and cash equivalents at beginning of period	191 341	198 634	146 951	146 951
Currency adjustment	-66	95	-18	-60
Net Cash and Cash Equivalents	**179 275**	**191 341**	**198 634**	**201 409**

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 01.01.2018	**1 400**	**224 143**	**1 467**	**-30 534**	**196 475**
Net result for the year				-19 798	-19 798
Other comprehensive income				0	0
Proceeds from share issue	140	69 841			69 981
Cost of share issue		-1 462			-1 462
Share based payments			695		695
Other changes in equity				-18	-18
Equity at 31.12.2018	**1 540**	**292 522**	**2 162**	**-50 350**	**245 873**

Equity at 01.01.2019	**1 540**	**292 522**	**2 162**	**-50 350**	**245 873**
Net result for the year				-27 620	-27 620
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			827		827
Other changes in equity				53	53
Equity at 30.06.2019	**1 540**	**292 522**	**2 989**	**-77 917**	**219 134**

2nd quarter Statement of Changes in Equity is not audited

NOTES

Accounting Principles

The interim report for Q2 2019 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 2018.

As of 1st January 2019, the Company has implemented IFRS 16 Leases with regards to operative leases. The effect of this implementation is that certain operative leases will be recognized in the Company's Statement of Financial Position as of 2019 as shown in the table here:

NOK	01.01.2019 after IFRS 16	01.01.2019 before IFRS 16
Right-of-use asset	5 024 575	-
Lease liability	-5 024 575	-

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

2019

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 2019 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, 14. August 2019

On behalf of Gentian Diagnostics AS:

_____	_____
Tomas Settevik (sign.) Chairman 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	Henrik Krefting (sign.) Board member

_____

Hilja Ibert
(sign.)
CEO