

Interim Report

First Quarter of 2021, BioPorto Group

May 12, 2021

Announcement no. 11

Highlights

Revenue growth of 33% in Q1 2021

In the first quarter of 2021, BioPorto grew revenue by 33% driven by strong sales of antibodies. Revenue from product sales of The NGAL Test™ was maintained at last year's high level with solid performance in both the US and Rest of the World (ROW).

Enrollment of patients in The NGAL Test US pivotal trial continues, summer completion anticipated

All internal studies to support BioPorto's US application for The NGAL Test for pediatric acute kidney injury (AKI) are being finalized according to schedule, and enrollment continues in the pivotal study of critically ill pediatric patients. Based on the current status of the COVID-19 pandemic, the company continues to expect to complete its pivotal study this summer, after which it will submit a De Novo 510(k) application to the US Food and Drug Administration (FDA).

Results from testing of the gRAD-based COVID-19 test expected in Q2 2021

BioPorto and University of California, Davis (US) are working diligently to obtain test results on the company's gRAD-based point-of-care test for SARS-CoV-2. Having experienced initial challenges early in 2021, the testing is progressing and will be finalized in the second quarter of 2021. If the results support BioPorto's initial laboratory findings, the company intends to submit an Emergency Use Authorization (EUA) request to the FDA and a CE mark filing in Europe.

Guidance for 2021 maintained

Based on the progress and results obtained in first quarter of 2021, BioPorto maintains its financial guidance for 2021, as most recently described in its Annual Report for 2020. Revenue of approximately DKK 30 million is expected in 2021. An operating loss (EBIT) of approximately DKK 73 million is forecast for the year.

Peter M. Eriksen, CEO, commented:

"Viewed in the light of a quarter still heavily influenced by the severity of the global third wave of COVID-19, I am satisfied with BioPorto's performance. We drove revenue up by more than 30% by utilizing all of our assets, despite limited access to key markets for key products. In this context, I believe maintaining revenue from product sales of The NGAL Test at last year's high level is a solid achievement and I am glad to see our own library of antibodies performing very well.

Our clinical efforts and regulatory processes have been difficult to advance in the current COVID-19 climate. In the first quarter of 2021, we have pushed hard on both clinical programs for The NGAL Test and the COVID-19 gRAD-based test to ensure we meet our timelines for the coming quarters. We have to accept the situation and join the rest of the world in hoping that strong public vaccination programs and increased reopening of societies will gradually normalize the health care and business environments to a point at which planning and execution can be more predictable than what we've experienced over the last year."

Investor Meeting

In connection with the release of the Interim Report for first quarter of 2021, BioPorto will host an online investor presentation on May 12, 2021 at 12:00 CET in Danish and at 16:00 CET in English. For further information regarding the online investor meeting, please visit www.bioporto.com/investor-relations.

Financial Highlights

	2021	2020	2020
	3 months DKK million	3 months DKK million	12 months DKK million
Revenue	5.6	4.2	23.2
Production costs	2.4	1.8	9.9
Sales and marketing costs	5.4	6.4	20.8
Research and development costs	8.2	5.0	28.1
Administrative costs	7.7	7.3	28.0
Operating profit/loss (EBIT)	(18.2)	(16.4)	(63.6)
Financial items, net	1.1	0.1	(3.2)
Operating profit/loss before tax	(17.1)	(16.4)	(66.8)
Profit/loss for the period	(15.4)	(15.4)	(61.6)
Total comprehensive income	(15.6)	(15.6)	(59.8)
Non-current assets	15.2	7.8	15.5
Current assets	106.2	19.8	124.8
Total assets	121.4	27.5	140.3
Equity	86.7	10.8	100.9
Non-current liabilities	8.3	2.0	8.4
Current liabilities	26.3	14.8	30.9
Total equity and liabilities	121.4	27.5	140.3
Cash flows from operating activities	(21.1)	(13.8)	(35.6)
Cash flows from investing activities, net	(0.2)	(0.4)	(1.5)
Of which investment in property, plant and equipment	(0.1)	(0.4)	(1.3)
Cash flows from financing activities	(1.0)	(0.6)	127.0
Total cash flows	(22.3)	(14.8)	89.9
Revenue growth	33%	(24%)	(13%)
Gross margin	57%	56%	57%
Equity ratio (solvency)	71%	39%	72%
Average number of employees	29	26	28
Number of shares by the end of the period (1,000)	266,582	174,944	266,582
Earnings per share (EPS), DKK	(0.06)	(0.09)	(0.30)
Net asset value per share, period-end, DKK	0.33	0.06	0.38
Share price, period-end, DKK	5.52	1.97	4.04

Management Review

Revenue growth of 33% in the first quarter of 2021

In the first quarter of 2021, BioPorto grew revenue to DKK 5.6 million from DKK 4.2 million in the same quarter last year – a growth of 33% year-on-year.

Revenue from product sales of The NGAL Test was maintained at last year's high level. Research Use Only sales in the US were impacted by reduced access to research facilities, while ROW sales increased moderately. Given the challenging global environment resulting from COVID-19, these results were in line with the company's expectations.

Growth in the first quarter 2021 was driven by strong sales of antibodies, which increased by 69% year-over-year, and regained some momentum after declines in this category in 2020. In total, revenue from antibodies in the first three months of 2021 was DKK 2.9 million compared to 1.7 million in the same period in 2020, as result of bulk sales increasing.

Sales of ELISA kits were DKK 0.4 million in the first quarter of 2021, compared to DKK 0.3 million last year, and reflect the continued phasing out of MBL ELISA kits from the company's portfolio.

US enrollment in the clinical trial of The NGAL Test in continues

In addition to finalizing all internal studies required for the submission of the De Novo 510(k) for use of The NGAL Test in pediatrics, during the quarter enrollment in the US pivotal trial continued. With eight leading children's hospitals participating, the company is in discussions with additional institutions to potentially join the study in the coming months. BioPorto maintains its expectation of completing the trial this summer, after which it will submit a De Novo 510(k) application to the FDA.

Results from BioPorto's point-of-care test for COVID-19 pending, expected in Q2 2021

Since December 2020, BioPorto and University of California, Davis (US) have been collaborating on testing a gRAD-based point-of-care test for SARS-CoV-2. The test is designed to quickly and easy identify infected patients using a non-invasive sample.

The testing, done using samples from COVID-19 patients, initially encountered technical challenges that were resolved in the first quarter of 2021. BioPorto is now awaiting the outcome of new testing – expected to be concluded in the second quarter of 2021. As previously communicated, if data supports BioPorto's initial laboratory findings, the company intends to submit an EUA request to the FDA and a undertake CE mark filing in Europe.

Related party transactions

On January 18, 2021, the Chairman of the Board of Directors, Thomas Magnussen, sold 40,000 shares in BioPorto at a price of DKK 6.14 as specified in Company announcement no. 1/2021 dated January 21, 2021.

Events after the reporting period

On April 8, 2021, BioPorto increased the company's share capital with nominally DKK 1.172,000, corresponding to 1,172,000 shares, as a result of the exercise of warrants issued under the Company's incentive warrant program. Total proceeds from the capital increase amount to approximately DKK 4.4 million.

The new shares have rights to dividends and other rights in the company as of April 8, 2021. The new shares were listed on Nasdaq Copenhagen, with the first day of trading being April 12, 2021.

After the share capital increase, BioPorto's share capital amounts to nominally DKK 267,754,404 divided into 267,754,404 shares each carrying 1 voting right, corresponding to a total of 267,754,404 voting rights, cf. section 32 of the Danish Capital Markets Act.

BioPorto has initiated search for a new CFO, as Ole Larsen has decided to pursue opportunities outside of the company. He has been with BioPorto since 2018 and will depart at the end of May 2021 but remain available for the company until October. As soon as the search process has been concluded, Ole Larsen's successor will be announced.

During the company's Annual General Meeting on April 29, 2021, Don Hardison, John McDonough and Jan Leth Christensen were elected as new members of the Board of Directors. They succeed Torben Arnth Nielsen and Kirsten Aarup Drejer, who did not seek re-election.

On May 5, 2021 it was announced that Peter Morch Eriksen will resign from BioPorto, having served since July 2013. Peter will continue to support the Company until end of January 2022, and will retain his position as CEO until his successor has been found.

Financial Review

Income Statement

The financial review is based on the Group's consolidated financial information for the period ended March 31, 2021, with comparative results for March 31, 2020 in brackets.

In the first quarter of 2021 revenues totaled DKK 5.6 million (DKK 4.2 million). Earnings before interest and taxes (EBIT) showed a loss of DKK 18.2 million (DKK 16.4 million). The cash position as of March 31, 2021 was DKK 86.7 million (DKK 3.3 million).

Revenue

Revenue in the first quarter of 2021 was DKK 5.6 million (DKK 4.2 million).

In the first quarter of 2021 NGAL revenue totaled DKK 2.1 million (DKK 2.1 million). Revenue consisted of DKK 1.2 million (DKK 1.6 million) from RUO sales in the US and DKK 0.9 million (DKK 0.5 million) from sales in the EU and rest of the world.

Revenue from the sale of antibodies amounted to DKK 2.9 million (DKK 1.7 million) in the first quarter of 2021.

Revenues from the sale of ELISA kits totaled DKK 0.4 million (DKK 0.3 million) during the first quarter of 2021.

Figure 1. Revenue by quarter (DKK million)

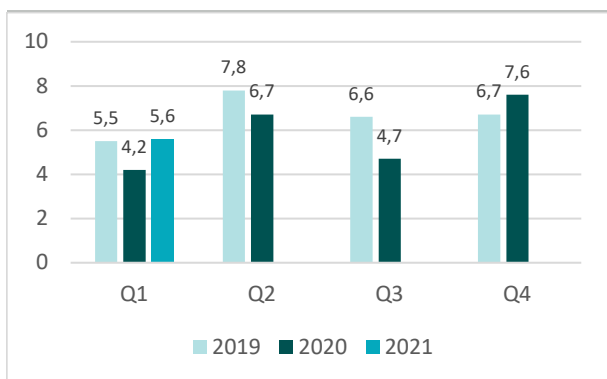


Figure 2. NGAL product revenue by quarter (DKK million)

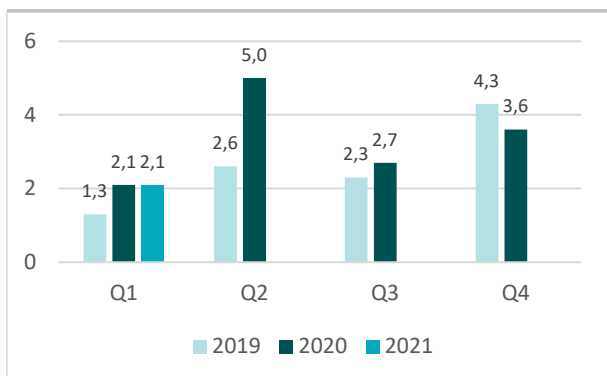
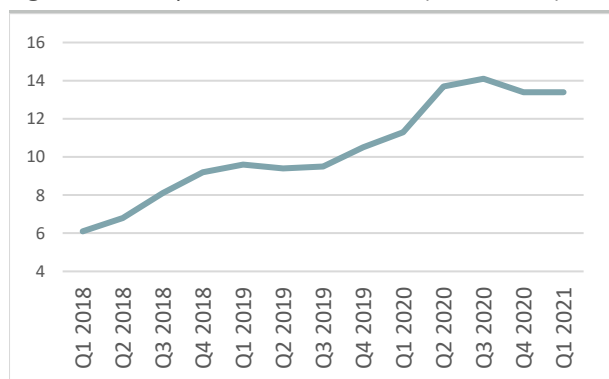


Figure 3. NGAL product revenue, LTM (DKK million)



Production Costs

Production costs in the first quarter of 2021 were DKK 2.4 million (DKK 1.8 million) bringing the gross profit for the quarter to DKK 3.2 million (DKK 2.4 million) and the gross margin for the quarter to 57% (56%).

The increase in production costs is primarily related to higher staff costs of DKK 0.3 million.

Sales and Marketing Costs

Sales and marketing costs totaled DKK 5.4 million (DKK 6.4 million) in the first quarter of 2021.

The decrease is driven by lower staff related costs of DKK 1.2 million and reduced travel costs of DKK 0.4 million, partly offset by increased depreciation of rights-of-use assets of DKK 0.5 million.

Research and Development Costs

Research and development costs in the first quarter of 2021 equaled DKK 8.2 million (DKK 5.0 million). For the first quarter of 2021, clinical study costs increased by DKK 2.0 million and were associated with activities for the NGAL pediatric clinical study. In addition, staff costs have increased by DKK 0.9 million compared to the same period in 2020.

Administrative Costs

Administrative costs in the first quarter of 2021 totaled DKK 7.7 million (DKK 7.3 million). The increase is related to staff costs of DKK 0.6 million partly offset by reduced travel spend of DKK 0.3 million compared to same period in 2020.

Financials Items, Net

Financial items, net was an income of DKK 1.1 million (income of DKK 0.1 million) for the first quarter of 2021.

Tax on Income for the Period

In the first quarter of 2021 tax on income for the year was an income of DKK 1.7 million (income of DKK 1.0 million). Tax on income for the year is primarily related to refunded tax losses originating from research and development costs.

Balance Sheet

The balance sheet total was DKK 121.4 million as of March 31, 2021 (DKK 27.5 million).

Assets

Intangible assets were DKK 1.3 million (DKK 1.2 million). The company has no capitalized research and development costs.

Fixtures and fittings, tools and equipment equaled DKK 2.4 million (DKK 1.8 million). The increase primarily consists of leasehold improvements and lab equipment, partly offset by depreciation of existing equipment.

Rights-of-use assets were DKK 9.8 million (DKK 3.0 million). Rights-of-use assets consists of the group leases of office spaces and vehicles. The increase is related to a new office space in Boston, US, partly offset by depreciation of existing rights-of-use assets.

Financial assets equaled DKK 1.7 million (DKK 1.7 million) and consist of deposits.

Inventories were DKK 2.6 million (DKK 3.8 million) and consist primarily of finished goods.

Total receivables were DKK 16.9 million (DKK 12.6 million), of which trade receivables totaled DKK 6.7 million (DKK 4.8 million).

Income tax receivables were DKK 7.0 million (DKK 5.7 million), other receivables were DKK 1.2 million (DKK 0.6 million) and prepayments were DKK 2.0 million (DKK 1.6 million).

As of March 31, 2021, BioPorto's cash position was DKK 86.7 million (DKK 3.3 million) and is primarily invested in deposit accounts with two Nordic banks.

Equity

After transfer of the loss of the period, equity stood at DKK 86.7 million (DKK 10.8 million).

Liabilities

Non-current liabilities equaled DKK 8.3 million (DKK 2.0 million). The increase is mainly due to a new lease of office space in Boston, US.

Current liabilities were DKK 26.3 million (DKK 14.8 million) of which trade payables were DKK 2.5 million (DKK 2.7 million), tax payables DKK 0.1 million (DKK 0.1 million) and other payables were DKK 21.3 million (DKK 9.7 million).

Cash Flow Statement

Net cash expenditure from operating activities amounted to DKK 21.1 million (DKK 13.8 million), the increase was primarily driven by changes in working capital.

Net cash spent on investing activities was DKK 0.2 million (DKK 0.4 million) which primarily consisted of investments in software. In 2020, the investment was primarily in property, plant and equipment.

In the first quarter of 2021 net cash from financing activities was a spend of DKK 1.0 million (spend of DKK 0.6 million) primarily related to repayment of lease obligations.

The net cash flow for the first quarter of 2021 was negative by DKK 22.3 million (negative by DKK 14.8 million).

Accounting Policies

The interim report for the first quarter of 2021 has been prepared in accordance with IAS 34 and the additional Danish regulations for the presentation of quarterly interim reports by listed companies. The interim report is presented as condensed interim financial statements.

The interim report for the first quarter of 2021 follows the same accounting policies as the Annual Report for 2020.

At the time of publishing this Interim Report, there are several new or modified standards and interpretations which have yet to come into effect and which are therefore not implemented in the consolidated financial statements. The new or modified standards and interpretations will be implemented when they become mandatory and are not expected to have an impact on the consolidated financial statements of the BioPorto Group.

Focus on finalizing and submitting FDA application for The NGAL Test in 2021

Management's priorities for 2021 are:

- » to finalize and submit the US FDA application for The NGAL Test in pediatrics
- » to accelerate commercialization of new and existing products in our portfolio
- » to secure data from clinical studies to support US and EU regulatory applications for a COVID-19 lateral flow test and to progress development of new rapid assays that use the gRAD platform
- » to review opportunities to initiate the US process for adult use of The NGAL Test
- » to grow total revenue by approximately 25% by increasing sales of The NGAL Test.

Guidance for 2021 maintained

BioPorto maintains its financial guidance for 2021, as most recently described in its annual report for 2020. BioPorto expects revenue of approximately DKK 30 million in 2021, excluding revenues from potential sales of a COVID-19 lateral flow test, and with only potential early sales from an FDA cleared NGAL product for pediatrics.

The main growth driver in 2021 will be product sales of The NGAL Test across the EU and ROW, while sales of antibodies and ELISA kits are expected to decline due to BioPorto's strategic refocus on products generated from its own antibody library. As has been the recent pattern, 2021 revenues will be back-end loaded.

BioPorto expects to incur a 2021 operating loss (EBIT) of approximately 73 million, as costs will increase due to more clinical and regulatory activity, as compared to 2020.

BioPorto is capitalized to execute strategic activities in to Q2 2022. The company is currently investigating further funding opportunities, including the option to potentially dual-list the company's shares, in order to strengthen BioPorto's long term financial position.

BioPorto's performance and guidance for 2021 is dependent on the development of the pandemic. The guidance above is predicated on the assumption of a gradual reopening of societies and the normalization of access to hospitals, research laboratories, and regulatory bodies.

Forward-looking statements

This interim report contains forward-looking statements, including forecasts of future revenue and net profit/loss. Such statements are subject to risks and uncertainties, as various factors, many of which are beyond BioPorto's control, may cause actual results and performance to differ materially from the forecasts made in this interim report.

For Further Information:

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About BioPorto

BioPorto is an in-vitro diagnostics company that provides diagnostic tests and antibodies to clinicians and researchers around the world. We use our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives. BioPorto is headquartered in Copenhagen, Denmark and is listed on the Nasdaq Copenhagen stock exchange (CPH:BIOPOR).

Statement by the Management

The Board of Directors and Executive Management today considered and approved the Interim Report of the BioPorto Group for the period January 1, 2021 – March 31, 2021.

The Interim Report, which is unaudited and has not been reviewed by the company's auditors, is presented in accordance with IAS 34 "Interim financial reporting" as adopted by the EU and additional Danish disclosure requirements for interim reports of listed companies.

In our opinion, the Interim Report gives a true and fair view of the Group's assets, liabilities and financial position as of March 31, 2021, and of the results of the Group's operations and cash flows for the period January 1, 2021 – March 31, 2021.

Furthermore, in our opinion the management's report includes a fair review of the development and performance of the business, the results for the period and the Group's financial position in general and describes the principal risks and uncertainties that it faces.

Hellerup, May 12, 2021

Executive Management:

Peter Mørch Eriksen
CEO

Board of Directors:

Thomas Magnussen
Chairman

Christopher Lindop
Vice Chairman

Michael Singer

Don Hardison

John McDonough

Jan Leth Christensen

Statement of comprehensive income

Income statement

	2021	2020	2020
	3 months DKK thousand	3 months DKK thousand	12 months DKK thousand
Revenue (Note 1)	5,577	4,194	23,204
Production costs	2,388	1,838	9,865
Gross profit/loss	3,189	2,356	13,339
Sales and marketing costs	5,406	6,449	20,786
Research and development costs	8,241	5,015	28,125
Administrative costs	7,720	7,307	28,018
Profit/loss before financial items (EBIT)	(18,178)	(16,415)	(63,590)
Financial income	1,334	145	4
Financial expenses	244	84	3,248
Profit/loss before tax	(17,088)	(16,354)	(66,834)
Total income taxes	(1,724)	(982)	(5,272)
Profit/loss for the period	(15,364)	(15,372)	(61,562)
	DKK	DKK	DKK
Profit/loss / comprehensive income per share (EPS & DEPS)	(0.06)	(0.09)	(0.30)

Statement of comprehensive income

	2021	2020	2020
	3 months DKK thousand	3 months DKK thousand	12 months DKK thousand
Profit/loss for the period	(15,364)	(15,372)	(61,562)
Amounts which will be re-classified to the income statement:			
Exchange rate adjustment foreign subsidiaries	(229)	(257)	1,772
Comprehensive income	(15,593)	(15,629)	(59,790)

Balance sheet

Assets

	2021	2020	2020
	31 March DKK thousand	31 March DKK thousand	31 December DKK thousand
Non-current assets			
Intangible assets, property, plant and equipment and right-of-use assets			
Rights and software	1,291	1,185	1,152
Fixtures and fittings, tools and equipment	2,407	1,846	2,448
Rights-of-use assets	9,799	3,037	10,261
Total intangible assets, property, plant and equipment and rights-of-use assets	13,497	6,068	13,861
Financial assets			
Deposits	1,685	1,729	1,645
Total financial assets	1,685	1,729	1,645
Total non-current assets	15,182	7,797	15,506
Current assets			
Inventories	2,629	3,757	3,165
Trade receivables	6,652	4,789	6,886
Income tax receivables	7,003	5,725	5,279
Other receivables	1,215	554	577
Prepayments	1,982	1,567	930
Total inventories and receivables	19,481	16,392	16,837
Cash	86,715	3,340	107,943
Total current assets	106,196	19,732	124,780
Total assets	121,378	27,529	140,286

Balance sheet

Liabilities

	2021	2020	2020
	31 March DKK thousand	31 March DKK thousand	31 December DKK thousand
Equity			
Share capital	266,582	174,944	266,582
Treasury shares	-	-	-
Exchange-rate adjustments	871	(929)	1,100
Retained earnings	(180,715)	(163,255)	(166,770)
Total equity	86,738	10,760	100,912
Liabilities			
Non-current liabilities			
Lease obligation	7,996	996	7,992
Other non-current liabilities	301	957	452
Total non-current liabilities	8,297	1,953	8,444
Current liabilities			
Current portion of non-current liabilities	2,426	2,366	2,828
Trade payables	2,490	2,702	4,636
Tax payables	81	78	77
Other payables	21,346	9,670	23,389
Total current liabilities	26,343	14,816	30,930
Total liabilities	34,640	16,769	39,374
Total equity and liabilities	121,378	27,529	140,286

Statement of changes in equity

	Share capital DKK thousand	Share premium DKK thousand	Exchange- rate adjustments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity on 1 January 2021	266,582	-	1,100	(166,770)	100,912
Comprehensive income					
Profit/loss for the year / Comprehensive income	-	-	-	(15,364)	(15,364)
Adjustment of foreign currency fluctuations on subsidiaries	-	-	(229)	-	(229)
Transactions with owners					
Share-based compensation	-	-	-	1,419	1,419
Equity on 31 March 2021	266,582	-	871	(180,715)	86,738

	Share capital DKK thousand	Share premium DKK thousand	Exchange- rate adjustments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity on 1 January 2020	174,944	-	(672)	(148,950)	25,322
Comprehensive income					
Profit/loss for the year/ Comprehensive income	-	-	-	(15,372)	(15,372)
Adjustment of foreign currency fluctuations on subsidiaries	-	-	(257)	-	(257)
Transactions with owners					
Share-based compensation	-	-	-	1,067	1,067
Equity on 31 March 2020	174,944	-	(929)	(163,255)	10,760

Cash flow statement

	2021	2020	2020
	3 months DKK thousand	3 months DKK thousand	12 months DKK thousand
Profit/loss before financial items	(18,178)	(16,415)	(63,590)
Amortization and depreciation	1,041	689	3,994
Warrant expenses	1,419	1,067	5,316
Other non-cash adjustments	-	-	334
Cash generated from operations before working capital	(15,718)	(14,659)	(53,946)
Changes in working capital	(5,109)	912	15,593
Cash generated from operations	(20,827)	(13,747)	(38,353)
Financial income, received	82	22	634
Financial expenses, paid	(324)	(110)	(2,640)
Tax refund, net	-	-	4,743
Cash flows from operating activities	(21,069)	(13,835)	(35,616)
Investments in rights and software	(196)	-	(184)
Investments in operating equipment	(53)	(389)	(1,315)
Investments in financial assets	-	-	(22)
Cash flows from investing activities	(249)	(389)	(1,521)
Issue, gross proceeds	-	-	146,620
Issue cost	-	-	(16,556)
Reduction of non-current liabilities	(151)	-	(170)
Reduction of lease obligation	(808)	(575)	(2,859)
Cash flows from financing activities	(959)	(575)	127,035
Net cash flow from operating, investing, and financing activities	(22,277)	(14,799)	89,898
Cash and cash equivalents at beginning of period	107,943	18,122	18,122
Currency adjustments	1,049	17	(77)
Cash and cash equivalents end of period	86,715	3,340	107,943

Note 1

Segment reporting

	2021	2020	2020
	3 months DKK thousand	3 months DKK thousand	12 months DKK thousand
Geographic distribution			
Europe	2,538	1,173	10,016
North America	2,186	2,634	10,374
Asia	847	375	2,806
Other countries	6	12	8
Revenue	5,577	4,194	23,204

	2021	2020	2020
	3 months DKK thousand	3 months DKK thousand	12 months DKK thousand
Product groups			
NGAL revenue:			
Product sales	2,147	2,117	13,430
Total NGAL revenue	2,147	2,117	13,430
Other products and license revenue:			
ELISA kits	369	260	2,541
Antibodies	2,928	1,723	6,791
Royalty	13	8	19
Other products and licenses	120	86	423
Total other products and license revenue	3,430	2,077	9,774
Revenue	5,577	4,194	23,204