# Fourth quarter 2020 results

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We innovate diagnostic efficiency

# GENTIAN DIAGNOSTICS

Gentian Diagnostics AS is a medical diagnostics company listed on the Oslo Stock Exchange, Euronext Growth. The company is involved in the production, R&D, marketing and distribution of immunoassays. It has its headquarter in Norway, and is supported globally by a strong distributor network and distribution subsidiaries in Sweden and the US and through a representative office in China.

Through in-depth research into Particle-Enhanced Turbidimetric Immunoassays (PETIA), and the development of proprietary antibody and nano-particle technology, Gentian's immunoassays 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.

Gentian serves the immunochemistry segment of the in vitro diagnostics (IVD) market with products which add value to healthcare suppliers by improving laboratory workflow and clinical outcomes. The value propositions of the new products will all be scientifically proven and promoted by investments into clinical studies, state-of-the art marketing, and selective commercial representation in key countries.

## Gentian Diagnostics' PETIA products and product pipeline

Gentian specialises in making highly relevant biomarkers available on the PETIA technology platform. Our current and future portfolio of diagnostic reagents spans areas of kidney disease, cardiac disease, inflammation, infection and veterinary medicine. The product lines of laboratory tests provide high accuracy and fast results and contribute to increased laboratory efficiency and improved outcomes for patients.

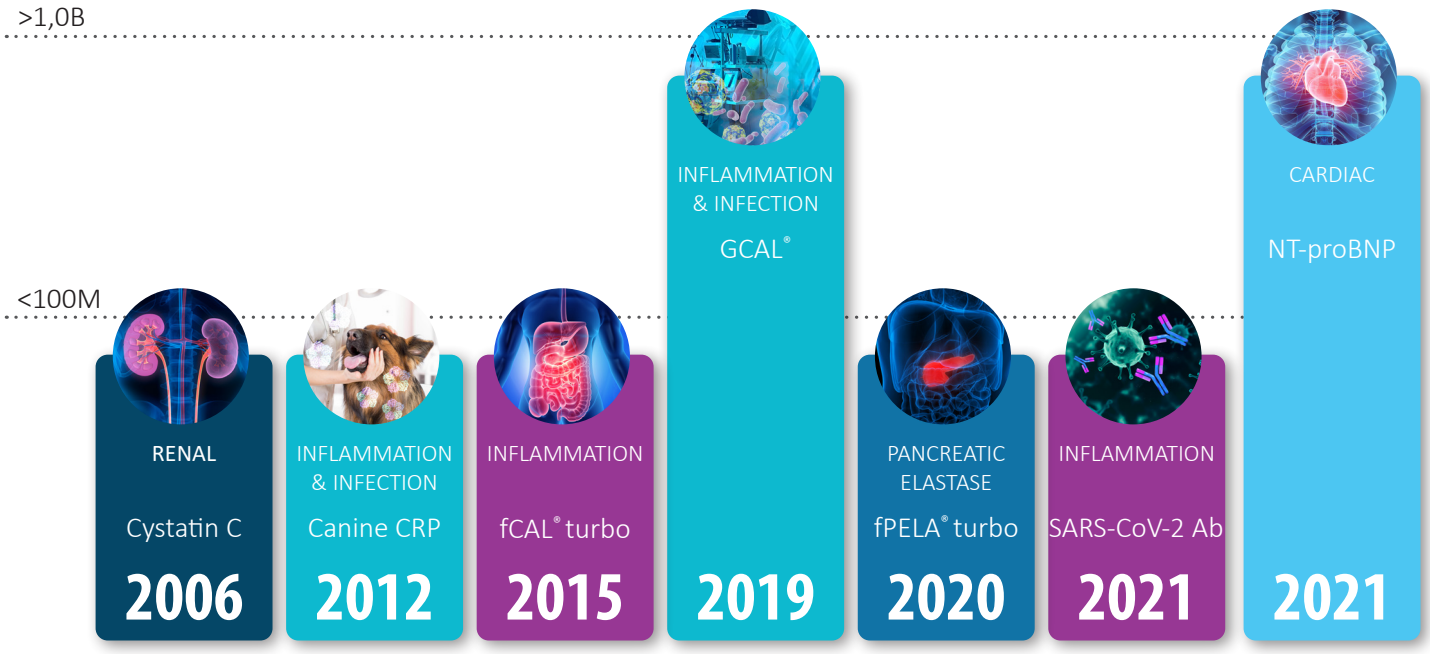
Gentian's current portfolio includes Cystatin C (CE marked, FDA-510(k) cleared), the calprotectin immunoassay GCAL® (CE marked) and Canine CRP.

In addition, Gentian is the sole reagent provider and manufacturer for the faecal calprotectin immunoassay fCAL® turbo (CE marked, FDA-510(k) cleared) in addition to the newly launched, pancreatic elastase immunoassay fPELA® turbo (CE marked, FDA exempt). These immunoassays are sold exclusively by Gentian's partner BÜHLMANN Laboratories AG.

Gentian is pleased to advise that it is on track for launch of its NT-proBNP immunoassay. This unique assay will be the first cardiac marker designed specifically for high volume clinical chemistry platforms. Estimated launch is Q4 2021.

Gentian's high throughput turbidimetric SARS-CoV-2 antibody assay is on a fast track development plan and is expected to launch in 2021.

## Market size by target category (USD)



# HIGHLIGHTS

- Gentian finished the year with record sales of MNOK 17.2 in the 4Q20 which corresponds to 22 % growth versus 4Q19
- Total sales revenue for the year was MNOK 63.3 representing a 32 % growth (22 % adjusted for currency effects) compared to the same period last year
- Double digit sales growth was achieved for all products and all regions in 2020
- Gentian's unique PETIA-based SARS-CoV-2 antibody test has reached the next development phase with an estimated launch by the end of 2021
- Encouraging scientific publications on GCAL® in context of COVID-19 patient management have spurred the interest of hospitals and laboratories from all over Europe

# OPERATIONAL SUMMARY

## Sales

Sales revenue in 4Q20 showed an increase of 22 % compared to 4Q19, ending the quarter at MNOK 17.2, which is a new record. For 2020 the sales revenue ended 32 % higher compared to 2019, with a currency neutral growth of 22 %.

Sales of Cystatin C was MNOK 6.6 for the quarter, an increase of 69 % compared to 4Q19, and MNOK 25.8 for the total year, an increase of 33 % compared to the same period 2019.

Sales of fCAL® turbo continues to recover from the low levels seen in 2Q20 due to the COVID-19 situation. Total year sales ended with MNOK 20.9 and an encouraging growth of 20 % versus last year. Although underlying growth prospects remain positive, we may see negative effects on sales if countries continue to impose strict measures of movement due to COVID-19.

Our Swedish distribution subsidiary, Gentian Diagnostics AB (GAB), continues to have a positive sales development for third party products totaling MNOK 6.9 in 2020, a 127 % increase compared to 2019. GAB achieved a major milestone reaching the EBITDA break-even point during H2 2020. It is expected further profitable growth going forward, although at lower growth rates than in 2020.

In 2Q20 the company launched fPELA® turbo and is pleased to announce that this product has exceeded expectations and has been well accepted in the market. Sales are still at a relatively low level, but the company's long-term ambition for this marker is to reach a sales level corresponding to approximately 25 % of the fCAL® turbo revenue potential.

The current outbreak of COVID-19 has had minor effect on Gentian to date. Gentian has robust business continuity plans in place, and production has been maintained at normal levels with staff working under enhanced safety conditions. The company has also been able to make deliveries to its customers on time and anticipate to maintain this going forward.

# Market development

## GCAL®

During H2 2020 several research studies have shown plasma and serum calprotectin as a promising biomarker for risk assessment and prognosis in COVID-19 patients, including disease severity, the need for mechanical ventilation and prediction of mortality[1-6].

Gentian and its research partners presented two posters related to the value of calprotectin in management of COVID-19 patients at the AACC (American Association of Clinical Chemistry) conference in December 2020. The results from these studies and the GCAL® assay were described and highlighted on several occasions and news platforms, including an AACC press release, articles in LabPulse and 360Dx.

Importantly, the value of calprotectin in the risk assessment and evaluation of the disease severity has also been confirmed in a study conducted in collaboration with the Charité University Hospital and Labor Berlin. The study demonstrated the ability of calprotectin to predict the development of multi-organ failure (MOF) in COVID-19 patients that are already present at the Emergency Department (ED) and the need for care at the intensive care unit (ICU). The study has been presented in a Letter to the Editor in the scientific journal "Journal of Infection"[6].

Results from the published studies and Gentian's overall marketing efforts have led to positive market responses and increased interest in implementing the GCAL® assay into the routine test menu of laboratories and hospitals throughout Europe.

# Product development

## NT-proBNP

Gentian's NT-proBNP test is the first turbidimetric assay which is used for testing of individuals suspected of having congestive heart failure (CHF). NT-proBNP is one of the most widely used diagnostics tests currently in the market with an estimated yearly sales value of BUSD 1.4 and represents a significant growth opportunity for Gentian. The uniqe turbidimetric NT-proBNP assay from Gentian is aming to address key customer needs of economics and quality. The assay development has advanced and is running according to plan.

Gentian has also commissioned additional and detailed market research projects to further identify the specific market potential and its requirements to support the optimal positioning of the product.

The company expects that the first patent applications for NT-proBNP will be published in February 2021.

The assay is planned to be launched by the end of Q4 2021.

## SARS-CoV-2 antibody test

This turbidimetric, semi-quantitative immunoassay detects antibodies towards SARS-CoV-2, hence supporting vaccination efforts and will aid in community management by the determination of the individual immunisation status. It is the first assay of its kind for use on high throughput open-access clinical chemistry platforms.

The assay development has now moved from the proof-of-concept phase to the project initiation and optimisation phase. The work is carried out in collaboration with University of Tromsø, The Artic University of Norway, where expert guidance on vaccine requirements and patient sample sourcing are provided.

The assay is planned for launch during Q4 2021.

**References:** 1. Shi H, et al. J Leukoc Biol. 2020 Sep 1. Epub ahead of print 2. Chen L, et al. Cell Mol Immunol. 2020 Sep;17(9):992-994 3. Luis García de Guadiana Romualdo, et al. J Infect. 2020 Aug 12:S0163-4453(20)30543-0 4. Silvin A, et al. Cell. 2020 Sep 17;182(6):1401-1418.e18 5. Sohn KM, et al. J Korean Med Sci. 2020 Sep 28;35(38):e343 6. Bauer W, et al. J Infect. 2020 Nov 17:S0163-4453(20)30711-8

## FINANCIAL PERFORMANCE

*Comparative numbers for Gentian 2019 in ()*

### Sales, Geographic Split and Product Split

Total operating revenue ended at MNOK 23.8 (MNOK 16.5) for 4Q20, and MNOK 78.9 (MNOK 55.4) for the full year.

Sales revenue in 4Q20 ended at a record high of MNOK 17.2 (MNOK 14.1), a 22 % increase compared to 4Q19. Sales revenue in 2020 ended at MNOK 63.3 (MNOK 48.0), a 32 % increase compared to the same period last year. Adjusted for currency effects sales growth was 22 % for the full year.

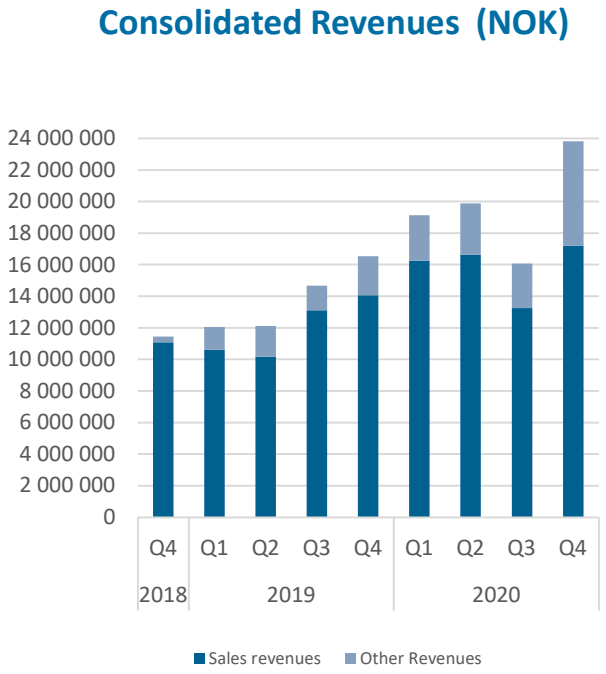
Geographic split:

| MNOK | 4Q20 | 4Q19 | 2020 | 2019 |
|---|---|---|---|---|
| US | 0.7 | 0.6 | 3.0 | 2.0 |
| Europe | 13.0 | 11.3 | 45.4 | 34.1 |
| Asia | 3.6 | 2.2 | 14.9 | 11.8 |
| Total | 17.2 | 14.1 | 63.3 | 48.0 |

Product split:

| MNOK | 4Q20 | 4Q19 | 2020 | 2019 |
|---|---|---|---|---|
| Cystatin C | 6.6 | 3.9 | 25.8 | 19.7 |
| fCAL®turbo | 6.2 | 7.0 | 20.9 | 17.5 |
| Other | 4.5 | 3.1 | 16.6 | 10.8 |
| Total | 17.2 | 14.1 | 63.3 | 48.0 |

Other operating revenue ended at MNOK 6.6 (MNOK 2.6) for 4Q20, and MNOK 15.6 (MNOK 7.4) for the full year. Other operating revenue includes the financial gain for the divestiture of the subsidiary PreTect AS, for more information see stock exchange notice 5th of November 2020.


### Cost of Goods Sold

COGS ended at MNOK 9.1 (MNOK 6.6) in 4Q20, which represents 53 % (47 %) of sales revenue. Total COGS for 2020 was MNOK 32.6 (MNOK 25.4), which represents 51 % (53 %) of sales revenue.

We continue to see quarterly variations but expect to see COGS declining as a percentage of sales over time.

### Total Other Operating Expenses

Total other operating expenses before capitalization of R&D expenses ended at MNOK 18.3 (MNOK 17.3) in 4Q20, and MNOK 60.9 (MNOK 54.0) for 2020.

Other operating expenses include salary and social expenses of MNOK 9.5 (MNOK 9.4) and other expenses of MNOK 8.9 (MNOK 7.9) for 4Q20. For the full year, salary and social expenses ended at MNOK 37.8 (MNOK 31.0) and other expenses ended at MNOK 23.1 (MNOK 23.1). SG&A also include a share-based compensation of MNOK 3.3 for 2020 with no cash effect.

R&D expenses amounted to 54 % (44 %) of total other operating expenses before capitalization for 4Q20, and 45 % (41 %) for the full year 2020. Capitalization of R&D expenses was MNOK 2.5 (MNOK 1.2) in 4Q20, and MNOK 3.4 (MNOK 3.1) for2020.

Total other operating expenses after capitalization of R&D expenses ended at MNOK 15.8 (MNOK 16.1) in 4Q20 and MNOK 57.5 (MNOK 51.0) for 2020.

### Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -1.1 (MNOK -6.2) for 4Q20, and MNOK -11.2 (MNOK -21.0) for the full year. Net profit ended at MNOK -3.5 (MNOK -7.1) for 4Q20, and MNOK -17.5 (MNOK -39.9) for 2020.

### Balance Sheet

Cash and cash equivalents as of 31.12.2020 were MNOK 158.0 (MNOK 171.6). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 31.12.2020 were MNOK 7.6 (MNOK 8.5).

Inventory as of 31.12.2020 were MNOK 20.9 (MNOK 18.2).

## OUTLOOK

Assuming no unpredictable effects of the COVID-19 outbreak, Gentian targets double digit sales growth on its established product line in 2021 versus 2020, with the expected quarterly variations. In addition, the company will continue its efforts to provide for a continued optimal commercialisation effect of GCAL® by actively pursuing sales opportunities in Europe.

For Cystatin C, the company expects continued growth in 2021 versus 2020, with the majority of the growth arriving from the Asian and US markets.

The underlying demand for fCAL® turbo remains strong. The marker has proven to be a great success at clinical laboratories all over Europe, and growth will continue to be driven by active competitive conversions in addition to a market growth of 10 % - 15 % per annum. The company expects to experience growth for both kit and bulk sales, but we may experience disturbances/variations in sales depending on the capacity of the respective health systems in Europe to process outpatient services under COVID-19 conditions and the severity of measures taken by said countries to contain the spread of COVID-19.

For GCAL®, several collaborations have been initiated with both clinicians and researchers in France, Germany, UK, Sweden and Spain with the objective to further investigate the role of calprotectin in COVID-19 and sepsis/bacterial infections. Once completed, the results from these studies will be communicated via scientific publications and conferences and will support further acceleration of the routine testing of GCAL® in laboratories and hospitals in Europe.

### COVID-19

At Gentian, the health and safety of our employees, as well as our customers and partners, is our primary concern. That continues to be our focus as we manage our response to the COVID-19 outbreak that has proliferated globally. Gentian has robust business-continuity plans in place and expects to maintain production even if the situation deteriorates. Gentian abides by policies of the health authorities in all countries of operation whilst continuing to seamlessly support our customers. Gentian may be affected by the COVID-19 outbreak by reduced demand for

diagnostic services, especially for outpatient markers, and we expect some delays with our R&D programs. The length of the delays will depend on the duration of the outbreak.

### CORPORATE

The board of directors intends to transform the company to an "ASA" (Public limited liability company) as this is a requirement for listing of the company's shares on a regulated market. The required resolutions will be proposed to the shareholders in connection with the Annual General Meeting planned to be held on May 4th 2021.

## 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 31.12.2020 according to VPS and disclosures from investors:

| Shareholder | No of Shares | % |
|---|---|---|
| Vatne Equity AS | 2 010 224 | 13,04 % |
| Holta Life Sciences AS | 1 214 702 | 7,88 % |
| Norda ASA | 1 190 068 | 7,72 % |
| Safrino AS | 1 050 000 | 6,81 % |
| Salix AS | 994 098 | 6,45 % |
| Verdipapirfondet Delphi Nordic | 736 989 | 4,78 % |
| Norron Sicav - Target | 723 753 | 4,70 % |
| Storebrand Vekst | 425 016 | 2,76 % |
| Verdipapirfondet DNB SMB | 419 253 | 2,72 % |
| Equinor Pensjon | 381 320 | 2,47 % |
| Portia AS | 300 000 | 1,95 % |
| Cressida AS | 235 000 | 1,52 % |
| Lioness AS | 220 000 | 1,43 % |
| Marstal AS | 212 407 | 1,38 % |
| Silvercoin Industries AS | 211 817 | 1,37 % |
| Mutus AS | 210 465 | 1,37 % |
| Bård Sundrehagen | 185 646 | 1,20 % |
| Vingulmork Predictor AS | 184 083 | 1,19 % |
| OM Holding AS | 179 000 | 1,16 % |
| Borgano AS | 173 877 | 1,13 % |
| Other Shareholders | 4 154 171 | 26,95 % |
| **Total Shares** | **15 411 889** | 100,00 % |

## Statement of Comprehensive Income Gentian Group

| | 2020 | 2020 | 2019 | 2019 |
|---|---|---|---|---|
| *(figures in NOK thousands)* | **Q4** | **01.01-31.12** | **Q4** | **01.01-31.12** |
| **Operating Revenue** | | | | |
| Sales revenue | 17 196 | 63 327 | 14 070 | 47 952 |
| Other operating revenue | 6 614 | 15 554 | 2 474 | 7 433 |
| **Total Operating Revenue** | **23 810** | **78 881** | **16 544** | **55 384** |
| **Operating Expenses/Costs** | | | | |
| Cost of goods sold | -9 097 | -32 586 | -6 607 | -25 449 |
| R&D costs | -9 973 | -27 308 | -7 579 | -22 283 |
| Selling, general & administrative costs | -8 358 | -33 606 | -9 705 | -31 746 |
| Capitalization | 2 520 | 3 421 | 1 192 | 3 071 |
| **Total Operating Expenses/Costs** | **-24 908** | **-90 080** | **-22 699** | **-76 407** |
| **EBITDA** | **-1 098** | **-11 199** | **-6 155** | **-21 023** |
| Depreciation | -1 958 | -6 630 | -1 412 | -6 132 |
| Impairment | - | - | - | -14 086 |
| **EBIT** | **-3 056** | **-17 829** | **-7 567** | **-41 241** |
| Financial income/expense | -480 | 361 | 502 | 1 447 |
| Tax | - | - | - | -63 |
| **Net Profit** | **-3 536** | **-17 468** | **-7 064** | **-39 857** |

*4th quarter Statement of Comprehensive Income is not audited*

## Statement of Financial Position Gentian Group

| | 2020 | 2019 |
|---|---|---|
| *(figures in NOK thousands)* | 31.12 | 31.12 |
| **Assets** | | |
| **Non-Current Assets** | | |
| Property, plants and equipment | 5 136 | 4 714 |
| Right-of-use asset | 20 417 | 3 062 |
| Capitalized development costs | 15 610 | 14 076 |
| Other intangible assets | - | 36 |
| Financial assets | 337 | 329 |
| **Total Non-Current Assets** | **41 500** | **22 216** |
| | | |
| **Current Assets** | | |
| Inventory | 20 876 | 18 224 |
| Accounts receivables | 7 633 | 8 493 |
| Other receivables | 7 608 | 7 012 |
| Cash and cash equivalents | 157 648 | 171 238 |
| **Total Currents Assets** | **193 764** | **204 967** |
| | | |
| **Total Assets** | **235 265** | **227 182** |
| | | |
| **Equity and Liabilities** | | |
| **Equity** | | |
| Net profit | -17 468 | -39 857 |
| Other equity | 212 047 | 248 096 |
| **Equity** | **194 579** | **208 240** |
| | | |
| **Non-Current Liabilities** | | |
| Interest-bearing loans and dept | 1 303 | 1 093 |
| Lease liability | 20 972 | 3 202 |
| **Total Non-Current Liabilities** | **22 275** | **4 295** |
| | | |
| **Current liabilities** | | |
| Accounts payable | 5 808 | 4 606 |
| Public dept | 3 127 | 2 501 |
| Accrued expenses | 9 476 | 7 541 |
| **Total Current Liabilities** | **18 411** | **14 648** |
| | | |
| **Total Equity and Liabilities** | **235 265** | **227 182** |

*4th quarter Statement of Financial Position is not audited*

## Cash Flow Statement

| *(figures in NOK thousands)* | 2020 Q4 | 2020 01.01 - 31.12 | 2019 Q4 | 2019 01.01 - 31.12 |
|---|---|---|---|---|
| **Cash Flow from Operating Activities** | | | | |
| Net profit (loss) | -3 197 | -17 468 | -7 064 | -39 857 |
| | - | - | - | - |
| Depreciation | 1 958 | 6 630 | 1 412 | 6 132 |
| Impairment | - | - | - | 14 086 |
| Change Inventory | 59 | -2 652 | -1 444 | -5 126 |
| Change Accounts Receivables | 1 940 | 860 | 62 | 792 |
| Change Accounts Payables | 1 723 | 1 202 | 1 224 | 1 310 |
| Change in other short-term receivables/ liabilities | 4 973 | 1 740 | 8 359 | -431 |
| **Net Cash Flow from Operating Activities** | **7 456** | **-9 688** | **2 549** | **-23 093** |
| | | | | |
| **Cash Flows from Investment Activities** | | | | |
| Acquisition of Property, plant and equipment | -1 996 | -2 730 | -187 | -1 589 |
| Investment in intangible assets | -2 520 | -3 733 | -1 192 | -3 071 |
| Investment in other companies | 1 893 | 1 893 | - | - |
| **Net Cash Flow from Investment Activities** | **-2 623** | **-4 570** | **-1 379** | **-4 660** |
| | | | | |
| **Cash Flow from Financial Activities** | | | | |
| New debt | 497 | 497 | - | 621 |
| Downpayment of loans | -73 | -287 | -70 | -226 |
| Cash flows from share issues | 462 | 462 | 259 | 259 |
| Dividend payment | - | - | - | - |
| **Net Cash Flow from Financial Activities** | **887** | **672** | **189** | **654** |
| | | | | |
| **Net Change in Cash and Cash Equivalents** | 5 720 | -13 585 | 1 359 | -27 099 |
| Cash and cash equivalents at beginning of period | 152 265 | 171 567 | 170 206 | 198 634 |
| Currency adjustment | - | 3 | 1 | 2 |
| **Net Cash and Cash Equivalents** | **157 985** | **157 985** | **171 567** | **171 567** |

*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 01.01.2019** | **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** |

| | | | | | |
|---|---|---|---|---|---|
| **Equity at 01.01.2020** | **1 540** | **292 780** | **4 031** | **-90 112** | **208 240** |
| Net result for the year | | | | -17 468 | -17 468 |
| Other comprehensive income | | | | | |
| Proceeds from share issue | 1 | 461 | | | 462 |
| Cost of share issue | | | | | |
| Share based payments | | | 3 278 | | 3 278 |
| Other changes in equity | | | | 68 | 68 |
| **Equity at 31.12.2020** | **1 541** | **293 241** | **7 309** | **-107 512** | **194 579** |

*4th quarter Statement of Changes in Equity is not audited*

## NOTES

### Accounting Principles

The interim report for Q4 2020 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 2019.

### Currency

The company uses currency rates given by DNB ASA.

### Capitalized R&D

There is currently one project where the Gentian group is capitalizing R&D expenses.