



First quarter 2021 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, Euronext Growth. The company is involved in the production, R&D, marketing and distribution of immunoassays. Its headquarters and production facilities are located in Moss, Norway, with distribution subsidiaries in Sweden and the USA, a representative office in China as well as globally by a strong commercial partner and distributor network.

Gentian serves the immunochemistry segment of the in vitro diagnostics (IVD) market by making assays available on fully automated, high-throughput platforms, utilising the Particle-Enhanced-Turbidimetric Immunoassay (PETIA) technology. Through in-depth research into PETIA, and its development of proprietary antibody and nano-particle technology, Gentian can offer immunoassays that enable clinical laboratories to move from low volume immunology platforms to fully automated, high throughput instruments with shorter turnaround times, better workflow and improved cost efficiency.

The current portfolio and pipeline of efficient and accurate reagents span areas of inflammations, severe infections, kidney failures and congestive heart failures and veterinary healthcare. The value propositions of the new products are 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 inflammations, severe infections, kidney failures and congestive heart failures and veterinary healthcare. The product lines of laboratory tests provide high accuracy and fast results and contribute to increased laboratory efficiency and improved outcomes for patients.

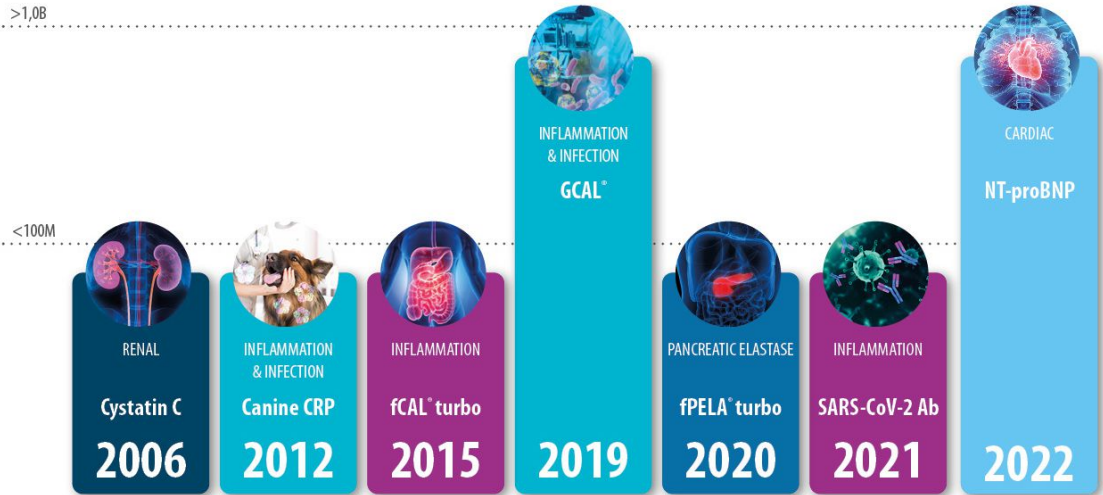
Gentian's current portfolio includes Cystatin C (CE marked, FDA-510(k) cleared), the calprotectin immunoassay GCAL® (CE marked) and Canine CRP.

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

Gentian is developing an innovative NT-proBNP immunoassay, which will be the first cardiac marker designed specifically for high volume clinical chemistry platforms. Due to an expanded development scope in order to enable industry standardization, expected to positively impact adoption rates, the launch date has been pushed to 1Q22 from 4Q21.

Gentian's high throughput turbidimetric SARS-CoV-2 Total Antibody assay is on a fast track development plan and is expected to be launched in 2H21.

Illustration of product categories and indicative market potential (USD)



HIGHLIGHTS

- ➔ Record sales revenue of MNOK 19.6 in 1Q21, a 33 % organic growth. Reported growth of 24 % on a currency neutral basis as 1Q20 includes revenues from the subsidiary Pretect AS, which was divested in 2H20.
- ➔ Growth of 60 % versus Q1 last year in fCAL® turbo sales.
- ➔ Increased commercial momentum for GCAL®, displaying early signs of the next revenue level, with new routine users in several European countries and new distribution contracts.
- ➔ Expanded NT-proBNP development scope in order to enable industry standardisation, expected to positively impact adoption rates. New launch date set to 1Q22.
- ➔ Decision to apply for a listing of the shares at Oslo Børs Main market. It is envisaged that a transfer of the listing from Euronext Growth to the main market will take place towards the latter part of 1H21.

OPERATIONAL SUMMARY

Sales

Sales revenue grew 33 % organically in 1Q21 ending the quarter at MNOK 19.6, a new record level. Reported growth was 21 % measured in NOK and 24 % on a constant currency basis as 1Q20 numbers included revenues from Pretect AS which as divested in 2H20.

Sales of Cystatin C was MNOK 7.4 for the quarter, an increase of 12 % compared to 1Q20. Sales in Asia continue to grow and was up by 23 % compared to 1Q20. Sales of Cystatin C in Europe and the US was somewhat lower than anticipated. Our Swedish subsidiary, Gentian Diagnostics AB, has established a successful cooperation with one of the major platform providers for a regional supply agreement for Cystatin C in the South-West region of Sweden. This collaboration shows the Gentian advantage of offering platform independent assays.

Sales of fCAL[®] turbo has gradually recovered after being negatively impacted by COVID-19 priorities. For 1Q21 sales reached a record high of MNOK 8.5 corresponding to an encouraging growth of 60 % versus 1Q20. The sales growth in 1Q21 was driven by increased demand for both kit and bulk segments. Although underlying growth prospects remain positive, we may experience negative effects on sales if countries continue to impose strict measures due to COVID-19.

Our Swedish distribution subsidiary, Gentian Diagnostics AB (GAB), continues to show a positive sales development for third party products totalling MNOK 1.6 in 1Q21, a 36 % increase compared to 1Q20. Further profitable growth is expected going forward.

The current outbreak of COVID-19 has had relatively limited 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 deliver to its customers on time and anticipates for this to continue.

Market development

GCAL[®]

The GCAL[®] Immunoassay is a novel biomarker for the early detection and risk stratification of inflammation and severe infections. Recent studies publications confirm promising results in the field of sepsis, COVID-19 and rheumatoid arthritis.

The interest in serum and plasma calprotectin has increased in 1Q21 with new customers implementing GCAL[®] in routine testing in Sweden, France and in the Czech Republic. Although still at low levels, the consistent and growing monthly sales for GCAL[®] demonstrate significant commercial progress and a positive market acceptance.

So far, Gentian has entered into distribution agreements with six partners in Europe and Asia to accelerate market penetration and awareness of the product. Additional distribution agreements are being finalised. Gentian also maintains dialogue with several potential OEM partners with an aim to secure high volume agreements. Due to the complex nature of such OEM agreements the exact timing will be difficult to predict.

A new review article by Udeh et al.¹ confirmed plasma and serum calprotectin as an emerging biomarker of interest in COVID-19 patient management. In addition, new studies were initiated with university hospitals in UK, France and Canada.

A webinar with Gentian's VP Clinical Affairs, Dr Aleksandra Havelka, on the role of calprotectin in COVID-19, is available at: www.gentian.com.

Product development

NT-proBNP

The Gentian NT-proBNP Immunoassay is positioned as an aid in the diagnosis, monitoring and assessment of severity in individuals suspected of having congestive heart failure (CHF). Gentian's proprietary technology will allow for comparable, consistent, biotin interference-free measurement of clinically relevant concentrations of NT-proBNP on high volume and easily accessible clinical chemistry analysers. The assay seeks to enable improvement of laboratory productivity based on higher throughput in comparison to currently used assays. It may also have the potential to contribute to the harmonisation and standardisation of the NT-proBNP assays, which is one of the major concerns stated by clinicians and laboratory managers in a company funded market sensing project. Based on this, the company has decided to expand the NT-proBNP development scope to enable industry standardisation, which is expected to positively impact the adoption rates. Therefore, a new launch date is moved to 1Q22 from 4Q21.

The first patent application was published in February 2021 by the World Intellectual Property Organization (PCT Application No. PCT/EP2020/072720) with WIPO number WO2021/028520. The technology described in the patent application enables Gentian to develop and commercialise an automated and fast NT-proBNP assay for open turbidimetric clinical chemistry platforms. Additional freedom-to-operate investigations were carried out to monitor existing 3rd party rights using NT-proBNP in the cardiac field. To date there are no negative findings.

SARS-CoV-2 Total Antibody Immunoassay

With the SARS-CoV-2 Total Antibody Immunoassay, Gentian will transfer SARS-CoV-2 serology testing to clinical chemistry platforms, increasing the testing capacity and improving laboratory efficiency. The assay detects total antibodies ensuring high sensitivity and target the spike protein of the virus providing high specificity and correlation to neutralising antibodies, as well as antibodies to targets of vaccine programs. The test will be a powerful high-throughput tool for the long-term monitoring and community management of COVID-19.

The assay is currently transferred into the verification phase and the launch is planned for 4Q21.

¹ Udeh, R.; Advani, S.; de Guadiana Romualdo, L.G.; Dolja-Gore, X. Calprotectin, an Emerging Biomarker of Interest in COVID-19: A Systematic Review and Meta-Analysis. *J. Clin. Med.* 2021, 10, 775. <https://doi.org/10.3390/jcm10040775>

FINANCIAL PERFORMANCE

Comparative numbers for Gentian 2020 in ()

Sales, Geographic Split and Product Split

Total operating revenue ended at MNOK 24.2 (MNOK 12.1) for 1Q21.

Sales revenue in 1Q21 ended at a record high of MNOK 19.6 (MNOK 16.2), a 21 % increase compared to 1Q20. Adjusted for currency effects sales growth was 24 % for the full year. Currency neutral growth, excluding sales from the divested subsidiary Pretect in 1Q20, ended at 33 %.

Geographic split:

MNOK	1Q21	1Q20
US	0.4	0.7
Europe	14.0	11.2
Asia	5.2	4.3
Total	19.6	16.2

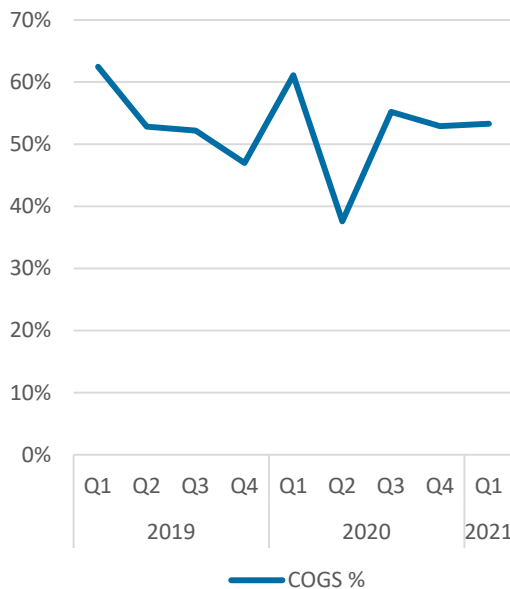
Product Split

MNOK	1Q21	1Q20
Cystatin C	7.4	6.6
fCAL®turbo	8.5	5.3
Other*	3.7	4.4
Total	19.6	16.2

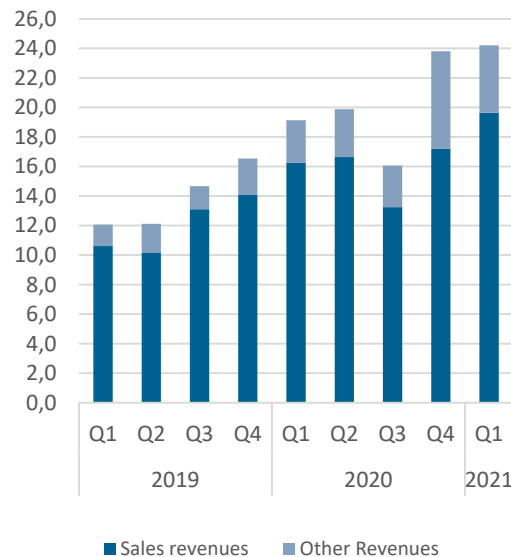
*Other revenues include sales from the subsidiary Prepect that was successfully divested in end of 3Q20.

Other operating revenue ended at MNOK 2.6 (MNOK 2.9) for 1Q21.

COGS %



Consolidated Revenues (MNOK)



Cost of Goods Sold

COGS ended at MNOK 10.5 (MNOK 9.9) in 1Q21, which represents 53 % (61 %) 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 17.2 (MNOK 14.2) in 1Q21.

Other operating expenses include salary and social expenses of MNOK 10.3 (MNOK 9.1) and other expenses of MNOK 6.8 (MNOK 5.1) for 1Q21. SG&A also include a share-based compensation of MNOK 1.0 (MNOK 0.9) for 1Q21 with no cash effect.

R&D expenses amounted to 45 % (39 %) of total other operating expenses before capitalization for 1Q21 and increase of 36 % compared to 1Q20. Capitalization of R&D expenses was MNOK 1.5 (MNOK 0.1) in 1Q21.

Total other operating expenses after capitalization of R&D expenses ended at MNOK 15.7 (MNOK 14.1) in 1Q21.

Earnings

Operating profit before depreciation and amortization (EBITDA) ended at MNOK -1.9 (MNOK -4.9) for 1Q21. Net profit ended at MNOK -4.9 (MNOK -5.5) for 1Q21.

Balance Sheet

Cash and cash equivalents as of 31.03.2021 were MNOK 146.1 (MNOK 161.4). The cash is placed in both savings accounts and current accounts.

Accounts receivables as of 31.03.2021 were MNOK 7.9 (MNOK 9.9). Inventory as of 31.03.2021 were MNOK 21.5 (MNOK 18.5).

OUTLOOK

With Gentian's customers having adapted to the COVID-19 outbreak measures and experiencing a positive business sentiment towards 2021, Gentian targets double digit sales growth on its established product line in 2021 versus 2020. Much focus will be on intensifying commercial efforts and distribution channels for GCAL[®] in Europe, but also taking advantage of the positive momentum for Gentian's Cystatin C product, especially in Asia and the US and for fCAL[®] turbo in Europe.

For cystatin C, increasing demand is foreseen in Asia as well as in the US as a result of targeted commercial and marketing initiatives from both Gentian and (its) partners. Double digit growth is anticipated for the remainder of 2021.

Continued customer and regional expansion of fCAL[®] turbo is expected in 2021, fuelling growth. In addition to continued competitive conversions the co-positioning with fPELA[®] turbo, which was introduced in 2020, will strengthen the market position for the product combination versus other suppliers.

For GCAL[®], the company expects further product acceptance and new customer implementations across Europe, both in hospital as well as in private laboratories. Additional distribution channels will also be implemented in selected countries in Europe. While the already initiated collaborations with both clinicians and researchers in France, Germany, UK, Sweden, Spain are expected to demonstrate the important role of calprotectin in COVID-19, sepsis and severe infections with associated positive patient outcomes, additional co-operations are planned to start, including in the US.

COVID-19

At Gentian, the health and safety of our employees, as well as our customers and partners, is our primary concern. Gentian has robust business-continuity plans in place and will be able to maintain production even if the situation would deteriorate. Gentian abides by policies of the health authorities in all countries in which it operates whilst it seeks to continue 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 potential delays will depend on the duration of the outbreak.

CORPORATE

The board of directors intend to apply for a listing of the Company's shares at the Oslo Stock Exchange main market, provided that a positive decision to transform the Company into an "ASA" (Public limited liability company) at the upcoming Annual General Meeting on May 4th 2021. It is envisaged that a transfer of the listing from Euronext Growth to the main market will take place towards the end of 1H21.

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 31.03.2021 according to VPS and disclosures from investors:

Shareholder	No of Shares	%
Vatne Equity AS	2 010 224	13.04%
Norda ASA	1 250 068	8.11%
Holta Life Sciences AS	1 214 702	7.88%
Safrino AS	1 050 000	6.81%
Salix AS	834 136	5.41%
Skandinaviska Enskilda Banken AB	762 510	4.95%
Verdipapirfondet Delphi Nordic	743 420	4.82%
Verdipapirfondet Storebrand Vekst	430 148	2.79%
Verdipapirfondet DNB SMB	408 632	2.65%
Equinor Pensjon	337 320	2.19%
Portia AS	300 000	1.95%
Cressida AS	235 000	1.52%
Lioness AS	220 000	1.43%
Silvercoin Industries AS	214 257	1.39%
Marstal AS	212 407	1.38%
Mutus AS	210 465	1.37%
Vingulmork Predictor AS	184 083	1.19%
Bård Sundrehagen	181 645	1.18%
OM Holding AS	179 000	1.16%
Viola AS	170 916	1.11%
Other Shareholders	4 262 956	27.66%
Total Shares	15 411 889	100.00%

Statement of Comprehensive Income Gentian Group

	2021	2020	2020
<i>(figures in NOK thousands)</i>	Q1	Q1	01.01-31.12
Operating Revenue			
Sales revenue	19 642	16 247	63 327
Other operating revenue	4 560	2 884	15 554
Total Operating Revenue	24 202	19 131	78 881
Operating Expenses/Costs			
Cost of goods sold	-10 464	-9 926	-32 586
R&D costs	-7 657	-5 638	-27 308
Selling, general & administrative costs	-9 514	-8 521	-33 606
Capitalization	1 489	65	3 421
Total Operating Expenses/Costs	-26 146	-24 021	-90 080
EBITDA	-1 945	-4 889	-11 199
Depreciation	-1 971	-1 567	-6 630
Impairment	-	-	-
EBIT	-3 916	-6 456	-17 829
Financial income/expense	-1 006	921	361
Tax	-	-	-
Net Profit	-4 922	-5 535	-17 468

1st quarter Statement of Comprehensive Income is not audited

Statement of Financial Position Gentian Group

	2021	2020	2020
<i>(figures in NOK thousands)</i>	31.03	31.12	31.03
Assets			
Non-Current Assets			
Property, plants and equipment	5 421	5 136	4 283
Right-of-use asset	19 467	20 417	2 528
Capitalized development costs	16 514	15 610	13 919
Other intangible assets	-	-	34
Financial assets	333	337	335
Total Non-Current Assets	41 735	41 500	21 099
Current Assets			
Inventory	21 541	20 876	18 453
Accounts receivables	7 883	7 633	9 926
Other receivables	9 959	7 608	9 161
Cash and cash equivalents	145 722	157 648	161 072
Total Currents Assets	185 105	193 764	198 611
Total Assets	226 841	235 265	219 711
Equity and Liabilities			
Equity			
Net profit	4 922	17 468	5 535
Other equity	-195 418	-212 047	-209 186
Equity	-190 496	-194 579	-203 651
Non-Current Liabilities			
Interest-bearing loans and debt	-1 206	-1 303	-1 022
Lease liability	-20 821	-20 972	-2 686
Total Non-Current Liabilities	-22 027	-22 275	-3 709
Current liabilities			
Accounts payable	-4 038	-5 808	-3 964
Public debt	-2 537	-3 127	-2 342
Accrued expenses	-7 742	-9 476	-6 045
Total Current Liabilities	-14 318	-18 411	-12 351
Total Equity and Liabilities	-226 841	-235 265	-219 711

1st quarter Statement of Financial Position is not audited

Cash Flow Statement

	2021	2020	2020
	Q1	01.01 - 31.12	Q1
<i>(figures in NOK thousands)</i>			
Cash Flow from Operating Activities			
Net profit (loss)	-4 922	-17 468	-5 535
Depreciation	1 971	6 630	1 567
Impairment	-	-	-
Change Inventory	-665	-2 652	-229
Change Accounts Receivables	-250	860	-1 433
Change Accounts Payables	-1 770	1 202	-642
Change in other short-term receivables/ liabilities	-3 804	1 740	-3 438
Net Cash Flow from Operating Activities	-9 439	-9 688	-9 710
Cash Flows from Investment Activities			
Acquisition of Property, plant and equipment	-738	-2 730	-63
Investment in intangible assets	-1 489	-3 733	-377
Investment in other companies	-	1 893	-
Net Cash Flow from Investment Activities	-2 227	-4 570	-440
Cash Flow from Financial Activities			
New debt	-	497	-
Downpayment of loans	-98	-287	-70
Cash flows from share issues	-	462	-
Dividend payment	-	-	-
Net Cash Flow from Financial Activities	-98	672	-70
Net Change in Cash and Cash Equivalents	-11 763	-13 585	-10 221
Cash and cash equivalents at beginning of period	157 985	171 567	171 567
Currency adjustment	-167	3	62
Net Cash and Cash Equivalents	146 055	157 985	161 407

1st 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 01.01.2020	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

Equity at 01.01.2021	1 541	293 241	7 309	-107 512	194 579
Net result for the year				-4 922	-4 922
Other comprehensive income					
Proceeds from share issue					
Cost of share issue					
Share based payments			971		971
Other changes in equity				-133	-133
Equity at 31.03.2021	1 541	293 241	8 280	-112 566	190 496

1st quarter Statement of Changes in Equity is not audited

NOTES

Accounting Principles

The interim report for 1Q21 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 2020.

Currency

The company uses currency rates given by DNB ASA.

Capitalized R&D

The Gentian group is currently capitalising R&D expenses for three projects.