Third quarter 2020 results

WE INNOVATE DIAGNOSTIC EFFICIENCY

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We innovate diagnostic efficiency

GENTIAN DIAGNOSTICS

Gentian Diagnostics AS is a medical diagnostics company listed on the Oslo Stock Exchange, Merkur Market. The company performs production, R&D, marketing and distribution of immunoassays at its headquarters in Norway. The company is supported globally by distribution subsidiaries in Sweden and the US and 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 health care suppliers by improving laboratory workflow and clinical outcome. The value propositions of new products will be scientifically proven and promoted by investments into clinical studies, state-of-the art marketing and selective commercial representation in focus countries.

In addition, 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 cancer.

Gentian Diagnostics' PETIA products and product pipeline

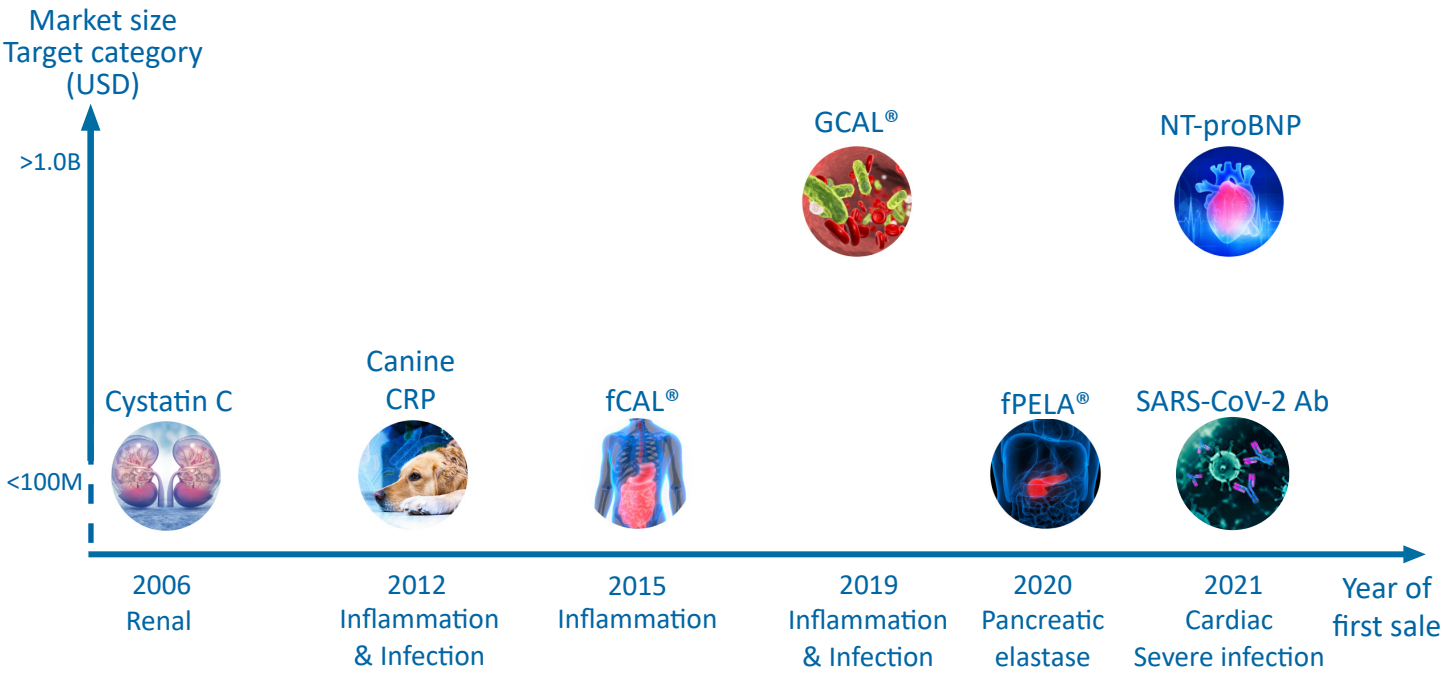
Gentian develops and manufactures high quality IVD reagents for a wide range of clinical chemistry analysers. Our product lines of laboratory tests, for diverse diagnostic targets, provide high accuracy and fast results for both human and veterinary healthcare. Current and pipeline products contribute to increased laboratory efficiency and improved outcome for patients with inflammatory/infectious, renal and cardiovascular diseases and cancer.

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

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

Gentian is pleased to announce that it is on track for launch of its NT-proBNP immunoassay, previously known as G-1001, by end of 2021. This assay will be the first cardiac marker designed specifically for high volume clinical chemistry platforms.

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



HIGHLIGHTS

- Sales revenue for the first nine months of MNOK 46.1 representing 36 % growth (24 % adjusted for currency effects) compared to the same period last year
- Gentian's Swedish distribution subsidiary, Gentian Diagnostics AB, has had a sales growth from third party products of 52 % YTD 2020 compared to the same period last year
- Scientific Advisory Board for NT-proBNP (formerly called G-1001) established
- Study confirms significantly elevated levels of calprotectin in patients with severe COVID-19, which is an opportunity for our GCAL® assay

OPERATIONAL SUMMARY

Sales

Sales revenue in 3Q20 showed an increase of 1 % compared to 3Q19, ending the quarter at MNOK 13.2. The reduced growth comes as a result of high Cystatin C warehouse levels in Asia. For YTD 2020 the sales revenue ended 36 % higher compared to YTD 2019, with a currency neutral growth of 24 %.

Sales of Cystatin C was MNOK 3.7 for the quarter, a decrease of 49 % compared to 3Q19, and MNOK 18.7 YTD. As described in the Q2 report, the high sales activity in 1H20 was partly due to stock building from some of our Asian customers, in relation to the COVID-19 situation. This explains the high quarterly variation in sales.

Sales of fCAL® turbo continues to recover from the low levels seen in 2Q20 due to the COVID-19 situation. Sales growth in 3Q20 was 56 % compared to 3Q19 and 41 % YTD. Although underlying growth prospects remain positive, we may see negative effects on sales if countries impose strict measures of movement due to COVID-19.

Our Swedish distribution subsidiary, Gentian Diagnostics AB, continues to have a positive sales development for third party sales totaling MNOK 4.6 YTD, a 52 % increase compared to the same period last year.

Sales of Canine CRP was MNOK 4.7, a 43 % increase compared to the same period last year.

The current outbreak of COVID-19 has had minor effect on Gentian so far. 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.

Market development

GCAL®

During the last few months, scientific publications have shown that calprotectin may be a promising biomarker for assessment of the disease severity and prediction of mortality in COVID-19 patients. Several of these studies have reported increased levels of calprotectin in patients with severe SARS-Cov-2 infections. Calprotectin may play a role as a diagnostic tool to differentiate between mild and severe forms of the disease, and assist physicians in determining which patients that need mechanical ventilation. Finally, studies have shown that plasma calprotectin may predict mortality in COVID-19 patients [1-3].

Gentian has, in collaboration with Santa Lucia University Hospital (Cartagena,Spain) and Akademiska University Hospital (Uppsala, Sweden) confirmed increased levels of calprotectin by using the GCAL® assay in patients with severe COVID-19. Circulating levels of calprotectin were significantly higher in COVID-19 patients who required mechanical ventilation and/or who died, indicating the role of the biomarker in the prognosis and assessment of the disease severity. Some of the study results are published in the scientific journal "Journal of Infection" in August 2020 [4], and some will be presented as posters at the AACC conference in December 2020. The knowledge and awareness about GCAL® and its clinical use in relation to COVID-19 are communicated to potential customers and partners.

As an answer to customer demand and clinical practice, Gentian has added a serum sample option to the GCAL® product range. This gives clinicians a greater choice of sample matrix for diagnosing severe infections in critically ill patients.

Product development

NT-proBNP (formerly referred to as G-1001)

The Gentian NT-proBNP assay is an in vitro diagnostic assay used for testing of individuals suspected of having congestive heart failure (CHF). Measurements of NT-proBNP are used as an aid in the diagnosis, monitoring and assessment of severity. Gentian estimates the IVD market value for NT-proBNP to be approximately BUSD 1.4 by 2023. Gentian will be the first supplier to offer the assay on high-throughput clinical chemistry analysers.

To strengthen the development of the Gentian NT-proBNP assay, Gentian has established a Scientific Advisory Board to provide the company with additional technology expertise, clinical knowhow and strategic input. The Scientific Advisory Board consist of key opinion leaders from industry and academia and it will be utilised by Gentian for the development and commercialisation of the NT-proBNP assay. The assay is planned for launch in late 2021.

References: 1. Shi H, et al. (2020) Neutrophil calprotectin identifies severe pulmonary disease in COVID-19 doi: doi.org/10.1101/2020.05.06.20093070. Preprint PMID: 32511540 **2.** Zuo Y, et al. (2020) Neutrophil extracellular traps and thrombosis in COVID-19. doi: doi.org/10.1101/2020.04.30.20086736. Preprint. PMID: 32511553 **3.** Silvin et al. (2020) Elevated calprotectin and abnormal myeloid cell subsets discriminate severe from mild COVID-19 Cell, doi: doi.org/10.1016/j.cell.2020.08.002 **4.** de Guadiana Romualdo L.G. et al. (2020) Circulating levels of GDF-15 and calprotectin for prediction of in-hospital mortality in COVID-19 patients: a case series. Journal of Infection, doi: doi.org/10.1016/j.jinf.2020.08.010

Gentian is following EU's implementation plan for the new In Vitro Diagnostics Regulation (IVDR) to ensure that we are ready towards the upcoming IVDR transition (Regulation (EU) 2017/746 on in vitro diagnostic medical devices). The whole organsiation, from R&D to production and marketing are involved in the transition work. We are therefore, well prepared to be certified and have approved products as of IVDR regulations before May 2022.

Anne-Mette Horsrud Akre,
VP Quality Assurance & Regulatory Affairs

It has become clear that calprotectin plays a key role in the hyperinflammatory response associated with severe form of SARS-CoV-2. We at Gentian are pleased to see that the biomarker is gaining attention and that several publications in well recognised scientific journals have confirmed the value of calprotectin in disease assessment and prognosis. We are communicating all new information and findings to potential customers and partners in order to confirm the use of the biomarker and GCAL® calprotectin assay in important clinical decisions.

Dr. Aleksandra Havelka,
Director Clinical Affairs

FINANCIAL PERFORMANCE

Comparative numbers for Gentian 2019 in ()

Sales, Geographic Split and Product Split

Total operating revenue ended at MNOK 16.1 (MNOK 14.7) for 3Q20, and MNOK 55,1 (MNOK 38.8) YTD 2020.

Sales revenue in 3Q20 ended at MNOK 13.2 (MNOK 13.1), a 1 % increase compared to 3Q19. Sales revenue YTD 2020 ended at MNOK 46.1 (MNOK 33.9), a 36 % increase compared to the same period last year. Adjusted for currency effects sales growth was 24 % YTD.

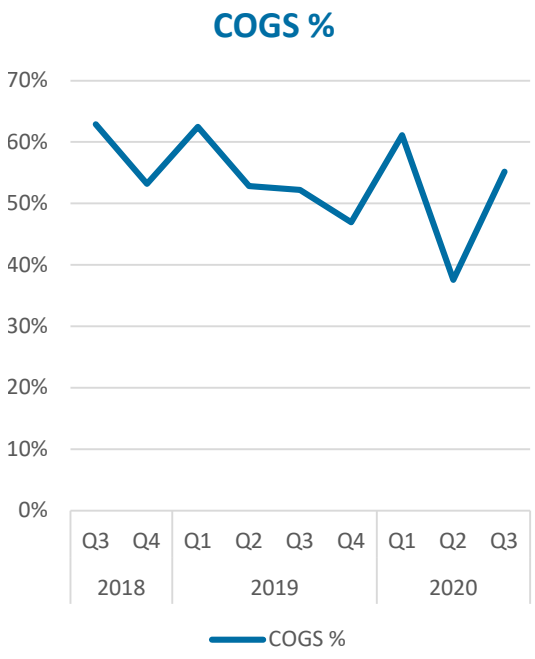
Geographic split:

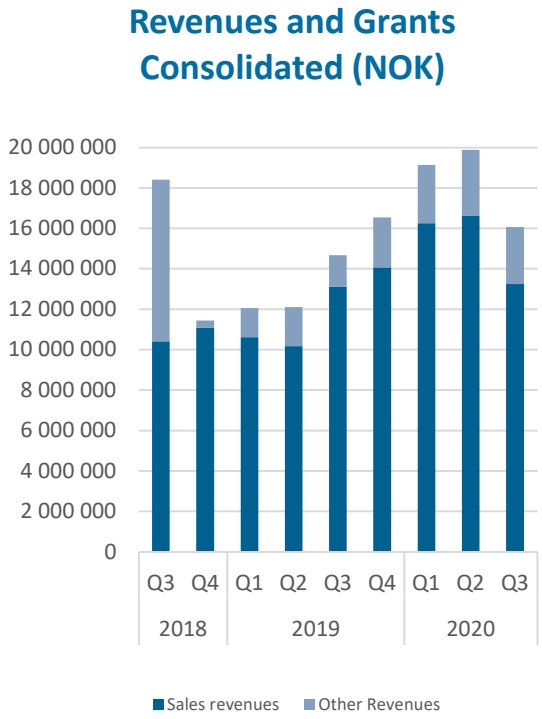
MNOK	3Q20	3Q19	YTD20	YTD19
US	0.6	0.3	2.3	1.4
Europe	11.4	7.7	32.5	22.8
Asia	1.3	5.0	11.4	9.6
Total	13.2	13.1	46.1	33.9

Product split:

MNOK	3Q20	3Q19	YTD20	YTD19
Cystatin C	3.7	7.2	18.7	15.8
fCAL®turbo	5.6	3.6	14.8	10.5
Other	4.0	2.4	12.8	7.6
Total	13.2	13.1	46.1	33.9

Other operating revenue ended at MNOK 2.8 (MNOK 1.6) for 3Q20, and MNOK 8.9 (MNOK 5.0) for YTD 2020.





Cost of Goods Sold

COGS ended at MNOK 7.3 (MNOK 6.8) in 3Q20, which represents 55 % (52 %) of sales revenue. Total COGS YTD 2020 ended at MNOK 23.5 (MNOK 18.8), which represents 51 % (56 %) 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 14.5 (MNOK 12.8) in 3Q20, and MNOK 42.6 (MNOK 36.8) YTD 2020.

Other operating expenses include salary and social expenses of MNOK 9.8 (MNOK 8.1) and other expenses of MNOK 4.7 (MNOK 4.7) for 3Q20. YTD total salary and social expenses ended at MNOK 28.4 (MNOK 21.6) and other expenses ended at MNOK 14.2 (MNOK 15.1). SG&A also include a share-based compensation of MNOK 2.5 year to date with no cash effect.

R&D expenses amounted to 46 % (42 %) of total other operating expenses before capitalization for 3Q20, and 41 % (40 %) YTD 2020. Capitalization of R&D expenses was MNOK 0.3 (MNOK 0.5) in 3Q20, and MNOK 0.9 (MNOK 1.9) YTD 2020.

Total other operating expenses after capitalization of R&D expenses ended at MNOK 14.2 (MNOK 12.3) in 3Q20 and MNOK 41.7 (MNOK 34.9) YTD 2020.

Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -5.5 (MNOK -4.5) for 3Q20, and MNOK -10.1 (MNOK -14.9) YTD 2020. Net profit ended at MNOK -7.0 (MNOK -5.2) for 3Q20, and MNOK -13.9 (MNOK -32.8) YTD 2020.

Balance Sheet

Cash and cash equivalents as of 30.09.2020 were MNOK 152.3 (MNOK 170.2). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 30.09.2020 were MNOK 9.6 (MNOK 8.6).

Inventory as of 30.09.2020 were MNOK 20.9 (MNOK 16.8).

OUTLOOK

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.

The company estimates continued sales growth in 2020 versus 2019, with expected quarterly variations and so far, unpredictable effects of the COVID-19 outbreak.

For Cystatin C, the company expects reduced orders from Asia for the remaining months of 2020 due to high warehouse levels. For the US and Europe sales growth are expected to be stable. Sales in 2H20 is expected to be lower than in 1H20.

For fCAL® turbo, we see an increase in demand in 2H 2020 compared to 1H 2020. The growth momentum will depend on the capacity of health systems to process outpatient services under COVID-19 conditions and the severity of measures taken by countries to contain the spread of COVID-19.

For GCAL®, we have focused on studies and collaborations related to COVID-19 and the role of calprotectin in prognosis and differentiation between mild and severe form of the disease. Results from one study have already been published in a scientific journal and more results will be presented at the world leading diagnostic congress AACC in December 2020.

In addition to the already established study program for GCAL® in context of Sepsis and severe infections, several collaborations are discussed with clinicians and researchers in Germany, UK, Sweden and Spain with aim to further investigate the role of calprotectin in COVID-19 and confirm benefits of GCAL® turbidimetric assay. Results from these studies will be communicated via scientific publications and conferences.

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 30.09.2020 according to VPS and disclosures from investors:

Shareholder	No of Shares	%
Vatne Equity AS	2 010 224	13,05 %
Holta Life Sciences AS	1 214 702	7,89 %
Norda ASA	1 190 068	7,73 %
Safrino AS	1 050 000	6,82 %
Salix AS	1 001 293	6,50 %
Verdipapirfondet Delphi Nordic	723 812	4,70 %
Norron Sicav - Target	699 609	4,54 %
Storebrand Vekst	467 343	3,03 %
Verdipapirfondet DNB SMB	445 382	2,89 %
Equinor Pensjon	381 320	2,48 %
Portia AS	300 000	1,95 %
Cressida AS	235 000	1,53 %
Lioness AS	220 000	1,43 %
Silvercoin Industries AS	211 712	1,37 %
Marstal AS	210 542	1,37 %
Mutus AS	210 465	1,37 %
Bård Sundrehagen	191 018	1,24 %
Borgano AS	186 499	1,21 %
Vingulmork Predictor AS	184 083	1,20 %
OM Holding AS	179 000	1,16 %
Other Shareholders	4 090 646	26,56 %
Total Shares	**15 402 718**	100,00 %

Statement of Comprehensive Income Gentian Group

	2020	2020	2019	2019
(figures in NOK thousands)	**Q3**	**01.01-30.09**	**Q3**	**01.01-30.09**
Operating Revenue				
Sales revenue	13 249	46 131	13 102	33 885
Other operating revenue	2 812	8 940	1 567	4 959
Total Operating Revenue	**16 061**	**55 071**	**14 668**	**38 844**
Operating Expenses/Costs				
Cost of goods sold	-7 313	-23 489	-6 837	-18 839
R&D costs	-6 671	-17 335	-5 373	-14 705
Selling, general & administrative costs	-7 783	-25 248	-7 437	-22 059
Capitalization	254	900	515	1 879
Total Operating Expenses/Costs	**-21 512**	**-65 172**	**-19 132**	**-53 723**
EBITDA	**-5 452**	**-10 102**	**-4 464**	**-14 880**
Depreciation	-1 539	-4 672	-1 342	-4 720
Impairment	-	-	-	-14 086
EBIT	**-6 990**	**-14 773**	**-5 806**	**-33 686**
Financial income/expense	9	841	625	948
Tax	-	-	-	-62
Net Profit	**-6 981**	**-13 932**	**-5 181**	**-32 800**

3nd quarter Statement of Comprehensive Income is not audited

Statement of Financial Position Gentian Group

	2020	2019	2019
(figures in NOK thousands)	30.09	31.12	30.09
Assets			
Non-Current Assets			
Property, plants and equipment	3 961	4 714	4 977
Right-of-use asset	1 497	3 062	3 585
Capitalized development costs	13 690	14 076	13 321
Other intangible assets	32	36	37
Financial assets	336	329	326
Total Non-Current Assets	**19 515**	**22 216**	**22 246**
Current Assets			
Inventory	20 935	18 224	16 780
Accounts receivables	9 573	8 493	8 556
Other receivables	12 181	7 012	10 991
Cash and cash equivalents	151 928	171 238	169 880
Total Currents Assets	**194 617**	**204 967**	**206 206**
Total Assets	**214 132**	**227 182**	**228 453**
Equity and Liabilities			
Equity			
Net profit	-13 932	-39 857	-32 800
Other equity	210 913	248 096	247 210
Equity	**196 981**	**208 240**	**214 409**
Non-Current Liabilities			
Financial lease	879	1 093	1 163
Operational lease	1 663	3 202	3 711
Total Non-Current Liabilities	**2 542**	**4 295**	**4 873**
Current liabilities			
Accounts payable	4 085	4 606	3 382
Public dept	2 851	2 501	1 569
Accrued expenses	7 673	7 541	4 219
Total Current Liabilities	**14 609**	**14 648**	**9 170**
Total Equity and Liabilities	**214 132**	**227 182**	**228 453**

3nd quarter Statement of Financial Position is not audited

Cash Flow Statement

	2020	2020	2019	2019
(figures in NOK thousands)	Q3	01.01 - 30.09	Q3	01.01 - 30.09
Cash Flow from Operating Activities				
Net profit (loss)	-6 981	-13 932	-5 181	-32 800
Depreciation	1 539	4 672	1 342	4 720
Impairment	-	-	-	14 086
Change Inventory	-1 163	-2 711	-1 387	-3 682
Change Accounts Receivables	-2 257	-1 080	147	729
Change Accounts Payables	435	-521	-885	87
Change in other short-term receivables/ liabilities	- -155	- 3 605	- 2 179	- 8 790
Net Cash Flow from Operating Activities	**-8 581**	**-17 176**	**-8 142**	**-25 650**
Cash Flows from Investment Activities				
Acquisition of Property, plant and equipment	-37	-734	-965	-1 401
Investment in intangible assets	-254	-1 213	-515	-1 879
Other changes in financial items	-	-	-	-
Net Cash Flow from Investment Activities	**-291**	**-1 947**	**-1 479**	**-3 281**
Cash Flow from Financial Activities				
New debt	-	-	621	621
Downpayment of loans	-72	-214	-78	-157
Cash flows from share issues	-	-	-	-
Dividend payment	-	-	-	-
Net Cash Flow from Financial Activities	**-72**	**-214**	**543**	**465**
Net Change in Cash and Cash Equivalents	-8 945	-19 337	-9 079	-28 467
Cash and cash equivalents at beginning of period	161 221	171 567	179 275	198 634
Currency adjustment	-11	35	9	38
Net Cash and Cash Equivalents	**152 265**	**152 265**	**170 206**	**170 206**

3rd 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				-13 932	-13 932
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			2 456		2 456
Other changes in equity				217	217
Equity at 30.09.2020	**1 540**	**292 780**	**6 487**	**-103 827**	**196 981**

3nd quarter Statement of Changes in Equity is not audited

NOTES

Accounting Principles

The interim report for Q3 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 are currently two projects where the Gentian group is capitalizing R&D expenses.