# Interim Report

# First nine months of 2021, BioPorto Group

November 17, 2021 Announcement no. 21



BioPorto A/S Tuborg Havnevej 15 DK-2900 Hellerup CVR DK-17500317

# Highlights

## Revenue growth driven by antibodies and RUO sales of The NGAL Test

In the first nine months of 2021, BioPorto's revenue grew by 19% in USD (11% in DKK), driven by strong sales of antibodies and higher research use only (RUO) sales of The NGAL Test<sup>™</sup> in the US. In third quarter 2021, ELISA kit sales also contributed to topline performance which grew 13% in USD (12% in DKK).

### Appointment of new CEO and CFO and changes to the board of directors

Following the conclusion of successful search processes, BioPorto in October 2021 announced the appointments of Anthony (Tony) Pare as its new Chief Executive Officer (CEO) and Neil A. Goldman as its new Executive Vice President (EVP) and Chief Financial Officer (CFO). They will be joining Bio-Porto from global medtech companies by mid-November 2021 and both brings decades of executive experience in launching products, growing businesses and revenue and raising capital to BioPorto.

In November 2021, Thomas Magnussen resigned as member of the board of directors and Christopher Lindop succeeded him as chairman of the Board of Directors while John McDonough was elected as vice chairman. Furthermore, Peter Mørch Eriksen was on an extraordinary meeting elected as member of the board of directors.

# Results from Interim Analysis of Data from The NGAL Test study are consistent with expectations, but enrollment delayed due to COVID-19

In August 2021, BioPorto concluded an interim analysis of data from the pediatric clinical trial to evaluate The NGAL Test as a tool for risk assessment of moderate to severe acute kidney injury (AKI). The interim analysis for the clinical performance of the assay provided results on sensitivity and specificity which were consistent with expectations.

While the number of participating study sites has increased in third quarter of 2021, enrollment of patients for the pediatric study has lately been impacted and delayed by the continuation of the COVID-19 pandemic which reduce access to patients. BioPorto therefore now expect to finalize data collection during the first half of 2022.

### Testing of The NGAL Test for Emergency Use Authorization in relation to COVID-19 patients initiated

BioPorto has in third quarter 2021 progressed the dialogue with FDA on the potential Emergency Use Authorization (EUA) of The NGAL Test for use in the assessment of kidney injury and prediction of need for renal replacement therapy in COVID-19 patients. The dialogue with FDA has been promising and BioPorto has hence initiated testing of the original samples using The NGAL Test on a Roche analyzer.

# Interim data for gRAD-based Sepsis test and results from COVID-19 test expected in fourth quarter 2021

The development of a gRAD-based test for the quantitative determination of thrombomodulin in human plasma or whole blood samples which Bio-Porto is undertaking with Rigshospitalet (DK) has further progressed in third quarter of 2021. Rigshospitalet, who is leading the study, is currently summarizing the results in an interim data report, which is expected to be finalized in fourth quarter 2021.

The data collection for a point-of-care assay for the COVID-19 continued in third quarter 2021. Initial testing results indicate a higher sensitivity compared to other rapid test formats. The results are currently being evaluated and BioPorto expects to conclude the analysis of the clinical potential before year-end 2021.

### Guidance for 2021

Based on the development year-to-date, BioPorto expect to reduce the EBIT loss for 2021 from approximately DKK 73 million to now approximately DKK 63 million.

The revised EBIT guidance will have a positive effect on BioPorto's cash position end-2021 compared to previous estimates. This implies that the Company based on the current outlook expects to have funding into third quarter 2022 whereas previously estimated to second quarter 2022.

For the financial year 2021, BioPorto adjust expectations for revenue to approximately DKK 24 million from previous guidance of DKK 30 million.

#### Peter M. Eriksen, CEO, commented:

"As in previous quarters, we have seen a satisfying development in our activities in third quarter 2021. Antibody sales continue to be at a high level, and sales of The NGAL Test in the US for RUO is rising. More importantly, we also in third quarter 2021 received the interim data analysis from The NGAL Test study to support our pediatric application to the FDA. The results are consistent with our expectations and supports our view that The NGAL Test is an important biomarker for AKI in children. The focus is now to accelerate patient enrollment to finalize the study while at the same time continuing to explore the opportunities our technology hold in other areas.

Finally, I am very excited that we also shortly after the end of third quarter of 2021 appointed Tony as new CEO and Neil CFO in BioPorto. They bring tons of experience from the medtech industry to the table and will together with our dedicated employees be pivotal in realizing the huge potential of our products and platforms."

### **Investor Meeting**

In connection with the release of the Interim Report for the third quarter of 2021, BioPorto will host an online investor presentation on November 17, 2021 at 14:00 CET in Danish and at 16:00 CET in English. For further information regarding the online investor meeting, please visit www.biooporto.com/investor-relations.

# **Financial Highlights**

	2021 3rd quarter DKK million	2020 3rd quarter DKK million	2021 9 months DKK million	9 months DKK million	2020 12 months DKK million
Revenue	5.3	4.7	17.4	15.7	23.2
Production costs	1.4	1.8	5.8	6.0	9.9
Sales and marketing costs	5.1	5.2	13.3	16.0	20.8
Research and development costs	7.6	9.6	23.1	24.1	28.1
Administrative costs	5.8	5.9	22.4	20.3	28.0
Operating loss (EBIT)	(14.5)	(17.7)	(47.2)	(50.8)	(63.6)
Net financials	0.6	(1.0)	1.1	(1.5)	(3.2)
Operating loss before tax	(13.9)	(18.7)	(46.1)	(52.3)	(66.8)
Loss for the period	(11.4)	(17.3)	(40.4)	(48.1)	(61.6)
Total comprehensive income	(11.9)	(16.4)	(41.1)	(46.9)	(59.8)
Non-current assets			18.2	16.7	15.5
Current assets			82.5	41.3	124.8
Total assets			100.7	58.1	140.3
Equity			62.8	19.0	100.9
Non-current liabilities			11.2	10.3	8.4
Current liabilities			26.7	28.8	30.9
Total equity and liabilities			100.7	58.1	140.3
Cash flows from operating activities			(49.9)	(27.5)	(35.6)
Cash flows from investing activities, net			(0.4)	(1.1)	(1.5)
Of which investment in property, plant and equipment			(0.1)	(1.0)	(1.3)
Cash flows from financing activities			1.8	35.0	127.0
Total cash flows			(48.5)	6.4	89.9
Revenue growth	12%	(28%)	11%	(22%)	(13%)
Gross margin	73%	63%	67%	62%	57%
Equity ratio (solvency)	62%	33%	62%	33%	72%
Average number of employees	26	28	28	27	28
Number of shares by the end of the period (1,000)	267,754	199,936	267,754	199,936	266,582
Earnings per share (EPS), DKK	(0.04)	(0.09)	(0.15)	(0.24)	(0.30)
Net asset value per share, period-end, DKK	0.23	0.09	0.23	0.09	0.38
Share price, period-end, DKK	3.16	4.01	3.16	4.01	4.04

# **Management Review**

# Sales of antibodies, The NGAL Test and ELISA kits drives growth

In the third quarter of 2021 revenue was DKK 5.3 million, corresponding to a growth of 13% in USD (12% in DKK) year-over-year.

Revenue from sales of antibodies was in the quarter at the same level as last year, whereas sales of ELISA kits increased from DKK 0.3 million last year to DKK 1.0 million this year. Revenue from RUO sales of The NGAL Test in the US increased 19% in USD (17% in DKK) in the third quarter of 2021 compared to last year, while ROW sales of the test in the quarter was down DKK 0.4 million compared to last year's DKK 0.9 million. BioPorto expects ROW sales to regain momentum in the last part of 2021, as one single large order has been postponed to fourth quarter 2021 as previously announced.

Revenue in the first nine months of 2021 was DKK 17.4 million, representing a growth of 19% in USD (11% in DKK) over last year. In the first three quarters of 2021, antibody sales grew 57% to DKK 7.0 million, and RUO sales from The NGAL Test in the US increased 25% in USD (18% in DKK) to DKK 5.8 million, whereas ROW sales of The NGAL Test was DKK 2.6 million in the period. Given the challenging global environment resulting from COVID-19, the results were in line with the company's expectations.

# Results from Interim Analysis of Data from The NGAL Test study are consistent with expectations

In August 2021, BioPorto concluded an interim analysis of data from the pediatric clinical trial to evaluate The NGAL Test as a tool for risk assessment of moderate to severe AKI. The study is being conducted to support a submission to the FDA.

Based on data collected from six different leading US children's hospitals over a twelve-month period, the interim analysis for the clinical performance of the assay provided results on key characteristics such as sensitivity and specificity which were consistent with expectations. The results are expected to support the case of The NGAL Test as a biomarker to identify risk of AKI in critical ill children.

# Enrollment for pediatric trial for The NGAL Test continues, but is delayed by COVID-19

Following this interim analysis of data from the pediatric clinical trial for The NGAL Test, BioPorto has expanded the ongoing patient enrollment to maximize the pediatric clinical study's statistical power for the upcoming FDA submission.

While the number of participating study sites has been increased to 14, enrollment of patients has lately been impacted and delayed by the continuation of the COVID-19 pandemic which affects the health care sector as focus shifts to treatment, fewer patients are submitted to the ICU and access for research coordinators is restricted.

Based on actual enrollment figures and the outlook on COVID-19, BioPorto consequently revised the enrollment forecast beginning of November 2021, and now expect to finalize data collection during the first half of 2022. After enrollment is complete, BioPorto will continue to work interactively with the FDA to submit a De Novo Classification Request, as the NGAL Test maintains its Breakthrough Designation status.

# Testing of The NGAL Test for Emergency Use Authorization of in relation to COVID-19 patients initiated

BioPorto has in third quarter 2021 progressed the dialogue with FDA on the potential EUA of The NGAL Test for use in the assessment of kidney injury and prediction of need for renal replacement therapy in COVID-19 patients.

The dialogue with FDA has been promising and BioPorto has hence initiated testing of the original samples collected by clinical researchers at Columbia University's Irving Medical Center (US) and published in Kidney International Reports (<u>https://www.kireports.org/article/S2468-0249(21)01445-5/fulltext</u>) using The NGAL Test on a Roche analyzer.

With a reported negative predictive value of 97% in the original study, NGAL could be an important biomarker in identifying COVID-19 patients who have low risk of requiring renal replacement therapy and hence aid staff in prioritizing scarce hospital resources, such as dialysis equipment and skilled staff.

# Interim data for gRAD-based Sepsis test expected in fourth quarter 2021

The development of a gRAD-based test for the quantitative determination of thrombomodulin in human plasma or whole blood samples which Bio-Porto is undertaking with Rigshospitalet has further progressed in the third quarter of 2021. The test is part of a trial evaluating the safety and efficacy in the administration of thrombomodulin versus placebo for 72 hours in trauma patients with hemorrhagic shock-induced endotheliopathy.

Rigshospitalet, who is leading the study, is currently summarizing the results in an interim data report, which is expected to be finalized in fourth quarter 2021.

#### Results from gRAD COVID-19 test pending

The data collection for a point-of-care assay for COVID-19 continued in third quarter 2021. Initial testing results indicate a higher sensitivity compared to other rapid test formats.

The results are currently being evaluated and BioPorto expects to conclude the analysis of the clinical potential before year-end 2021.

#### Anthony Pare appointed new CEO of BioPorto

In October 2021, BioPorto announced the appointment of Anthony (Tony) Pare as its new Chief Executive Officer (CEO). Tony Pare joins BioPorto from T2 Biosystems, a US Nasdaq-listed in vitro diagnostics company, where he served as the Chief Commercial Officer and presided over several successful product launches.

Tony has for 24 years headed product development, commercialization, marketing and operations improvements in leading medtech and diagnostic companies and delivered strong results, driving business value, increasing product presence and growing sales, both in the US and globally.

Tony Pare will assume the CEO position as of November 20, 2021.

#### Neil A. Goldman appointed new CFO of BioPorto

In October 2021, BioPorto furthermore announced the appointment of Neil A. Goldman, CPA, as its new Executive Vice President (EVP) and Chief Financial Officer (CFO).

Most recently, Neil Goldman was EVP and CFO at Chembio Diagnostics, Inc., a global developer and manufacturer of point-of-care tests for infectious disease. He started his career as an auditor with Ernst & Young and since served as an executive at J.S. Held LLC and Unwired Technology LLC.

Neil brings three decades of valuable experience within establishing strong relations with investors and global capital markets, raising capital reliably and successfully, optimizing business operations, and expanding business through organic growth and strategic partnerships.

Neil started as EVP and CFO in BioPorto at November 15, 2021.

#### Events after the reporting period

On November 15, 2021, BioPorto A/S conveyed an extraordinary general meeting on which Peter Mørch Eriksen was elected as a new member to the Board of Directors of BioPorto A/S. Peter has been CEO of BioPorto A/S in the period 2013-2021 and has extensive experience from leading, growing and funding global companies in the life science and MedTech.

At the extraordinary general meeting, Thomas Magnussen resigned as chairman and member of the Board of Directors, and following the event, Christopher Lindop was appointed as new chairman of the Board of Directors and John McDonough was elected as vice chairman.

Furthermore, the Board of Directors' proposal to renew the authorization to issue warrants in articles 17a of the Articles of Association and increase the number of warrants that can be allocated was accepted on by the extraordinary general meeting.

# **Financial Review**

### **Income Statement**

The financial review is based on the Group's consolidated financial information for the period ended September 30, 2021, with comparative results for September 30, 2020 in brackets.

In the third quarter of 2021 revenues totaled DKK 5.3 million (DKK 4.7 million) and for the first nine months of 2021 totaled DKK 17.4 million (DKK 15.7 million). Earnings before interest and taxes (EBIT) showed a loss of DKK 14.5 million (DKK 17.7 million) in the third quarter of 2021 and in the first nine months of 2021 showed a loss of DKK 47.2 million (DKK 50.8 million). The cash position as of September 30, 2021 was DKK 59.6 million (DKK 24.5 million).

#### Revenue

Revenue in the third quarter of 2021 was DKK 5.3 million (DKK 4.7 million) and for the first nine months of 2021 totaled DKK 17.4 million (DKK 15.7 million).

In the third quarter of 2021 NGAL revenue totaled DKK 2.6 million (DKK 2.7 million) and for the first nine months of 2021 totaled DKK 8.4 million (DKK 9.8 million).

Revenue in the third quarter of 2021 totaled DKK 2.1 million (DKK 1.8 million) from RUO sales in the US, DKK 0.5 million (DKK 0.9 million) from sales in ROW. For the first nine months of 2021 revenue from The NGAL Test was DKK 5.8 million (DKK 4.9 million) from RUO sales in the US, DKK 2.6 million (DKK 4.9 million) from sales in ROW.

Revenue from the sale of antibodies amounted to DKK 1.7 million (DKK 1.7 million) in the third quarter of 2021. For the first nine months of 2021 revenue from sale of antibodies was DKK 7.0 million (DKK 4.4 million).

Revenues from the sale of ELISA kits totaled DKK 1.0 million (DKK 0.3 million) during the third quarter of 2021, and DKK 1.8 million (DKK 1.1 million) for the first nine months of 2021.



#### Figure 1. Revenue by quarter (DKK million)

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







#### **Production Costs**

Production costs in the third quarter of 2021 were DKK 1.4 million (DKK 1.8 million) bringing the gross profit for the quarter to DKK 3.9 million (DKK 3.0 million) and the gross margin for the quarter to 73% (63%).

For the first nine months of 2021 production costs totaled DKK 5.8 million (DKK 6.0 million) bringing the gross profit for first nine months of 2021 to DKK 11.6 million (DKK 9.7 million) and the gross margin for the first nine months of 2021 to 67% (62%).

The decrease in production costs is primarily related to lower spending of staff costs during the first nine months of DKK 0.4 million.

#### Sales and Marketing Costs

Sales and marketing costs totaled DKK 5.1 million (DKK 5.2 million) in the third quarter of 2021 and DKK 13.3 million (DKK 16.0 million) for the first nine months of 2021.

The decrease is driven by lower staff related costs of DKK 1.2 million and reduced travel costs of DKK 0.5 million.

#### **Research and Development Costs**

Research and development costs in the third quarter of 2021 equaled DKK 7.6 million (DKK 9.7 million) and for the first nine months of 2021 were DKK 23.1 million (DKK 24.1 million). For the first nine months of 2021, clinical study costs decreased by DKK 2.7 million compared to the same period in 2020.

#### Administrative Costs

Administrative costs in the third quarter of 2021 totaled DKK 5.8 million (DKK 5.9 million) and for the first nine months of 2021 totaled DKK 22.4 million (DKK 20.3 million). The increase is primarily related to increased consultancy costs in the second and third quarter of 2021 of DKK 3.0 million related to the replacement process regarding the CEO and CFO positions.

#### Financials Items, Net

Financial items, net was an income of DKK 0.6 million (expense of DKK 1.0 million) for the third quarter of 2021. For the first nine months of 2021 financial net was an income of DKK 1.1 million (expense of DKK 1.5 million).

#### Tax on Income for the Period

In the third quarter of 2021 tax on income for the year was an income of DKK 2.5 million (income of DKK 1.3 million), and for the first nine months of 2021 an income of DKK 5.7 million (income of DKK 4.1 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 100.7 million as of September 30, 2021 (DKK 58.1 million).

#### Assets

Intangible assets were DKK 1.2 million (DKK 1.1 million). The company has no capitalized research and development costs.

Fixtures and fittings, tools and equipment equaled DKK 2.1 million (DKK 2.4 million). The increase primarily consists of leasehold improvements and lab equipment, partly offset by depreciation of existing equipment.

Rights-of-use assets were DKK 13.2 million (DKK 11.6 million). Rights-of-use assets consists of the group leases of office spaces and vehicles. The increase is related to extension of the office lease in Hellerup, DK, partly off-set 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 3.9 million (DKK 3.8 million) and consists primarily of finished goods.

Total receivables were DKK 19.1 million (DKK 13.1 million), of which trade receivables totaled DKK 7.1 million (DKK 5.7 million).

Income tax receivables were DKK 10.6 million (DKK 4.1 million), other receivables were DKK 0.6 million (DKK 2.3 million) and prepayments were DKK 0.8 million (DKK 1.0 million). As of September 30, 2021, BioPorto's cash position was DKK 59.6 million (DKK 24.5 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 62.8 million (DKK 19.0 million).

The share-based compensation in the first nine months of 2021 was an income of DKK 1.3 million (expense of DKK 3.3 million), following reversal of share-based compensation to 'bad leavers' of DKK 3.9 million partly offset by expenses related to ongoing programs of DKK 2.6 million.

#### Liabilities

Non-current liabilities equaled DKK 11.2 million (DKK 10.3 million). The increase is mainly due to an extension of the office lease in Hellerup, DK.

Current liabilities were DKK 26.7 million (DKK 28.8 million) of which trade payables were DKK 5.4 million (DKK 2.2 million), tax payables were DKK 0.1 million (DKK 0.1 million) and other payables were DKK 18.2 million (DKK 23.2 million).

#### **Cash Flow Statement**

Net cash expenditure from operating activities amounted to DKK 49.9 million (DKK 27.5 million), the increase in expenditure was primarily driven by changes in working capital and lower tax refunds.

Net cash spent on investing activities was DKK 0.4 million (DKK 1.1 million) which consisted of investment in software. In 2020, the investments were primarily in property, plant and equipment.

Net cash provided from financing activities totaled DKK 1.8 million (DKK 35.0 million) primarily related to proceeds from share capital increase.

The net cash flow for the first nine months of 2021 was negative by DKK 48.5 million (positive by DKK 6.4 million).

### **Accounting Policies**

The interim report for the first nine months 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 nine months 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

Management's priorities for 2021 are:

- » to continue enrollment of patients for the US FDA application for The NGAL Test in pediatrics
- » to accelerate commercialization of new and existing products in our portfolio
- » to evaluate clinical studies for Sepsis and COVID-19 lateral flow tests and to progress development of new rapid assays that use the gRAD platform
- » to grow total revenue by increasing sales of The NGAL Test and antibodies

### Guidance for 2021

Based on the development year-to-date, BioPorto expect to reduce the EBIT loss for 2021 from approximately DKK 73 million to now approximately DKK 63 million. The revised guidance rests on a tight cost focus throughout the year, changes to the organisation and expectations of reduced clinical activity due to the continuation of the COVID-19 pandemic.

The revised EBIT guidance will have a positive effect on BioPorto's cash position end-2021 compared to previous estimates. This implies that the Company based on the current outlook expects to have funding into third quarter 2022 whereas previously estimated to second quarter 2022. The company is currently investigating further funding opportunities, including the option to potentially dual-list the company's shares, in order to further strengthen BioPorto's long term financial position.

For the financial year 2021, BioPorto adjust expectations for revenue to approximately DKK 24 million from previous guidance of DKK 30 million.

BioPorto's performance and guidance for 2021 is dependent on the development of the COVID-19 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:

Peter Mørch Eriksen, CEO Tel: +45 4529 0000 E-mail: investor@bioporto.com

#### 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 – September 30, 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 September 30, 2021, and of the results of the Group's operations and cash flows for the period January 1, 2021 – September 30, 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, November 17, 2021

**Executive Management:** 

Peter Mørch Eriksen CEO

Board of Directors:

Christopher Lindop Chairman Peter Mørch Eriksen

Michael Singer

Don Hardison

John McDonough

Jan Leth Christensen

# Statement of comprehensive income

### Income statement

	2021 3rd quarter DKK thousand	2020 3rd quarter DKK thousand	2021 9 months DKK thousand	2020 9 months DKK thousand	2020 12 months DKK thousand
Revenue (Note 1)	5,294	4,742	17,447	15,672	23,204
Production costs	1,405	1,750	5,834	5,997	9,865
Gross loss	3,889	2,992	11,613	9,675	13,339
Sales and marketing costs	5,055	5,176	13,318	15,980	20,786
Research and development costs	7,560	9,646	23,083	24,114	28,125
Administrative expenses	5,750	5,875	22,382	20,338	28,018
Loss before financial items (EBIT)	(14,476)	(17,705)	(47,170)	(50,757)	(63,590)
Financial income	843	-	1,765	4	4
Financial expenses	226	969	692	1,512	3,248
Loss before tax	(13,859)	(18,674)	(46,097)	(52,265)	(66,834)
Total income taxes	(2,475)	(1,325)	(5,726)	(4,123)	(5,272)
Loss for the period	(11,384)	(17,349)	(40,371)	(48,142)	(61,562)
	DKK	DKK	DKK	DKK	DKK
Loss / comprehensive income per share (EPS & DEPS)	(0.04)	(0.09)	(0.15)	(0.24)	(0.30)

# Statement of comprehensive income

	2021	021 2020 2021	2020	2020	
	3rd quarter DKK thousand	3rd quarter DKK thousand	9 months DKK thousand	9 months DKK thousand	12 months DKK thousand
Loss for the period	(11,384)	(17,349)	(40,371)	(48,142)	(61,562)
Amounts which will be re-classified to the income statement:					
Exchange rate adjustment foreign subsidiaries	(534)	957	(737)	1,193	1,772
Comprehensive income	(11,918)	(16,392)	(41,108)	(46,949)	(59,790)

# **Balance sheet**

### Assets

ASSETS	2021 30 September DKK thousand	2020 30 September DKK thousand	2020 31 December DKK thousand
Non-current assets			
Intangible assets, property, plant and equipment and right-of-use assets			
Rights and software	1,179	1,059	1,152
Fixtures and fittings, tools and equipment	2,109	2,407	2,448
Right-of-use assets	13,210	11,567	10,261
Total intangible assets, property, plant and equipment and right-of-use assets	16,498	15,033	13,861
Financial assets			
Deposits	1,720	1,688	1,645
Total financial assets	1,720	1,688	1,645
Total non-current assets	18,218	16,721	15,506
Current assets			
Inventories	3,866	3,752	3,165
Trade receivables	7,086	5,693	6,886
Income tax receivable	10,554	4,129	5,279
Other receivables	604	2,290	577
Prepayments	809	958	930
Total inventories and receivables	22,919	16,822	16,837
Cash	59,554	24,510	107,943
Total current assets	82,473	41,332	124,780
Total assets	100,691	58,053	140,286

# Balance sheet

### Liabilities

LIABILITIES	2021 30 September DKK thousand	<b>2020</b> 30 September DKK thousand	2020 31 December DKK thousand
Equity			
Share capital	267,754	199,936	266,582
Treasury shares	-	-	-
Exchange-rate adjustments	363	521	1,100
Retained earnings	(205,296)	(181,491)	(166,770)
Total equity	62,821	18,966	100,912
Liabilities			
Non-current liabilities			
Lease obligation	10,904	8,722	7,992
Other non-current liabilities	301	1,553	452
Total non-current liabilities	11,205	10,275	8,444
Current liabilities			
Current portion of non-current liabilities	3,015	3,348	2,828
Trade payables	5,409	2,204	4,636
Tax payables	82	93	77
Other payables	18,159	23,167	23,389
Total current liabilities	26,665	28,812	30,930
Total liabilities	37,870	39,087	39,374
Total liabilities	100,691	58,053	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 at 1 January 2021	266,582	-	1,100	(166,770)	100,912
<b>Comprehensive income</b> Loss for the period / Comprehensive income				(40,371)	(40,371)
Adjustment of foreign currency fluctuations on subsidiaries	-	-	(737)	-	(737)
Transactions with owners					
Warrant programs exercised	1,172	3,189	-	-	4,361
Issue cost	-	(23)	-	-	(23)
Share-based compensation	-	-	-	(1,321)	(1,321)
Transferred to retained earnings	-	(3,166)	-	3,166	-
Equity at 30 September 2021	267,754	-	363	(205,296)	62,821

	Share capital DKK thousand	Share premium DKK thousand	Exchange-rate adjustments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity at 1 January 2020	174,944	-	(672)	(148,950)	25,322
Comprehensive income					
Loss for the period/ comprehensive income	-	-	-	(48,142)	(48,142)
Adjustment of foreign currency fluctuations on subsidiaries	-	-	1,193	-	1,193
Transactions with owners					
Issue	24,992	14,995	-	-	39,987
Issue cost	-	(2,693)	-	-	(2,693)
Share-based compensation	-	-	-	3,299	3,299
Transferred to Retained earnings	-	(12,302)	-	12,302	-
Equity at 30 september 2020	199,936	-	521	(181,491)	18,966

# Cash flow statement

	2021 9 months DKK thousand	2020 9 months DKK thousand	2020 12 months DKK thousand
Loss before financial items	(47,170)	(50,757)	(63,590)
Amortization, depreciation and impairment losses	3,264	2,843	3,994
Share-based compensation	(1,321)	3,299	5,316
Other non-cash adjustments	-	866	334
Cash generated from operations before working capital	(45,227)	(43,749)	(53,946)
Changes in working capital	(5,264)	11,804	15,593
Cash generated from operations	(50,491)	(31,945)	(38,353)
Financial income, received	1,163	121	634
Financial income, paid	(974)	(438)	(2,640)
Tax refund	452	4,756	4,743
Cash flows from operating activities	(49,850)	(27,506)	(35,616)
Purchase of rights and software	(270)	(25)	(184)
Purchase of operating equipment	(148)	(1,046)	(1,315)
Purchase of financial assets	(23)	(22)	(22)
Cash flows from investing activities	(441)	(1,093)	(1,521)
Proceeds from warrant program exercised	4,361	-	-
Issue, gross proceeds	-	39,987	146,620
Issue cost	(23)	(2,693)	(16,556)
Repayment of non-current liabilities	(151)	(166)	(170)
Repayment of lease obligation	(2,368)	(2,101)	(2,859)
Cash flows from financing activities	1,819	35,027	127,035
Net cash flow from operating, investing and financing activities	(48,472)	6,428	89,898
Cash and cash equivalents at beginning of period	107,943	18,122	18,122
Currency adjustments	83	(40)	(77)
Cash and cash equivalents end of period	59,554	24,510	107,943

# Segment reporting

GEOGRAPHIC DISTRIBUTION:	2021 3rd quarter DKK thousand	2020 3rd quarter DKK thousand	2021 9 months DKK thousand	2020 9 months DKK thousand	2020 12 months DKK thousand
Europe	672	1,745	5,352	6,824	10,016
North America	4,039	2,505	9,626	7,066	10,374
Asia	568	492	2,438	1,765	2,806
Other countries	15	-	31	17	8
Revenue	5,294	4,742	17,447	15,672	23,204

PRODUCT GROUPS:	2021 3rd quarter DKK thousand	2020 3rd quarter DKK thousand	2021 9 months DKK thousand	2020 9 months DKK thousand	2020 12 months DKK thousand
NGAL revenue:					
Product sales	2,582	2,680	8,380	9,790	13,430
Total NGAL revenue	2,582	2,680	8,380	9,790	13,430
Other products and license revenue:					
ELISA kits	993	313	1,844	1,137	2,541
Antibodies	1,742	1,657	6,994	4,445	6,791
Royalty	22	13	47	34	19
Other products and licenses	(45)	79	182	266	423
Total other products and license revenue	2,712	2,062	9,067	5,882	9,774
Revenue	5,294	4,742	17,447	15,672	23,204