

# ***gentian***

## **Third quarter 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

- Record sales revenues of MNOK 13.1 in 3Q19, up from MNOK 10.4 in 3Q18, totaling a 26 % growth YOY
- Record sales revenue for the first nine months of MNOK 33.9 representing 18% growth compared to the same period of 2018
- In July, Gentian and Beckman Coulter, one of the top 5 global diagnostics companies, prolonged their partnership agreement for Cystatin C by 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 14.7 (MNOK 18.4) for 3Q19, and MNOK 38.8 (MNOK 40.6) year to date. Note that total operating revenue in 3Q18 included a one-off royalty license fee of MNOK 6.2.

Sales revenue in 3Q19 ended at MNOK 13.1 (MNOK 10.4), a 26 % increase compared to 3Q18. Sales revenue for year to date ended at MNOK 33.9 (MNOK 28.8), a 18 % increase compared to the same period last year.

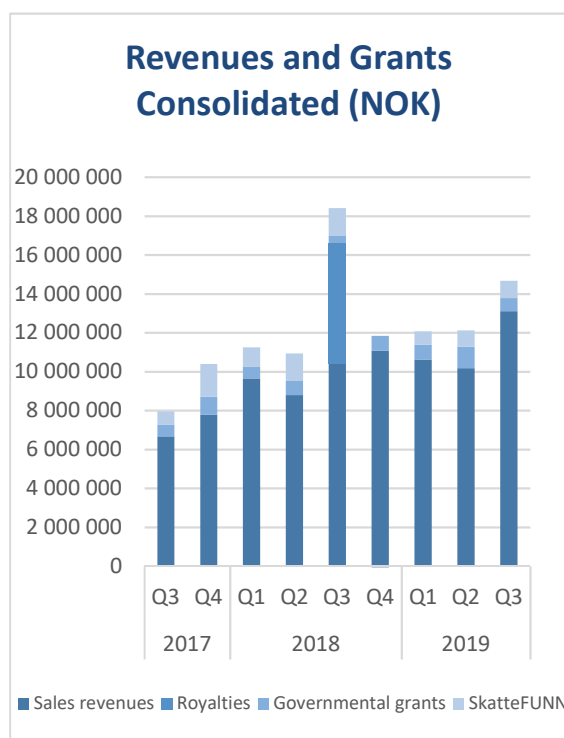
Geographic split:

MNOK	3Q19	3Q18	YTD19	YTD18
US	0.3	0.3	1.4	1.3
Europe	7.7	6.0	22.8	19.6
Asia	5.0	4.1	9.6	7.9
Total	13.1	10.4	33.9	28.8

Product split:

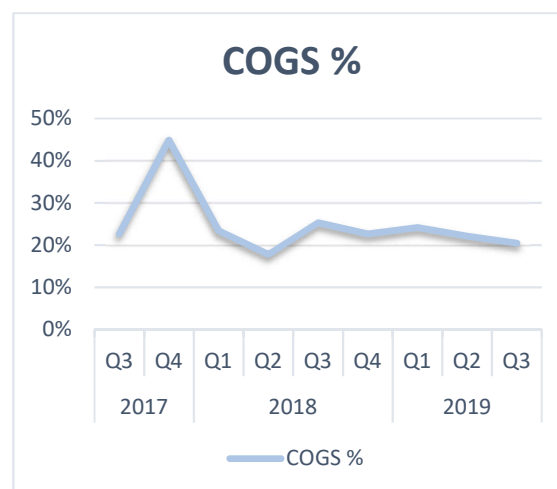
MNOK	3Q19	3Q18	YTD19	YTD18
Cystatin C	7.2	6.8	15.8	16.2
fCAL®turbo	3.6	2.0	10.5	6.6
Other	2.4	1.6	7.6	6.1
Total	13.1	10.4	33.9	28.8

Other operating revenue ended at MNOK 0.7 (MNOK 8.0, including a one-off license fee) for 3Q19. SkatteFUNN funding ended at MNOK 0.9 (MNOK 1.4) for 3Q19.



### Cost of Goods Sold

COGS ended at MNOK 2.7 (MNOK 2.6) in 3Q19, which represents 20 % (25 %) of sales revenue. Total COGS year to date ended at MNOK 7.5 (MNOK 6.5), which represents 22 % (22 %) of sales revenue.



### Total Operating Expenses

Total operating expenses before capitalization of R&D expenses ended at MNOK 17.0 (MNOK 16.8) in 3Q19, and MNOK 48.1 (MNOK 41.5) year to date.

Operating expenses include total salary and social expenses of MNOK 11.4 (MNOK 9.9) and other expenses of MNOK 5.5 (MNOK 6.9) for 3Q19. Total salary and social expenses year to date ended at MNOK 30.7 (MNOK 24.0) and other expenses ended at MNOK 17.4 (MNOK 17.5). SG&A also include a share-based compensation of MNOK 1.2 year to date with no cash effect.

Total operating expenses after capitalization of R&D expenses ended at MNOK 16.5 (MNOK 15.5) in 3Q19, and MNOK 46.2 (MNOK 38.4) year to date.

### R&D Expenses

R&D expenses amounted to 32 % (32 %) of total operating expenses before capitalization for 3Q19, and 31 % (34 %) year to date.

### Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -4.5 (MNOK 0.2) for 3Q19, and MNOK -14.9 (MNOK -4.3) year to date.

Net financial income ended at MNOK 0.6 (MNOK 0.2) for 3Q19, and MNOK 0.9 (MNOK 0.5) year to date.

Net profit ended at MNOK -5.2 (MNOK -0.6) for 3Q19, and MNOK -32.8 (MNOK -6.8) year to date.

### **Balance Sheet**

Cash and cash equivalents as of 30.09.2019 were MNOK 170.2 (MNOK 194.8). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 30.09.2019 were MNOK 8.6 (MNOK 13.8).

Inventory as of 30.09.2019 were MNOK 16.8 (MNOK 13.3).

### **Cash Flow**

Cash flow from operating activities ended at MNOK -25.7 (MNOK -16.9) year to date, and MNOK -8.1 (MNOK -5.2) for 3Q19.

Cash flow from investment activities ended at MNOK -3.3 (MNOK -3.9) year to date, and MNOK -1.5 (MNOK -1.3) for 3Q19. Included in investment activities are capitalization of R&D expenses, which amounted to MNOK 1.9 (MNOK 3.1) year to date, and MNOK 0.5 (MNOK 1.2) for 3Q19.

Cash flow from financial activities ended at MNOK 0.5 (MNOK 68.8) year to date, and MNOK 0.5 (MNOK 0.0) for 3Q19.

## **OPERATIONAL STATUS**

### **Product Sales**

Sales in 3Q19 showed an increase of 26 % compared to 3Q18, ending the quarter with a sales revenue of MNOK 13.1. The increase is

driven mainly by continued increase in fCAL<sup>®</sup> turbo sales compared to 3Q18.

The quarter ended at a new all-time high for product sales in total.

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 3<sup>rd</sup> of July 2019.

In August, Gentian launched an educational webinar on the clinical value of Cystatin C in collaboration with the AACC (American Association of Clinical Chemistry). The webinar was well perceived by healthcare professionals from all over the world.

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<sup>®</sup> turbo immunoassay reagents to the Roche/Bühlmann co-branded test-kit. With this agreement fCAL<sup>®</sup> turbo will be available to Roche's laboratory customers globally. For more information see the announcement dated 13<sup>th</sup> of August 2019.

### **R&D**

For G-1001 the R&D team achieved additional positive results and the development is on track for a launch in 2021.

The Gentian Fecal Pancreatic Elastase<sup>1</sup> product reached several milestones in the last development phase before market release and the project is on track for its launch in 2020.

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<sup>1</sup> 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.

The clinical studies of the performance of our GCAL product for diagnosis and monitoring of sepsis and severe infections are progressing according to plan.

### Post-period events

In October, Gentian announced a collaboration agreement with BioHealth Innovation (BHI) in order to expand Gentian's presence in the USA. BHI's market expertise will allow Gentian to gain valuable insight to market both its existing products and its pipeline product developments to the US market.

### 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. The Cystatin C sales in 2H2019 is expected to be significantly higher than 1H2019. One contributing factor to this is good sales growth in China. The company expects the total Cystatin C sales in 2019 to be in line with 2018 sales.

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 end of 2019.

For GCAL, new independent publications are in preparations, some of them 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 commercial partners.

### ORGANISATION

Co-founder and former CEO, Bård Sundrehagen, has resigned from his role as Executive Vice President Business Development in Gentian. Mr. Sundrehagen will continue to work for Gentian until 31<sup>st</sup> December 2019.

### EVENTS AFTER THE BALANCE SHEET DATE

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

### SHAREHOLDER INFORMATION

20 largest shareholders in Gentian Diagnostics AS as of 30.09.2019 according to VPS:

Shareholder	No of Shares	%
Holta Life Sciences AS	2 014 702	13,09 %
Vatne Equity AS	2 010 224	13,06 %
Safrino AS	1 300 000	8,44 %
Salix AS	1 123 807	7,30 %
Norron Sicav - Target	608 100	3,95 %
Storebrand Vekst	481 064	3,12 %
Norda ASA	463 867	3,01 %
Portia AS	425 000	2,76 %
Equinor Pensjon	392 690	2,55 %
Verdipapirfondet DNB SMB	376 630	2,45 %
Bård Sundrehagen	307 010	1,99 %
Silvercoin Industries AS	292 570	1,90 %
Cressida AS	235 000	1,53 %
Vingulmork Predictor AS	224 083	1,46 %
Lioness AS	220 000	1,43 %
Mutus AS	210 465	1,37 %
Marstal AS	202 500	1,32 %
Strawberry Capital AS	200 300	1,30 %
Viola AS	199 990	1,30 %
Spar Kapital Investor AS	192 291	1,25 %
Other Shareholders	3 915 628	25,43 %
<b>Total Shares</b>	<b>15 395 921</b>	<b>100,00 %</b>

## Statement of Comprehensive Income Gentian Group

	2019	2019	2018	2018
<i>(figures in NOK thousands)</i>	Q3	01.01-30.09	Q3	01.01-30.09
<b>Operating Revenue</b>				
Sales revenue	13 102	33 885	10 410	28 849
Other operating revenue	1 567	4 959	7 998	11 747
<b>Total Operating Revenue</b>	<b>14 668</b>	<b>38 844</b>	<b>18 407</b>	<b>40 596</b>
<b>Operating Expenses/Costs</b>				
Cost of goods sold	-2 680	-7 501	-2 636	-6 466
Production costs	-4 157	-11 338	-3 914	-10 087
R&D costs	-5 373	-14 705	-5 434	-14 160
Selling, general & administrative costs	-7 437	-22 059	-7 426	-17 260
Capitalization	515	1 879	1 206	3 066
<b>Total Operating Expenses/Costs</b>	<b>-19 132</b>	<b>-53 723</b>	<b>-18 204</b>	<b>-44 907</b>
<b>EBITDA</b>	<b>-4 464</b>	<b>-14 880</b>	<b>203</b>	<b>-4 311</b>
Depreciation	-1 342	-4 720	-964	-2 915
Impairment	-	-14 086	-	-
<b>EBIT</b>	<b>-5 806</b>	<b>-33 686</b>	<b>-761</b>	<b>-7 226</b>
Financial income/expense	625	948	170	456
Tax	-	-62	-	-
<b>Net Profit</b>	<b>-5 181</b>	<b>-32 800</b>	<b>-591</b>	<b>-6 770</b>

*3<sup>rd</sup> quarter Statement of Comprehensive Income is not audited*

## Statement of Financial Position Gentian Group

	2019	2018	2018
<i>(figures in NOK thousands)</i>	30.09	31.12	30.09
<b>Assets</b>			
<b>Non-Current Assets</b>			
Property, plants and equipment	4 977	4 736	4 925
Right-of-use asset	3 585	-	-
Capitalized development costs	13 321	18 691	17 876
Other intangible assets	37	8 883	13 277
Financial assets	326	329	347
<b>Total Non-Current Assets</b>	<b>22 246</b>	<b>32 640</b>	<b>36 425</b>
<b>Current Assets</b>			
Inventory	16 780	13 098	13 254
Accounts receivables	8 556	9 285	13 797
Other receivables	10 991	4 652	9 892
Cash and cash equivalents	169 880	198 305	194 487
<b>Total Currents Assets</b>	<b>206 206</b>	<b>225 340</b>	<b>231 430</b>
<b>Total Assets</b>	<b>228 453</b>	<b>257 980</b>	<b>267 855</b>
<b>Equity and Liabilities</b>			
<b>Equity</b>			
Net profit (Loss)	32 800	19 798	6 770
Other equity	-247 210	-265 671	-264 943
<b>Equity</b>	<b>-214 409</b>	<b>-245 873</b>	<b>-258 173</b>
<b>Non-Current Liabilities</b>			
Interest-bearing loans and dept	-1 163	-698	-737
Lease liability	-3 711	-	-
<b>Total Non-Current Liabilities</b>	<b>-4 873</b>	<b>-698</b>	<b>-737</b>
<b>Current liabilities</b>			
Accounts payable	-3 382	-3 295	-4 006
Public dept	-1 569	-2 176	-1 249
Accrued expenses	-4 219	-5 937	-3 691
<b>Total Current Liabilities</b>	<b>-9 170</b>	<b>-11 409</b>	<b>-8 946</b>
<b>Total Equity and Liabilities</b>	<b>-228 453</b>	<b>-257 980</b>	<b>-267 855</b>

3<sup>rd</sup> quarter Statement of Financial Position is not audited

## Cash Flow Statement

	2019	2019	2018	2018
<i>(figures in NOK thousands)</i>	Q3	01.01.-30.09	Q3	01.01.-30.09
<b>Cash Flow from Operating Activities</b>				
Net profit (loss)	-5 181	-32 800	409	-6 770
Depreciation	1 342	4 720	964	2 915
Impairment	-	14 086	-	-
Change Inventory	-1 387	-3 682	-681	-2 161
Change Accounts Receivables	147	729	-5 489	-6 988
Change Accounts Payables	-885	87	710	457
Change in other short-term receivables/ liabilities	-2 179	-8 790	-1 149	-4 409
<b>Net Cash Flow from Operating Activities</b>	<b>-8 142</b>	<b>-25 650</b>	<b>-5 236</b>	<b>-16 956</b>
<b>Cash Flows from Investment Activities</b>				
Acquisition of Property, plant and equipment	-965	-1 401	-89	-820
Investment in intangible assets	-515	-1 879	-1 206	-3 066
Other changes in financial items	-	-	-	-
<b>Net Cash Flow from Investment Activities</b>	<b>-1 479</b>	<b>-3 281</b>	<b>-1 296</b>	<b>-3 887</b>
<b>Cash Flow from Financial Activities</b>				
New debt	621	621	-	379
Downpayment of loans	-78	-157	-39	-109
Cash flows from share issues	-	-	-	68 519
Dividend payment	-	-	-	-
<b>Net Cash Flow from Financial Activities</b>	<b>543</b>	<b>465</b>	<b>-39</b>	<b>68 790</b>
<b>Net Change in Cash and Cash Equivalents</b>	<b>-9 079</b>	<b>-28 467</b>	<b>-6 571</b>	<b>47 947</b>
Cash and cash equivalents at beginning of period	179 275	198 634	201 409	146 951
Currency adjustment	9	38	-3	-64
<b>Net Cash and Cash Equivalents</b>	<b>170 206</b>	<b>170 206</b>	<b>194 835</b>	<b>194 835</b>

*3<sup>rd</sup> quarter Cash Flow Statement is not audited*



<b>Equity at 01.01.2018</b>	<b>1 399 629</b>	<b>224 142 533</b>	<b>1 467 131</b>	<b>-30 533 929</b>	<b>196 475 364</b>
Net result for the year				-19 798 354	-19 798 354
Other comprehensive income				235	235
Proceeds from share issue	139 963	69 841 437			69 981 400
Cost of share issue		-1 461 978			-1 461 978
Share based payments			694 859		694 859
Other changes in equity				-18 287	-18 287
<b>Equity at 31.12.2018</b>	<b>1 539 592</b>	<b>292 521 992</b>	<b>2 161 990</b>	<b>-50 350 335</b>	<b>245 873 239</b>

<b>Equity at 01.01.2019</b>	<b>1 539 592</b>	<b>292 521 992</b>	<b>2 161 990</b>	<b>-50 350 335</b>	<b>245 873 239</b>
Net result for the year				-32 800 375	-32 800 375
Other comprehensive income					0
Proceeds from share issue					0
Cost of share issue					0
Share based payments			1 248 003		1 248 003
Other changes in equity				88 549	88 549
<b>Equity at 30.09.2019</b>	<b>1 539 592</b>	<b>292 521 992</b>	<b>3 409 993</b>	<b>-83 062 161</b>	<b>214 409 416</b>

*3<sup>rd</sup> quarter Statement of Changes in Equity is not audited*

## NOTES

### Accounting Principles

The interim report for Q3 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.