

gentian

Fourth Quarter 2019 results & Preliminary Annual Report



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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

- Record sales revenues of MNOK 14.1 in 4Q19, up from MNOK 11.1 in 4Q18, totaling a 27 % growth y/y
- Total sales revenue for the year of MNOK 48.0 representing 20 % growth compared to 2018
- Strong fCAL® turbo sales in Q4 resulting in a y/y growth of 112% driven by continued growth in kit sales and positive effect from bulk orders
- fPELA development completed. External validation ongoing

FINANCIAL PERFORMANCE

Comparative numbers for Gentian 2018 in ()

Sales, Geographic Split and Product Split

Total operating revenue ended at MNOK 16.5 (MNOK 11.4) for 4Q19, and MNOK 55.4 (MNOK 52.0) year to date. Note that total operating revenue in 3Q18 included a one-off royalty license fee of MNOK 6.2.

Sales revenue in 4Q19 ended at MNOK 14.1 (MNOK 11.1), a 27 % increase compared to 4Q18. Sales revenue for the year ended at MNOK 48.0 (MNOK 39.9), a 20 % increase compared to the same period last year.

Geographic split:

MNOK	4Q19	4Q18	YTD19	YTD18
US	0.6	0.9	2.0	2.2
Europe	11.3	7.5	34.1	27.1
Asia	2.2	2.7	11.8	10.6
Total	14.1	11.1	48.0	39.9

Product split:

MNOK	4Q19	4Q18	YTD19	YTD18
Cystatin C	3.9	5.6	19.7	21.7
fCAL®turbo	7.0	3.3	17.5	9.9
Other	3.1	2.2	10.8	8.3
Total	14.1	11.1	48.0	39.9

Other operating revenue ended at MNOK 1.3 (MNOK 0.8) for 4Q19, and MNOK 3.8 (MNOK 2.5) for the year. SkatteFUNN funding ended at MNOK 1.2 (MNOK -0.4) for 4Q19, and MNOK 3.6 (MNOK 3.4) year to date.



Cost of Goods Sold

COGS ended at MNOK 6.6 (MNOK 5.9) in 4Q19, which represents 47 % (53 %) of sales revenue. Total COGS year to date ended at MNOK 25.4 (MNOK 22.4), which represents 53 % (56 %) of sales revenue.



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. 2018 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 17.3 (MNOK 15.1) in 4Q19, and MNOK 54.0 (MNOK 46.5) year to date.

Other operating expenses include salary and social expenses of MNOK 9.4 (MNOK 7.2) and other expenses of MNOK 7.9 (MNOK 7.8) for 4Q19. Total salary and social expenses year to date ended at MNOK 31.0 (MNOK 22.6) and other expenses ended at MNOK 23.1 (MNOK 23.9). SG&A also include a share-based compensation of MNOK 1.9 year to date with no cash effect.

Total other operating expenses after capitalization of R&D expenses ended at MNOK 16.1 (MNOK 13.0) in 4Q19, and MNOK 51.0 (MNOK 41.3) year to date.

R&D Expenses

R&D expenses amounted to 44 % (32 %) of total operating expenses before capitalization for 4Q19, and 41 % (41 %) year to date.

Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -6.2 (MNOK -7.4) for 4Q19, and MNOK -21.0 (MNOK -11.7) year to date.

Net financial income ended at MNOK 0.5 (MNOK 0.5) for 4Q19, and MNOK 1.5 (MNOK 1.0) year to date.

Net profit ended at MNOK -7.1 (MNOK -13.0) for 4Q19, and MNOK -39.9 (MNOK -19.8) year to date.

Balance Sheet

Cash and cash equivalents as of 31.12.2019 were MNOK 171.6 (MNOK 198.6). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 31.12.2019 were MNOK 8.5 (MNOK 9.3).

Inventory as of 31.12.2019 were MNOK 18.2 (MNOK 13.1).

Cash Flow

Cash flow from operating activities ended at MNOK -23.1 (MNOK -15.9) year to date, and MNOK 2.5 (MNOK 0.9) for 4Q19.

Cash flow from investment activities ended at MNOK -4.7 (MNOK -1.1) year to date, and MNOK -1.4 (MNOK 2.8) for 4Q19. Included in investment activities are capitalization of R&D expenses, which amounted to MNOK 3.1 (MNOK 5.2) year to date, and MNOK 1.1 (MNOK 2.1) for 4Q19.

Cash flow from financial activities ended at MNOK 0.7 (MNOK 68.8) year to date, and MNOK 0.2 (MNOK 0.0) for 4Q19.

OPERATIONAL STATUS

Product Sales

Sales in 4Q19 showed an increase of 27 % compared to 4Q18, ending the quarter with record high sales revenues of MNOK 14.1. The increase is driven mainly by continued growth in fCAL[®] turbo sales throughout the year with a particularly strong development in 4Q19.

The fiscal year ended with a total sales income of MNOK 48.0, a new all-time high for product sales in total.

The development in our Swedish distribution subsidiary, Gentian Diagnostics AB, has been positive in 4Q19 with onboarding of new customers buying 3rd party products. The positive development is expected to continue in 2020.

R&D

G-1001

For G-1001 the Company has started to test patient samples and the development continues to be on track for a launch in 2021. In addition, the patent application is expected to be published towards the end of 2020.

GCAL

After a poster presentation in 2018 (ref. stock exchange release 01.10.2018), one of our Swedish study sites (University of Upsala) has published an article in *Scandinavian Journal of Clinical and Laboratory Investigation* (ICLB). The article is available online under the title: "Calprotectin is superior to procalcitonin as a sepsis marker and predictor of 30-day mortality in intensive care patients". This represents another positive step for the continued clinical documentation of GCAL.

fPELA

The development of the Fecal Pancreatic Elastase (fPELA) product is completed and external validation is ongoing. Launch of this product by our partner Bühlmann is expected to take place within 2Q20.

CORPORATE

In November, Gentian launched an Employee Share Purchase Program. A total of 6797 shares were issued at a subscription price of NOK 38.1. For more information, see stock exchange release dated 29.11.2019.

OUTLOOK

The company estimate continued sales growth in 2020 versus 2019, with expected quarterly variations.

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, the company expects to experience continued sales growth in Europe. The first customer conversions in the US after the FDA clearance are to be expected in early 2020.

For GCAL, new and independent clinical publications are in preparations. In addition, the company will continue to intensify its strategic plan to engage 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 virus and bacterial infections.

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 31.12.2019 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	1 092 543	7,09 %
Norron Sicav - Target	629 228	4,09 %
Norda ASA	549 186	3,57 %
Storebrand Vekst	481 064	3,12 %
Portia AS	425 000	2,76 %
Equinor Pensjon	381 320	2,48 %
Verdipapirfondet DNB SMB	376 630	2,45 %
Bård Sundrehagen	307 010	1,99 %
Silvercoin Industries AS	288 281	1,87 %
Cressida AS	235 000	1,53 %
Vingulmork Predictor AS	224 083	1,45 %
Lioness AS	220 000	1,43 %
Mutus AS	210 465	1,37 %
Marstal AS	206 752	1,34 %
Strawberry Capital AS	200 300	1,30 %
Viola AS	199 990	1,30 %
Borgano AS	186 499	1,21 %
Other Shareholders	4 064 441	26,39 %
Total Shares	15 402 718	100,00 %

Statement of Comprehensive Income Gentian Group

	2019	2019	2018	2018
<i>(figures in NOK thousands)</i>	Q4	01.01-31.12	Q4	01.01-31.12
Operating Revenue				
Sales revenue	14 070	47 952	11 079	39 928
Other operating revenue	2 474	7 433	361	12 109
Total Operating Revenue	16 544	55 384	11 440	52 036
Operating Expenses/Costs				
Cost of goods sold	-6 607	-25 449	-5 895	-22 448
R&D costs	-7 579	-22 283	-4 800	-18 960
Selling, general & administrative costs	-9 705	-31 746	-10 281	-27 541
Capitalization	1 192	3 071	2 098	5 165
Total Operating Expenses/Costs	-22 699	-76 407	-18 878	-63 785
EBITDA	-6 155	-21 023	-7 438	-11 748
Depreciation	-1 412	-6 132	-981	-3 897
Impairment	-	-14 086	-5 040	-5 040
EBIT	-7 567	-41 241	-13 459	-20 685
Financial income/expense	502	1 447	499	954
Tax	-	-63	-66	-66
Net Profit	-7 064	-39 857	-13 027	-19 797

4th quarter Statement of Comprehensive Income is not audited

Statement of Financial Position Gentian Group

	2019	2018
<i>(figures in NOK thousands)</i>	31.12	31.12
Assets		
Non-Current Assets		
Property, plants and equipment	4 714	4 736
Right-of-use asset	3 062	-
Capitalized development costs	14 076	18 691
Other intangible assets	36	8 883
Financial assets	329	329
Total Non-Current Assets	22 216	32 640
Current Assets		
Inventory	18 224	13 098
Accounts receivables	8 493	9 285
Other receivables	7 012	4 652
Cash and cash equivalents	171 238	198 305
Total Currents Assets	204 967	225 340
Total Assets	227 182	257 980
Equity and Liabilities		
Equity		
Net profit (Loss)	39 857	19 798
Other equity	-248 096	-265 671
Equity	-208 240	-245 873
Non-Current Liabilities		
Interest-bearing loans and dept	-1 093	-698
Lease liability	-3 202	-
Total Non-Current Liabilities	-4 295	-698
Current liabilities		
Accounts payable	-4 606	-3 295
Public dept	-2 501	-2 176
Accrued expenses	-7 541	-5 937
Total Current Liabilities	-14 648	-11 409
Total Equity and Liabilities	-227 182	-257 980

4th quarter Statement of Financial Position is not audited

Cash Flow Statement

	2019	2019	2018	2018
<i>(figures in NOK thousands)</i>	Q4	01.01.-31.12	Q4	01.01.-31.12
Cash Flow from Operating Activities				
Net profit (loss)	-7 064	-39 857	-13 027	-19 798
Depreciation	1 412	6 132	981	3 897
Impairment	-	14 086	5 040	5 040
Change Inventory	-1 444	-5 126	156	-2 006
Change Accounts Receivables	62	792	4 512	-2 476
Change Accounts Payables	1 224	1 310	-710	-253
Change in other short-term receivables/ liabilities	8 359	-431	9 010	4 700
Net Cash Flow from Operating Activities	2 549	-23 093	5 962	-10 897
Cash Flows from Investment Activities				
Acquisition of Property, plant and equipment	-187	-1 589	-92	-989
Investment in intangible assets	-1 192	-3 071	-2 098	-5 165
Other changes in financial items	-	-	-	-
Net Cash Flow from Investment Activities	-1 379	-4 660	-2 191	-6 153
Cash Flow from Financial Activities				
New debt	-	621	-	379
Downpayment of loans	-70	-226	-39	-147
Cash flows from share issues	259	259	-	68 519
Dividend payment	-	-	-	-
Net Cash Flow from Financial Activities	189	654	-39	68 751
Net Change in Cash and Cash Equivalents	1 359	-27 099	3 733	51 701
Cash and cash equivalents at beginning of period	170 206	198 634	194 835	146 951
Currency adjustment	1	32	67	-18
Net Cash and Cash Equivalents	171 567	171 567	198 634	198 634

4th 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				-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

4th quarter Statement of Changes in Equity is not audited

NOTES

Accounting Principles

The interim report for Q4 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:

<i>NOK</i>	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.