

# Second quarter and first half 2018 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<sup>TM</sup> technology. The goal is to offer efficient and accurate reagents within the areas of kidney disease, cardiac disease, inflammation and veterinary medicine. The Nanosense<sup>TM</sup> 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

- 37% revenue growth vs 1H 2017
- fCAL turbo and CCRP with record sales in 2Q18
- Proof of concept achieved for new pancreatic elastase assay
- Share issue with net proceeds of MNOK 68.5

#### FINANCIAL PERFORMANCE

Comparative numbers for Gentian 2017 in ()

#### **Sales and Geographic Split**

Total operating revenue ended at MNOK 10.9 (MNOK 10.4) for 2Q18, and MNOK 22.2 (MNOK 16.7) for 1H 2018.

Sales revenue in 2Q18 ended at MNOK 8.8 (MNOK 8.6), a 2% increase compared to 2Q17. 2Q17 included a one-off order from our previous distributor in China of MNOK 2.0.

Sales revenue for 1H 2018 ended at MNOK 18.4 (MNOK 13.4), a 37% increase compared to 1H 2017.

Geographic split:

MNOK	2Q18	2Q17	1H18	1H17
US	0,6	0,2	1,0	0,6
Europe	7,4	5,3	13,5	8,8
Asia	0,8	3,1	3,9	4,1
Total	8,8	8,6	18,4	13,4

Other operating revenue ended at MNOK 0.7 (MNOK 0.7) for 2Q18. SkatteFUNN funding ended at MNOK 1.4 (MNOK 0.9) for 2Q18.



#### **Cost of Goods Sold**

COGS ended at MNOK 1.6 (MNOK 1.1) in 2Q18, which represents 18% (13%) of sales revenue. Total COGS for 1H 2018 ended at MNOK 3.8 (MNOK 2.3), which represents 21% (17%) of sales revenue.



#### **Total Operating Expenses**

Total operating expenses before capitalization of R&D expenses ended at MNOK 12.0 (MNOK 10.0) in 2Q18, and MNOK 24.7 (MNOK 22.3) for 1H 2018.

Operating expenses include total salary and social expenses of MNOK 5.7 (MNOK 5.9) and other expenses of MNOK 6.3 (MNOK 4.1) for 2Q18. For 1H 2018 total salary and social

expenses ended at MNOK 14.2 (MNOK 13.1) and other expenses ended at MNOK 10.6 (MNOK 9.2). The increase is according to the planned acceleration of activities.

Total operating expenses after capitalization of R&D expenses ended at MNOK 10.8 (MNOK 8.3) in 2Q18, and MNOK 22.9 (MNOK 18.3) 1H 2018.

#### **R&D** Expenses

R&D expenses amounted to 40% (36%) of total operating expenses before capitalization for 2Q18, and 35% (35%) for 1H 2018.

#### Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -1.5 (MNOK 0.9) for 2Q18, and MNOK -4.5 (MNOK -3.9) for 1H 2018.

Net financial income/expense ended at MNOK 0.2 (MNOK 0.3) for 2Q18, and MNOK 0.3 (MNOK 0.5) for 1H 2018.

Net profit ended at MNOK -2.3 (MNOK 0.4) for 2Q18, and MNOK -6.2 (MNOK -4.9) for 1H 2018.

#### **Balance Sheet**

Cash and cash equivalents as of 30.06.2018 were MNOK 201.4 (MNOK 156.0).

Capitalization of R&D expenses in 2Q18 amounted to MNOK 1.2 (MNOK 1.7), which gives a total capitalization of MNOK 1.9 (MNOK 4.0) for 1H 2018.

Accounts receivables as of 30.06.2018 were MNOK 8.3 (MNOK 4.7).

#### **Cash Flow**

Cash flow from operating activities ended at MNOK -11.7 (MNOK -11.8) for 1H 2018 and MNOK -6.2 (MNOK -3.9) for 2Q18.

Cash flow from investment activities ended at MNOK -2.6 (MNOK -4.3) for 1H 2018 and MNOK -1.8 (MNOK -1.0) for 2Q18.

Cash flow from financial activities ended at MNOK 68.8 (MNOK 96.1) for 1H 2018 and MNOK 68.9 (MNOK 0) for 2Q18.

#### **OPERATIONAL STATUS**

#### **Product Sales**

Cystatin C sales decreased by 29% vs 1Q18. The decline in sales was related to postponements of shipments to Asia from 2Q18 to 3Q18. Sales of Cystatin C to our partners in Europe and the US have been increasing. Gentian has historically experienced and continue to expect similar variations in the quarterly order patterns of our distributors.

Sales of fCAL turbo increased by 21% from 1Q18 and reached a new quarterly sales record. cCRP also demonstrated a strong growth rate.

#### R&D

Two new Proof-of-Concepts where announced in Q218.

- Gentian announced on 11 April that Proofof-Concept was achieved for measuring hemoglobin and plasma ferritin from the same whole-blood sample. Fully commercialized this can be a significant improvement in detecting insufficient iron storage in blood donors on-site, as well as monitoring iron deficiency at General Practitioners offices and following up results from iron supplement treatment.
- On 22 June Gentian announced a Proof-of-Concept was achieved for Fecal Pancreatic Elastase (fPELA). The project was initiated in November 2017 in collaboration with Gentian's established partner BÜHLMANN Laboratories AG in Basel. The test to be developed from this concept is a

measurement of Pancreatic Exocrine Insufficiency (PEI) associated with various health conditions, chronic e.g. pancreatitis, cystic fibrosis, celiac disease, post-pancreatic diabetes, surgery, gastrectomy etc. fPELA testing today is only commercially available on ELISA platforms, and testing is likely to increase if the test is made available on highly automated, high throughput chemistry analysers. If successful, Gentian and its partner BÜHLMANN estimates that the annual test volume could reach between 5 - 10 million tests annually, ex. USA.

Progress in the clinical studies for Gentian's new plasma Calprotectin assay, GCAL is continuing. The objective of these studies is to demonstrate that the new product may have a potential to become a superior test in diagnosing and monitoring sepsis, severe inflammations and infections, and inflammatory diseases like rheumatoid arthritis. There are currently 11 studies in progress or currently being planned related to GCAL and the Company will report on the outcome of these studies as the results are published.

The optimization of ultrasensitive assays for cardiovascular diseases, and prototype studies of assays for monitoring therapy of HIV infections are ongoing.

#### CORPORATE

On 15 June the Company announced a private placement of 1,399,628 shares at NOK 50 per share with net proceeds of MNOK 68.5. The share issue became effective on 25 June and the number of outstanding shares increased to 15,395,921 as of this date. In connection with the private placement the Company's board of directors was increased by one member and Mr. Henrik Krefting was elected to the board of directors on July 13. On July 16 the Company announced that Dr. Hilja Ibert was appointed as new CEO to the Company. Dr. Ibert has previously held the position of Vice President International Diagnostic Solutions at Hologic, as well as several senior positions with Becton Dickinson and bioMerieux within the field of diagnostics. She holds a PhD degree in Nutrition Science from the University of Bonn, Germany. Dr. Ibert also has experience with early stage R&D companies, lastly in her position as Chief Executive Officer for miDiagnostics in Belgium.

#### OUTLOOK

For Cystatin C, the Company expects total sales to be higher in 2H 2018 compared to 1H 2018, especially as orders from Asia were moved from Q2 to Q3. Sales of fCAL Turbo and cCRP are expected to continue the positive development with high year-on-year growth in 2H2018. However, for all our products quarterly variations in sales should be anticipated going forward.

Within R&D, Gentian expects to progress into the verification phase for our cardiovascular marker, G-1001, within approximately 6 months. The company is also preparing for new commercial launches in 2019 and 2020.

In addition, it is expected that more clinical evidence for the use of GCAL in sepsis and inflammation will be published.

#### **EVENTS AFTER THE BALANCE SHEET DATE**

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

#### SHAREHOLDER INFORMATION

20 largest shareholders in Gentian Diagnostics AS as of 29.06.2018 according to VPS:

Shareholder	No of Shares	%
Holta Life Sciences AS	2 028 502	14,49 %
Safrino AS	1 300 000	9,29 %
Salix AS	1 218 630	8,71 %
Vatne Equity AS	900 000	6,43 %
Silvercoin Industries AS	568 520	4,06 %
Storebrand Vekst	554 375	3,96 %
Vingulmork Predictor AS	535 710	3,83 %
Portia AS	425 000	3,04 %
Statoil Pensjon	400 131	2,86 %
Verdipapirfondet DNB SMB	384 249	2,75 %
Bård Sundrehagen	307 010	2,19 %
Cressida AS	235 000	1,68 %
OM Holding AS	209 000	1,49 %
Marstal AS	202 000	1,44 %
Strawberry Capital AS	200 300	1,43 %
DNB NOR Markets	200 000	1,43 %
Spar Kapital Investor AS	192 291	1,37 %
Mutus AS	187 210	1,34 %
Viola AS	174 990	1,25 %
Lioness AS	150 000	1,07 %
Other Shareholders	3 623 375	25,89 %
Total Shares	13 996 293	100,00 %

Note: The share issue of 1,399,628 shares approved by the board on 25 June 2018 was not registered in VPS as of 29 June 2018. Actual number of outstanding shares as of 29 June was 15,395,921 shares.

	2018	2018	2017	2017
(figures in NOK thousands)	Q2	01.01-30.06	Q2	01.01-30.06
Operating Revenue				
Sales revenue	8 795	18 439	8 629	13 384
Royalties	-	-	48	96
Other operating revenue	732	1 328	686	1 390
SkatteFUNN - tax deduction	1 414	2 422	910	1 764
Total Operating Revenue	10 940	22 189	10 273	16 635
Operating Expenses/Costs				
Cost of goods sold	-1 567	-3 830	-1 112	-2 251
Operating costs	-12 031	-24 733	-10 031	-22 277
Capitalization	1 199	1 860	1 727	4 008
Total Operating Expenses/Costs	-12 399	-26 703	-9 416	-20 521
EBITDA	-1 459	-4 514	857	-3 885
Depreciation	-1 005	-1 951	-708	-1 492
EBIT	-2 464	-6 465	149	-5 377
Financial income/expense	165	286	263	460
Net Profit	-2 299	-6 179	412	-4 917

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# Statement of Comprehensive Income Gentian Group

2. Quarter Statement of Comprehensive Income in 2018 is not audited

# Statement of Financial Position Gentian Group

	2018	2017	2017
(figures in NOK thousands)	30.06	31.12	30.06
Assets			
Non-Current Assets			
Property, plants and equipment	5 106	5 097	4 497
Capitalized development costs	16 991	16 357	15 586
Other intangible assets	13 398	13 641	13 883
Financial assets	362	1 949	1874
Total Non-Current Assets	35 858	37 043	35 840
Current Assets			
Inventory	12 572	11 092	11 050
Accounts receivables	8 308	6 809	4 749
Otherreceivables	9 649	5 283	8 2 3 1
Cash and cah equivalents	201 047	145 003	154 118
Total Currents Assets	231 576	168 187	178 148
Total Assets	267 434	205 230	213 988
Equity and Liabilities			
Equity			
Net profit (Loss)	6 179	15 170	4 917
Other equity	-264 695	-211 645	-211 629
Equity	-258 516	-196 475	-206 712
Non-Current Liabilities			
Interest-bearing loans and dept	-776	-466	-
Total Non-Current Liabilities	-776	-466	-
Current liabilities			
Accounts payable	-3 295	-3 549	-3 183
Public dept	-2 735	-1 694	-2 664
Accrued expenses	-2 733	-3 046	-2 004 -1 429
Total Current Liabilities	-2 111 -8 142	-3 040 -8 288	-1 429 -7 276
	-0 142	-0 200	-7270
Total Equity and Liabilities	-267 434	-205 230	-213 988

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2. Quarter Statement of Financial Position is not audited

#### **Cash Flow Statement**

	2018	2018	2017	2017
(figures in NOK thousands)	Q2	Q1	31.12	30.06
Cash Flow from Operating Activities				
Net profit (loss)	-2 299	-3 880	-15 170	-4 917
Depreciation	1 005	946	3 016	1 492
Change Inventory	-290	-1 190	-3 546	-3 504
Change Accounts Receivables	-1 116	-383	-3 954	-1 894
Change Accounts Payables	-476	223	29	-336
Change in other short-term receivables/liabilities	-3 000	-1 260	992	-2 642
Net Cash Flow from Operating Activities	-6 175	-5 545	-18 633	-11 801
Cash Flows from Investment Activities				
Acquisition of Property, plant and equipment	-639	-93	-1 375	-254
Investment in intangible assets	-1 199	-661	-5 534	-4 008
Other changes in financial items	-	-	-	-
Net Cash Flow from Investment Activities	-1 838	-753	-6 909	-4 262
Cash Flow from Financial Activities				
New debt	379	-	466	-
Downpayment of loans	-40	-30	-	-
Cash flows from share issues	68 519	-	96 069	96 069
Dividend payment	-	-	-	-
Net Cash Flow from Financial Activities	68 859	-30	96 535	96 069
Net Change in Cash and Cash Equivalents	60 846	-6 328	70 993	80 006
Cash flow from last period	140 578	146 951	75 958	75 958
Currency adjustment	-15	-46	-	-60
Net Cash and Cash Equivalents	201 409	140 578	146 951	155 903

2. Quarter Cash Flow Statement is not audited

# Statement of Changes in Equity

(figures in NOK thousands)

	Share	Share Other paid-in		Retained	Total
	capital	premium	capital	earnings	equity
Equity at 01.01.2017	1 114	128 359	1 467	-15 399	115 541
Net result for the year				-15 170	-15 170
Other comprehensive income				35	35
Proceeds from share issue	286	99 714			100 000
Cost of share issue		-3 931			-3 931
Other changes in equity					
Equity at 31.12.2017	1 400	224 143	1 467	-30 534	196 475

Equity at 01.01.2018	1 400	224 143	1 467	-30 534	196 475
Net result for the year				-6 179	-6 179
Other comprehensive income					
Proceeds from share issue	140	69 841			69 981
Cost of share issue		-1 462			-1 462
Other changes in equity				-300	-300
Equity at 30.06.2018	1 540	292 522	1 467	-37 013	258 516

2. Quarter Statement of Changes in Equity is not audited

# **Gentian Diagnostics AS**

	2018	2018	2017	2017
(figures in NOK thousands)	Q2	01.01-30.06	Q2	01.01-30.06
Operating Revenue				
Sales revenue	-	-	-	-
Royalties	-	-	-	-
Other operating revenue	-	-	13	25
SkatteFUNN - tax deduction	-	-	-	-
Total Operating Revenue	-	-	13	25
Operating Expenses/Costs				
Cost of goods sold	-	-	-	-
Operating costs	-231	-755	-310	-960
Capitalization	-	-	-	-
Total Operating Expenses/Costs	-231	-755	-310	-960
EBIDTA	-231	-755	-298	-935
Depreciation	-120	-240	-414	-828
EBIT	-351	-995	-712	-1 763
Financial income/expense	171	306	-	-
Net Profit	-180	-688	-712	-1 763

# Statement of Comprehensive Income Gentian Diagnostics AS

2. Quarter Statement of Comprehensive Income is not audited

Statement of Financial Position Gentian Diagnostics AS

	2018	2017	2017
(figures in NOK thousands)	30.06	31.12	30.06
Assets			
Non-Current Assets			
Property, plants and equipment	-	5	1
Capitalized development costs	-	8 910	8 327
Other intangible assets	8 315	9 034	8 794
Shares in subsidiaries	87 500	47 010	46 900
Receivables from subsidiaries	23 766	18 989	37 057
Financial assets	299	1 870	1874
Total Non-Current Assets	119 880	85 819	102 953
Current Assets			
Inventory		_	_
Accounts receivables		-	-
Other receivables	295	923	- 952
Cash and cah equivalents	196 483	69 260	146 552
Derivatives	-	-	-
Total Currents Assets	196 779	70 183	147 504
Total currents Assets	150775	70 105	147 304
Total Assets	316 659	156 001	250 457
Equity and Liabilities			
Equity	<b>COO</b>	4 0 2 4	4 2 6 2
Net profit (Loss)	688	4 931	1 362
Other equity	-298 348	-141 641	-232 669
Equity	-297 660	-136 710	-231 306
Non-Current Liabilities			
Interest-bearing loans and dept	-	-	-
Loan subsidiaries	-18 945	-18 945	-18 945
Total Non-Current Liabilities	-18 945	-18 945	-18 945
Current liabilities			
Accounts payable	-1	-347	-206
Public dept	-53	- 347	-200
Accrued expenses		-	-
Derivatives		-	-
Total Current Liabilities	-54	-347	-206
Total Equity and Liabilities	-316 659	-156 001	-250 457

2. Quarter Statement of Financial Position is not audited

Cash Flow Statement Gentian Diagnostics AS

	2018	2018	2017
(figures in NOK thousands)	Q2	Q1	31.12
Cash Flow from Operating Activities			
Net profit (loss)	-180	-508	-2 840
	-	-	-
Depreciation	120	120	1 652
Change Inventory	-	-	-
Change Accounts Receivables	-	-	-
Change Accounts Payables	-37	25	-333
Change in other short-term receivables/liabilities	-126	-166	972
Change in Receivables from subsidiaries	-8 523	-3 215	6 961
Net Cash Flow from Operating Activities	-8 746	-3 745	6 412
Cash Flows from Investment Activities			
Acquisition of Property, plant and equipment		_	_
Investment in intangible assets			7 743
Investment in other companies			7745
Loan to other companies			_
Other changes in financial items			_
Shares in subsidiaries	_	-	-40 600
Net Cash Flow from Investment Activities	_		-32 857
Net cush now non investment Activities			52 057
Cash Flow from Financial Activities			
New debt	-	-	-
Downpayment of loans	-	-	-
Change in Bankoverdraft	-	-	-
Cash flows from share issues	68 519	-	96 069
Dividend payment	-	-	-
Net Cash Flow from Financial Activities	68 519	-	96 069
Net Change in Cash and Cash Equivalents	59 774	-3 745	69 624
Cash flow from last period	137 008	140 753	71 130
Currency adjustment	-0	0	-0
Net Cash and Cash Equivalents	196 782	137 008	140 753

2. Quarter Cash Flow Statement is not audited

#### NOTES

#### **Accounting Principles**

The interim report for Q2 2018 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 2017.

#### Currency

The Company uses currency rates given by DNB ASA.

#### **Capitalized R&D**

There are currently three projects where the Gentian Group is capitalizing R&D expenses.

# **GENTIAN DIAGNOSTICS AS**

### **SEMI-ANNUAL REPORT AND DECLERATION**

#### 2018

#### **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 2018 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 company's and 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, 16. August 2018

On behalf of Gentian Diagnostics AS:

Tomas Settevik (sign.) Chairman of the board

Bendik Sundrehagen (sign.) Board member

Kari E. Krogstad (sign.) Board member Espen Tidemann Jørgensen (sign.) Board member

Ingrid Teigland Akay (sign.) Board member

Henrik Krefting (sign.) Board member

Hilja Ibert (sign.) CEO