

# First quarter 2019 results



## **First Quarter 2019 results**



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>™</sup> technology. Through in-depth research into Particle-Enhanced Turbidimetric Immunoassays (PETIA), Gentian developed Nanosense<sup>™</sup>. Nanosense<sup>™</sup> 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<sup>™</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

- Good start to the new fiscal year with sales revenues of MNOK 10.6 for the quarter.
- Record sales achieved for fCAL<sup>®</sup>turbo, our innovative biomarker for the diagnosis of inflammatory bowel disease.
- New scientific study results confirm GCAL as a promising biomarker for the diagnosis of bacterial infections.

#### FINANCIAL PERFORMANCE

Comparative numbers for Gentian 2018 in ()

Sales, Geographic Split and Product Split Total operating revenue ended at MNOK 12.1 (MNOK 11.2) for 1Q19. Sales revenue in 1Q19 ended at MNOK 10.6 (MNOK 9.6), a 10 % increase compared to 1Q18.

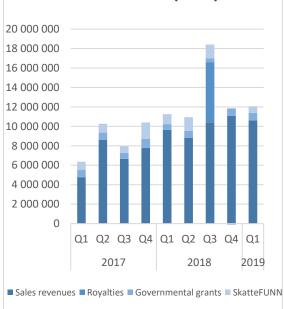
Geographic split:

| MNOK   | 1Q19 | 1Q18 |
|--------|------|------|
| US     | 0.5  | 0.4  |
| Europe | 7.4  | 6.1  |
| Asia   | 2.7  | 3.1  |
| Total  | 10.6 | 9.6  |

Product split:

| MNOK       | 1Q19 | 1Q18 |
|------------|------|------|
| Cystatin C | 4.7  | 5.5  |
| fCAL®turbo | 3.9  | 2.1  |
| Other      | 2.0  | 2.0  |
| Total      | 10.6 | 9.6  |

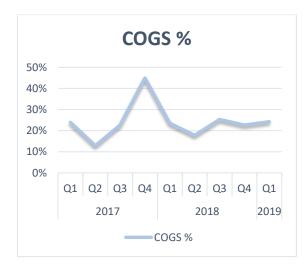
Other operating revenue ended at MNOK 0.8 (MNOK 0.6) for 1Q19. SkatteFUNN funding ended at MNOK 0.7 (MNOK 1.0) for 1Q19.



# Revenues and Grants Consolidated (NOK)

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

COGS ended at MNOK 2.6 (MNOK 2.3) in 1Q19, which represents 24 % (23 %) of sales revenue.



#### **Total Operating Expenses**

Total operating expenses before capitalization of R&D expenses ended at MNOK 16.0 (MNOK 12.7) in 1Q19.

Operating expenses include total salary and social expenses of MNOK 10.9 (MNOK 8.4) and

other expenses of MNOK 5.1 (MNOK 4.2) for 1Q19. The increase is according to the planned acceleration of activities. SG&A also include a share-based compensation of MNOK 0.4 with no cash effect.

Total operating expenses after capitalization of R&D expenses ended at MNOK 15.1 (MNOK 12.0) in 1Q19.

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

R&D expenses amounted to 26 % (31 %) of total operating expenses before capitalization for 1Q19.

#### Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -5.6 (MNOK -3.1) for 1Q19.

Net financial income ended at MNOK 0.0 (MNOK 0.1) for 1Q19.

Net profit ended at MNOK -7.3 (MNOK -3.9) for 1Q19.

#### **Balance Sheet**

Cash and cash equivalents as of 31.03.2019 were MNOK 191.3 (MNOK 140.6). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 31.03.2019 were MNOK 6.7 (MNOK 7.2).

Inventory as of 31.03.2019 were MNOK 14.3 (MNOK 12.3). The increase in inventory is due to higher sales and build-up of an inventory buffer.

#### **Cash Flow**

Cash flow from operating activities ended at MNOK -6.2 (MNOK -5.5) for 1Q19.

Cash flow from investment activities ended at MNOK -1.2 (MNOK -0.8) for 1Q19. Included in investment activities are capitalization of R&D

expenses, which in 1Q19 amounted to MNOK 0.9 (MNOK 0.7).

Cash flow from financial activities ended at MNOK 0.0 (MNOK 0.0) for 1Q19.

#### **OPERATIONAL STATUS**

#### **Product Sales**

Sales in 1Q19 showed an increase of 10 % compared to 1Q18, ending the quarter with a sales revenue of MNOK 10.6. The increase is driven by MNOK 3.9 record sales of fCAL®turbo (biomarker for the diagnosis of inflammatory bowel disease). These revenues include some special orders, due to Brexit preparations by our customers in the UK.

Due to normal quarterly variations in the order patterns of our partners, Cystatin C kidney health biomarker sales revenue decreased compared to 1Q18. The underlaying sales performance is still indicated to be strong.

#### R&D

New scientific study results for GCAL, our biomarker for severe infections, sepsis and rheumatoid arthritis, have confirmed GCAL as a promising biomarker for the diagnosis of bacterial infections. Larsson et al. concluded that the rapid determination of calprotectin should be an improvement in the management of infections and allow more selective use of antibiotics.

The product development for our cardiac marker G-1001 continues to deliver the expected milestones for a market launch in 2021.

Our Fecal Pancreatic Elastase<sup>1</sup> product development project has been moved into the verification phase, which confirms our plan to

launch in 2020 together with our commercial partner Bühlmann Laboratories AG.

#### CORPORATE

The company has appointed Mr. Torsten Knüttel as Vice President of Research and Development. Mr. Knüttel will commence in his new position at the latest on the 5th of August 2019.

#### OUTLOOK

The company expects continued sales growth in 2Q19 versus 2Q18. The variations in order patterns will continue to result in normal quarterly variations.

For Cystatin C the company expects continued growth, primarily driven by increased demand in China and an increased focus on the US market. The company expects continued sales growth in Europe for fCAL®turbo. The FDA 510k efforts of our partner Bühlmann Laboratories AG are progressing as planned and a regulatory decision is expected by the end of 2Q19.

The market development efforts for calprotectin as a biomarker for severe infections, sepsis and rheumatoid arthritis will continue with presentations at scientific congresses and articles in international journals. In addition, the company will intensify its efforts to engage with key opinion leaders. As part of this market development program, the company organizes an educational workshop at the Euromedlab (European Congress of Clinical Chemistry and Laboratory Medicine) in Barcelona on 21st May 2019. The workshop will be held under the title "Plasma Calprotectin: A promising early biomarker for the diagnosis of bacterial infections and

<sup>&</sup>lt;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.

sepsis". The Euromedlab is the most important European event in laboratory medicine.

#### 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 29.03.2019 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    | 724 000      | 4,70 %   |
| Vingulmork Predictor AS  | 535 710      | 3,48 %   |
| Storebrand Vekst         | 497 807      | 3,23 %   |
| Portia AS                | 425 000      | 2,76 %   |
| Statoil Pensjon          | 388 564      | 2,52 %   |
| Verdipapirfondet DNB SMB | 384 249      | 2,50 %   |
| Silvercoin Industries AS | 359 628      | 2,34 %   |
| Bård Sundrehagen         | 307 010      | 1,99 %   |
| Cressida AS              | 235 000      | 1,53 %   |
| Norda ASA                | 225 447      | 1,46 %   |
| 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       | 3 845 123    | 24,97 %  |
| Total Shares             | 15 395 921   | 100,00 % |

|   | 2019    | 2018    | 2018        |
|---|---------|---------|-------------|
| (figures in NOK thousands)              | Q1      | Q1      | 01.01-31.12 |
| Operating Revenue                       |         |         |             |
| Sales revenue                           | 10 613  | 9 645   | 39 912      |
| Other operating revenue                 | 1 450   | 1 604   | 12 108      |
| Total Operating Revenue                 | 12 063  | 11 249  | 52 020      |
| Operating Expenses/Costs                |         |         |             |
| Cost of goods sold                      | -2 570  | -2 263  | -8 969      |
| Production costs                        | -4 060  | -4 288  | -13 458     |
| R&D costs                               | -4 109  | -3 270  | -19 057     |
| Selling, general & administrative costs | -7 874  | -5 144  | -27 450     |
| Capitalization                          | 907     | 661     | 5 165       |
| Total Operating Expenses/Costs          | -17 705 | -14 304 | -63 769     |
| EBITDA                                  | -5 642  | -3 055  | -11 749     |
| Depreciation                            | -1 656  | -946    | -3 897      |
| Impairment of Goodwill                  | -       | -       | -5 040      |
| EBIT                                    | -7 298  | -4 001  | -20 686     |
| Financial income/expense                | 21      | 121     | 951         |
| Тах                                     | -       | -       | -64         |
| Net Profit                              | -7 277  | -3 880  | -19 798     |

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## Statement of Comprehensive Income Gentian Group

1<sup>st</sup> quarter Statement of Comprehensive Income is not audited

# **Statement of Financial Position Gentian Group**

|  | 2010                      | 2010                      | 2010                    |
|--|---------------------------|---------------------------|-------------------------|
| (figures in NOK thousands)                 | <b>2019</b><br>31.03      | <b>2018</b><br>31.12      | <b>2018</b><br>31.03    |
| Assets                                     | 51.05                     | 51.12                     | 51.05                   |
| Non-Current Assets                         |                           |                           |                         |
| Property, plants and equipment             | 4 622                     | 4 736                     | 4 879                   |
| Right-of-use asset                         | 4 512                     | -                         | -                       |
| Capitalized development costs              | 19 721                    | 18 691                    | 16 502                  |
| Other intangible assets                    | 7 994                     | 8 883                     | 13 520                  |
| Financial assets                           | 329                       | 329                       | 1 947                   |
| Total Non-Current Assets                   | 37 178                    | 32 640                    | 36 848                  |
| Current Assets                             |                           |                           |                         |
| Current Assets                             | 14 202                    | 12 009                    | 17 707                  |
| Inventory<br>Accounts receivables          | 14 303<br>6 749           | 13 098<br>9 285           | 12 282<br>7 192         |
| Other receivables                          | 7 032                     | 9 285<br>4 652            | 6 943                   |
| Cash and cash equivalents                  | 191 012                   | 4 052<br>198 305          | 138 631                 |
| Total Currents Assets                      | <b>219 096</b>            | <b>225 340</b>            | <b>165 049</b>          |
|  | 219 090                   | 225 540                   | 105 049                 |
| Total Assets                               | 256 274                   | 257 980                   | 201 896                 |
|  |                           |                           |                         |
| Equity and Liabilities                     |                           |                           |                         |
| Equity                                     |                           | 40 700                    | 2 000                   |
| Net profit (Loss)                          | 7 277                     | 19 798                    | 3 880                   |
| Other equity                               | -246 384                  | -265 671                  | -196 428                |
| Equity                                     | -239 107                  | -245 873                  | -192 548                |
| Non-Current Liabilities                    |                           |                           |                         |
| Interest-bearing loans and dept            | -659                      | -698                      | -436                    |
| Lease liability                            | -4 560                    | -                         | -                       |
| Total Non-Current Liabilities              | -5 219                    | -698                      | -436                    |
| Current liabilities                        |                           |                           |                         |
| Current liabilities                        | 2 450                     | -3 295                    | רדד כ                   |
| Accounts payable                           | -3 450<br>-1 379          | -3 295<br>-2 176          | -3 772<br>-1 321        |
| Public dept                                | -1 379<br>-7 119          | -2 176<br>-5 937          |                         |
| Accrued expenses Total Current Liabilities | -7 119<br>- <b>11 948</b> | -5 937<br>- <b>11 409</b> | -3 819<br><b>-8 912</b> |
|  | -11 548                   | -11 409                   | -0 312                  |
| Total Equity and Liabilities               | -256 274                  | -257 980                  | -201 896                |

1<sup>st</sup> quarter Statement of Financial Position is not audited

### **Cash Flow Statement**

|   | 2019    | 2018        | 2018    |
|---|---------|-------------|---------|
| (figures in NOK thousands)                          | Q1      | 01.01-31.12 | Q1      |
|   |         |             |         |
| Cash Flow from Operating Activities                 |         |             |         |
| Net profit (loss)                                   | -7 277  | -19 798     | -3 880  |
|   |         |             |         |
| Depreciation  | 1 656   | 3 897       | 946     |
| Impairment of Goodwill                              | -       | 5 040       | -       |
| Change Inventory                                    | -1 205  | -2 006      | -1 190  |
| Change Accounts Receivables                         | 2 536   | -2 476      | -383    |
| Change Accounts Payables                            | 155     | -253        | 223     |
| Change in other short-term receivables/ liabilities | -2 044  | 4 700       | -1 260  |
| Net Cash Flow from Operating Activities             | -6 179  | -10 897     | -5 545  |
|   |         |             |         |
| Cash Flows from Investment Activities               |         |             |         |
| Acquisition of Property, plant and equipment        | -263    | -989        | -93     |
| Investment in intangible assets                     | -907    | -5 165      | -661    |
| Other changes in financial items                    | -       | -           | -       |
| Net Cash Flow from Investment Activities            | -1 170  | -6 153      | -753    |
|   |         |             |         |
| Cash Flow from Financial Activities                 |         |             |         |
| New debt  | -       | 379         | -       |
| Downpayment of loans                                | -39     | -147        | -30     |
| Cash flows from share issues                        | -       | 68 519      | -       |
| Dividend payment                                    | -       | -           | -       |
| Net Cash Flow from Financial Activities             | -39     | 68 751      | -30     |
|   |         |             |         |
| Net Change in Cash and Cash Equivalents             | -7 388  | 51 701      | -6 328  |
| Cash and cash equivalents at beginning of period    | 198 634 | 146 951     | 146 951 |
| Currency adjustment                                 | 95      | -18         | -46     |
| Net Cash and Cash Equivalents                       | 191 341 | 198 634     | 140 578 |

1<sup>st</sup> 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 01.01.2018       | 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    |         |         |               | -7 277   | -7 277  |
| Other comprehensive income |         |         |               | 15       | 15      |
| Proceeds from share issue  |         |         |               |          |         |
| Cost of share issue        |         |         |               |          |         |
| Share based payments       |         |         | 411           |          | 411     |
| Other changes in equity    |         |         |               | 84       | 84      |
| Equity at 31.03.2019       | 1 540   | 292 522 | 2 573         | -57 528  | 239 107 |

1<sup>st</sup> quarter Statement of Changes in Equity is not audited

#### NOTES

#### **Accounting Principles**

The interim report for Q1 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:

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

In addition, the implementation causes a reallocation of costs, related to the operative leases. The reallocation gives a positive effect on EBITDA and a negative effect on Depreciation and Finance.

#### 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.