# Annual Report 2019

*Transforming novel research tools into clinically actionable biomarkers*

bioporto

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# About BioPorto

BioPorto is an in vitro diagnostics company that provides tests and antibodies to clinicians and researchers around the world. The Company uses its antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives.

The Company's portfolio includes antibodies used by pharmaceutical and diagnostic companies in the research and development of new products, as well as antibodies used in BioPorto's own biomarker programs.

BioPorto's programs have created The NGAL Test a unique assay that is designed to detect acute kidney injury (AKI) earlier and more reliably than other tests that are currently available. AKI is a well-known complication resulting from injury to the kidney, commonly after surgeries, particularly cardiac surgery, and after exposure to medications that are nephrotoxic. The NGAL Test is designed to enable doctors to identify patients at risk of AKI and to enable them to adjust management strategies before permanent kidney damage occurs. By aiding in earlier detection and improving care, it is BioPorto's hope that The NGAL Test will ultimately help to improve health and reduce the economic burden of AKI.

## Focus on securing additional data, US clearance and commercialization of The NGAL Test

BioPorto's product portfolio of antibodies and biomarkers is distributed worldwide through the company's own sales team, distributors and OEM partnerships.

The company's strategy focuses on realizing the significant growth potential inherent in the global market penetration of The NGAL Test. In 2020, BioPorto expects to submit a US regulatory application to the US Food and Drug Administration (FDA) for use of the test in critically ill children. Following FDA clearance, BioPorto will commercialized the test in the US, which is regarded as the largest and most important market for in vitro diagnostics.

# Contents

# Financial highlights 2015 - 2019

See Note 1 of the consolidated financial statements for definitions of financial highlights.

| | 2019<br>DKK million | 2018<br>DKK million | 2017<br>DKK million | 2016<br>DKK million | 2015<br>DKK million |
|---|---|---|---|---|---|
| Revenue | 26.6 | 26.0 | 25.2 | 20.7 | 20.4 |
| Production costs | (9.3) | (8.2) | (6.9) | (5.0) | (4.9) |
| Sales and marketing costs | (39.3) | (20.9) | (18.5) | (18.0) | (8.9) |
| Research and development costs | (24.6) | (18.7) | (21.9) | (9.7) | (9.9) |
| Administrative expenses | (27.8) | (20.0) | (14.3) | (13.0) | (9.4) |
| Operating profit/loss (EBIT) | (74.3) | (41.8) | (36.5) | (25.0) | (12.8) |
| Net financials | 0.1 | 0.2 | (0.6) | 0.1 | (0.3) |
| Operating profit/loss before tax | (74.2) | (41.6) | (37.1) | (24.9) | (13.0) |
| Profit/loss for the year | (69.6) | (38.0) | (32.2) | (22.8) | (10.7) |
| Total comprehensive income | (70.0) | (38.3) | (32.0) | (23.1) | (10.7) |
| Non-current assets | 8.2 | 3.6 | 2.6 | 3.1 | 1.7 |
| Current assets | 34.5 | 62.6 | 63.0 | 47.6 | 47.3 |
| Total assets | 42.7 | 66.2 | 65.6 | 50.6 | 49.0 |
| Equity | 25.3 | 56.2 | 56.1 | 44.3 | 44.5 |
| Non-current liabilities | 2.5 | 0.8 | 0.9 | 1.2 | 0.1 |
| Current liabilities | 14.9 | 9.2 | 8.7 | 5.1 | 4.4 |
| Total equity and liabilities | 42.7 | 66.2 | 65.6 | 50.6 | 49.0 |

| | 2019<br>DKK million | 2018<br>DKK million | 2017<br>DKK million | 2016<br>DKK million | 2015<br>DKK million |
|---|---|---|---|---|---|
| Cash flows from operating activities | (60.2) | (38.0) | (29.2) | (19.7) | (16.6) |
| Cash flows from investing activities, net | (2.1) | (1.5) | (0.1) | (0.4) | (0.5) |
| Of which investment in property, plant and equipment | (0.6) | (1.4) | (0.0) | (0.2) | (0.1) |
| Cash flows from financing activities | 33.6 | 39.1 | 40.7 | 20.8 | 26.5 |
| Total cash flows | (28.6) | (0.4) | 11.4 | 0.8 | 9.4 |
| Revenue growth | 2% | 3% | 21% | 2% | 9% |
| Gross margin | 65% | 69% | 73% | 76% | 76% |
| Equity ratio (solvency) | 59% | 85% | 85% | 87% | 91% |
| Average number of employees | 34 | 28 | 25 | 27 | 22 |
| Number of shares by the end of year (1,000) | 174,944 | 165,688 | 155,510 | 142,494 | 129,599 |
| Earnings per share (EPS), DKK | (0.41) | (0.24) | (0.22) | (0.17) | (0.09) |
| Net asset value per share, year-end, DKK | 0.14 | 0.34 | 0.36 | 0.31 | 0.34 |
| Share price, year-end, DKK | 2.93 | 3.50 | 3.31 | 2.10 | 4.82 |

# To BioPorto's shareholders

**Peter Mørch Eriksen**

CEO

## Locked on the Target

The year 2019 was important for BioPorto, with our focus locked on two strategic goals. First, we pursued our aim to expand knowledge of NGAL as an early and important biomarker able to improve outcomes for critically ill patients by allowing early identification of AKI. Second, we achieved Breakthrough Designation from the FDA for our application focused on patients under the age of 22. This was the first pediatric IVD Breakthrough Designation awarded by the FDA in many years.

While we have successfully increased awareness of NGAL for AKI diagnosis over the last several years, in 2019, this effort was bolstered by US governmental attention on kidney health initiatives, recognizing the significant need for improved treatment and diagnosis. A series of US public programs catalyzed by an executive order from President Trump are putting renal diseases at the center of healthcare policy. We expect this political attention to support the case for NGAL and the need to improve the diagnosis and management of AKI.

All was, however, not blue skies in 2019. In November it became clear that FDA, as part of their review of our pediatric application for The NGAL Test, was concerned about potential bias in the dataset on which we based our application. Though this dataset was part of a study published in *New England Journal of Medicine*, and the authors of the paper, as well as other leading nephrologists, disagreed with the Agency's bias concern, BioPorto decided to supplement our application with additional data in order to address the matter. Following a scheduled pre-submission dialogue with FDA in Q1 2020, we expect to collect and analyze the supplemental data and submit a revised pediatric application in Q2 2020.

The design and execution of the protocol for the additional pediatric data collection and submission of the revised application is BioPorto's single most important task in 2020. To lead this process, we have a new and experienced US medical, clinical and regulatory team with successful track-records in global medtech companies.

Our ability to attract experts from the largest companies in the world to our management team is testament to the strength of the product vision we have relentlessly pursued over the last few years. The team shares a conviction that BioPorto is an a unique position to help patients, providers and the healthcare ecosystem by changing a 50 year old practice into new standard of care for AKI risk assessment.

The importance of our mission is also validated by the strong support that we continue to receive from patient organizations, the clinical and scientific communities and the financial markets. In 2019, we raised DKK 36 million in cash from a share issue. Commitments from existing shareholders were renewed and we attracted new international shareholders and board members to our cause, which is an important affirmation and validation of our strategy, focus and potential.

As announced earlier we are currently pursuing financing. It was our ambition to finalize the financing prior to the announcement of our Annual Report 2019. However, the increased volatility and negative reactions in the financial markets caused by the global outbreak of the COVID-19 virus has pushed our timeline. We now expect the financing to be finalized by mid-April.

This financing represents an important milestone for the long term and will enable us to execute with single-minded focus on our key targets for 2020, which we hope will be a defining year in BioPorto's history.

Peter Mørch Eriksen

CEO

# Significant events in 2019 and financial guidance for 2020

## Regulatory development

### Submission of supplemented US application for The NGAL Test for pediatric use expected in the second quarter of 2020

In May 2019, BioPorto submitted its application to the FDA for marketing clearance of The NGAL Test for risk assessment of AKI in patients under the age of 22. Following a dialogue with the FDA, BioPorto announced in November that it had decided to supplement its pediatric application with additional data in order to fully respond to the feedback shared by the Agency.

The seminal study from which BioPorto drew its original dataset was published in *The New England Journal of Medicine*, and analysis of samples from this study demonstrated that The NGAL Test can be successfully deployed to assess risk of pediatric AKI in the critical care setting. However, during review of BioPorto's submission the FDA expressed concern over the risk of clinician bias inherent in the study's design and the potential impact of this bias on the NGAL application.

Taking the insights gained into FDA's thinking, BioPorto decided to build a follow-on dataset designed to address Agency's concern. The Company expects to submit a revised and supplemented application in the second quarter of 2020.

### FDA application for AKI risk assessment in adults to follow the pediatric submission

In 2019, BioPorto also continued to enroll patients in the US clinical study of The NGAL Test for AKI risk assessment in adults using plasma samples.

Having gained a deeper understanding of FDA's requirements during the regulatory process for the pediatric application, BioPorto seeks to improve and augment its ongoing adult studies to optimize its future adult submission. As a result, the company plans to submit its US application for adult risk assessment of AKI after the pediatric clearance is granted.

## Awareness and traction

### Political support and increasing awareness of kidney health on the US's healthcare agenda

BioPorto continued activities to build awareness of NGAL as an important and early biomarker for AKI in 2019. This activity centered on the US, where clinical experts, including intensivists and nephrologists, believe NGAL can have a significant impact on AKI identification, prevention and management strategies.

In July 2019, US President Donald J. Trump signed an executive order launching a kidney health initiative to improve the lives of Americans suffering from kidney disease. Through a series of programs, the US government aims to minimize end-stage renal disease through better diagnosis, treatment, and preventative care. BioPorto expects that this political focus will help provide additional policy momentum and increased governmental expenditures in kidney-related innovation.

The unmet clinical need for noninvasive tests to identify kidney injury is clear. Physicians want better tools to identify patients at risk of AKI, and to use that information to optimize their patient management. The desire for novel biomarkers was clear during the world's premier nephrology conference, Kidney Week, which took place in November 2019 in Washington DC. The conference included numerous studies related to both AKI and biomarkers like NGAL, giving BioPorto the opportunity to engage in discussions with leading nephrologists about the potential value of The NGAL Test.

### Quality assessments completed by significant industry partners

In 2019, Roche Diagnostics, a leading IVD player, undertook quality testing and documentation procedures to support use of The NGAL Test on their clinical chemistry instruments. Both Siemens and Roche have concluded all internal and external quality assessments to be prepared to launch the test following marketing clearance by FDA.

## FDA dialogue led to the decision to supplement the pediatric application for The NGAL Test

In November 2019, when BioPorto decided to supplement its regulatory application for pediatric risk assessment of AKI it was because FDA expressed concerns over potential bias in the design of the AWARE study – a study from 2014 published in *The New England Journal of Medicine* by a group of the world's leading nephrologists. It was this study that was the basis of BioPorto's retrospective analysis and application.

The dataset comprised 4,653 patients of which 1,261 developed AKI and 543 developed severe AKI. A subset of the samples were tested with The NGAL Test, with results showing strong clinical value with a sensitivity of 65.0% and a specificity of 81.8% and a negative predictive value of 95.4%.

However, the goal of the AWARE study was to select patients in the Intensive Care Unit (ICU) who were sicker and therefore more at risk of AKI. Therefore, only patients who the physician judged would still be in the ICU 48 hours after admission were included. This selection constituted a potential bias in the dataset, FDA argued.

As a consequence, BioPorto decided to supplement its pediatric application with data from a new study, and has set a target to submit the supplemented application for pediatric use of the NGAL Test in second quarter of 2020.

### BioPorto to focus on its own library of antibodies

Following a ceased collaboration with a supplier of antibodies, in 2019 BioPorto narrowed its strategic focus to center on biomarkers and sales of its own antibodies. Beginning in 2020, revenue from antibodies is therefore expected to normalize at a new level.

## Organization

### Strong commercial, clinical and regulatory additions to the US organization strengthen BioPorto

Throughout 2019, BioPorto added important resources to the organization to position the company for success in obtaining regulatory clearances and for future commercial growth.

In April 2019, Amy Winslow, former President and CEO of Magellan Diagnostics, was appointed President for BioPorto's US subsidiary, BioPorto Diagnostics, Inc. and member of BioPorto's Corporate Management. Amy is responsible for building and leading the US organization as BioPorto prepares to launch The NGAL Test for clinical use following expected clearance by the FDA.

In August 2019, Christopher Bird joined as Chief Medical Officer and member of BioPorto's Corporate Management. He was previously Head of North American Medical and Scientific Affairs for Roche Diagnostics Inc. At BioPorto he is responsible for building and executing the company's clinical regulatory program and for future diagnostic product development strategy.

In November 2019, Miranda Deverall joined BioPorto as Vice President of Regulatory Affairs from Roche Diagnostics Inc., where she led the team responsible for FDA submissions for clinical chemistry and toxicology reagents. With extensive experience in medical device submissions, clinical data review and validation of diagnostic devices she is responsible for submissions, Agency dialog and clearance of BioPorto's FDA applications.

### New members of BioPorto's Board of Directors

In August 2019, at an extraordinary general meeting, Christopher Lindop, a US citizen with deep experience in the management of US listed health care and diagnostic companies, and Michael Singer, a US citizen with significant experience in developing and launching new healthcare and biopharma companies, were both elected to the Board of Directors.

### US organization adjusted to reflect postponed FDA clearance

In December 2019, because of the adjusted timeline for expected FDA clearance of The NGAL Test, BioPorto reorganized its US commercial organization, leading to a five-person headcount reduction.

## Funding

### Successful share capital increase yielded gross proceeds of DKK 36.7 million

In June 2019, BioPorto completed a private placement cash issue. The proceeds are supporting the FDA application processes and will enable the Company to continue preparing for US commercialization, support sales and strengthen the company's overall liquidity.

In total, 9,256,577 new shares at nominally DKK 1 each, equivalent to 5.59% of BioPorto's registered share capital prior to the capital increase, were offered at a subscription price of DKK 3.97 per share. The Board of Directors had received binding advance subscription commitments for the entire offering of new shares from existing shareholders and new US investors. The fully subscribed and successful private placement yielded gross proceeds of DKK 36.7 million.

## Financial results for 2019

### Performance in 2019 on par with revised expectations

BioPorto's 2019 revenue totaled DKK 27 million, compared to DKK 26 million in 2018, corresponding to a growth of 2.3%. Revenue from NGAL in the US was up 9% from 2018 to 2019 and total NGAL sales grew 9% in the same period. In 2019 total revenue from antibodies was at the same level as in 2018. Growth leveled off in fourth quarter 2019 due to the ceased collaboration with an antibody supplier. The change in antibody revenue in the last quarter of 2019 was the primary reason for total revenue being slightly below the Company's prior guidance of DKK 29 million for 2019.

The operating loss (EBIT) for the full year 2019 was DKK 74 million compared to an EBIT loss of DKK 42 million in 2018. BioPorto incurred higher costs related to the build-up of the US organization, full-year effects of hiring in 2018 and costs related to the ceased collaboration with a vendor.

## Financial Guidance for 2020

### Focus on collection of additional data for FDA clearance of The NGAL Test and growth in NGAL revenues

In 2020, BioPorto's focus will be to collect the additional data required to submit an updated application for The NGAL Test for pediatrics to the FDA, with the expectation of clearance following standard Agency timelines. During the year the Company will also work to secure data to support a bolstered application for FDA clearance of The NGAL Test in adults and will begin to review new opportunities for NGAL and the antibody library in order to define a pipeline of future targeted assays and biomarkers.

BioPorto expects revenue of approximately DKK 30 million in 2020. The top line will be supported by an increase in NGAL revenues across regions, while sales of antibodies and ELISA kits are expected to decline due to BioPorto's narrower focus on its own antibody library. It is expected that revenue will be back-end loaded, with approximately one third of the revenues in 1H 2020, one third of the revenues in the third quarter of 2020 and one third of the revenues in the fourth quarter of 2020.

BioPorto expects to incur an operating loss (EBIT) of approximately 73 million affected by full year impact of 2019 hires and by higher costs related to clinical studies.

The guidance does not include any sales of an FDA-cleared NGAL test in the US in 2020.

As disclosed in note 22 to the consolidated financial statements, the Board of Directors will, together with Management, monitor the development of the Company's cash position throughout 2020, ensuring appropriate financial readiness at all times.

| | 2019 financial guidance | 2019 actual | 2020 financial guidance |
|---|---|---|---|
| Revenue | Approximately DKK 29 million | DKK 27 million | Approximately DKK 30 million |
| EBIT | Loss of approximately DKK 70 million | Loss of DKK 74 million | Loss of approximately DKK 73 million |

## Events after the reporting period

There have been no events after the balance sheet date which would have a significant impact on an assessment of BioPorto's position as of December 31, 2019.

### 2020 OBJECTIVES

- Commence and finalize collection of additional patient data for the FDA application of The NGAL Test for pediatrics
- Obtain FDA approval of The NGAL Test for pediatrics
- Collect supplementary data to support submission of an application for The NGAL Test in adults
- Review new opportunities for NGAL and BioPorto's antibody library; define a pipeline of targeted assays and biomarkers
- Grow total revenue by 10%

# Strategy and objectives

## Business model based on R&D and product development as core competencies

BioPorto's business model is designed to leverage its unique library of monoclonal antibodies and its assay development expertise to transform novel research tools into actionable biomarkers that address unmet clinical needs to make a difference in patients' lives.

BioPorto's value creation is based on three key deliverables. First, on the research and development of assays and biomarkers from its antibody library. Second, on rigorous quality assessment and development processes that can bring new products to and through regulatory review and approval. Finally, commercialization based on internal expertise to build product knowledge and value propositions that resonate with experts and early adopters, and the ability to create collaborations with industry partners to leverage their scale to gain global momentum and broad market penetration.

Production of antibodies and tests is outsourced to selected, highly qualified manufacturers around the world to ensure supply chain flexibility.

The NGAL Test is an example of BioPorto's transformation of an antibody from discovery to a commercially available clinical assay. Initially developed as a unique monoclonal NGAL antibody, it was transformed into a microtiter plate assay for research, and subsequently to The NGAL Test for automated testing on clinical chemistry systems. Today, the test is sold directly and via partners to hospitals' central laboratories in Europe and Asia.

### Vertical and horizontal pipeline

BioPorto's strategy is based on a combination of horizontal and vertical product development. The Company's horizontal pipeline is defined by the development of individual biomarker candidates derived from research and development activities based on its antibody portfolio. In addition to the NGAL biomarker for early detection of AKI, BioPorto plans to evaluate targets in obesity, immune defense and other areas of significant medical interest. BioPorto's vertical pipeline is defined by leveraging opportunities for individual biomarkers that are developed by uncovering, evaluating and pursuing clinical and regulatory approval for novel indications and applications.

For example, following regulatory clearance in pediatrics and adults for AKI, BioPorto intends to explore further vertical opportunities for The NGAL Test, such as for nephrotoxicity, therapeutic monitoring, evaluation of trauma, and transplant assessment, all of which will ensure that the product's full potential is maximized for the benefit of patients and the healthcare system.

## Optimizing conditions for FDA clearance

In 2020, BioPorto's strategic focus is on two primary end-points. First, collecting additional patient data for the submission to the FDA for risk assessment of AKI children, and second, to continue to build awareness and support in the US for novel, early biomarkers of AKI and to expand research testing with NGAL. Both elements are essential to build a strong foundation in the US for the NGAL platform.

**Antibody Library**

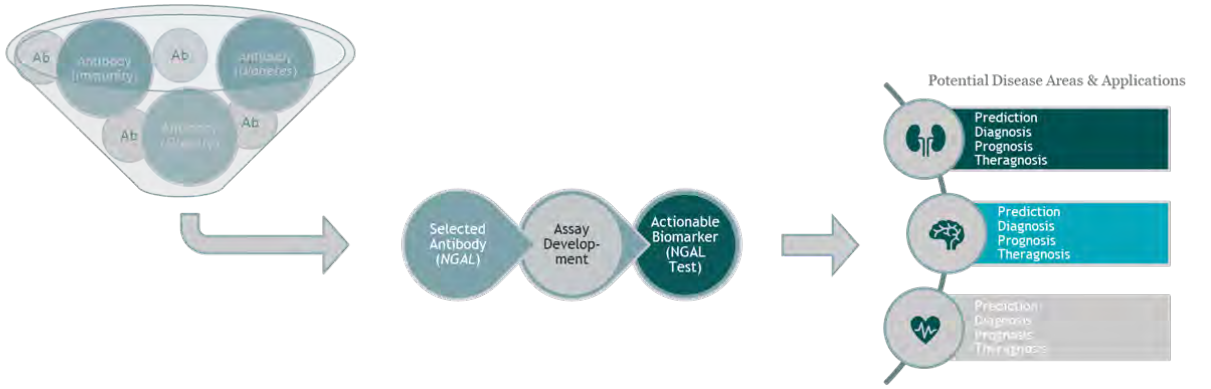
- 150+ Abs in significant disease states
- Steady revenue source (275+ customers in 40+ countries)
- Insight into high value diagnostic targets

**Assay Development Expertise**

- Technical expertise: ELISA kits, automated assays & rapids
- Partnerships with key academic researchers & institutions
- Production/scale up partnerships

**Actionable Biomarkers**

- Novel markers that address unmet clinical needs
- Thought leader supported, IP protected
- Expertise & partnerships needed to drive awareness/education



## Redesigned US application for pediatric use of The NGAL Test to be submitted in the second quarter of 2020

Following a dialogue with the FDA in November 2019 on the US application for regulatory clearance of The NGAL Test for pediatric risk assessment of AKI, BioPorto decided to supplement its application with additional data and plans to submit a revised application in the second quarter of 2020.

The design and execution of the protocol for the additional data collection and submission of the application is BioPorto's single most important task in 2020. The regulatory strategy and execution are the responsibility of BioPorto's strengthened R&D and regulatory teams under the direction of BioPorto's Chief Medical Officer, Christopher Bird, and the VP of Regulatory Affairs, Miranda Deverall. Together they form a leadership team with a track-record of driving FDA applications from start to successful completion during their tenures at Roche Diagnostics.

BioPorto's regulatory team, based on their experience and on input from experts, believes that the revised pediatric application will most likely be a *De Novo* 510(k) application, which is a type of 510(k) for novel devices and diagnostics that are low risk and that do not have another similar product to which they can be compared (called a predicate device). The type of 510(k) application will be determined following a pre-submission dialogue with the FDA, scheduled in Q1 2020.

Comparison of FDA submission types

| | ***De Novo* 510(k)** | **Traditional 510(k)** |
|---|---|---|
| Method | Safety and efficacy | Substantial equivalence |
| Comparison | None – use scientific evidence | Predicate device |
| Risk assessment | Yes | No |
| Agency review timeline | 150 days | 90 days |

## Insights gained from the pediatric application to inform the adult application

Based on the experiences and deeper understanding of FDA's requirements gleaned from regulatory discussions over the course of BioPorto's pediatric application, the Company seeks to improve and augment its ongoing adult studies in 2020. Optimizing the FDA application process for The NGAL Test for risk assessment of AKI in adults should smooth the review process for this next application, which BioPorto plans to submit once the pediatric application is concluded.

## Expansion of NGAL knowledge to drive market penetration and future growth of The NGAL Test

Parallel to enrolling patients for clinical studies and finalizing the application for pediatric use of The NGAL Test, BioPorto will continue its efforts to cultivate awareness and interest in novel AKI biomarkers and grow scientific research on NGAL in 2020.

BioPorto saw a dramatic increase in attention on improving kidney health in 2019 along with the acknowledgement of the vast unmet need for innovation in the diagnosis and management of kidney disease. The US public policy focus brought to this area is expected to add momentum to BioPorto's efforts to highlight the need for novel management approaches for AKI.

# Products and markets

BioPorto's product portfolio and pipeline is comprised of highly specialized, unique diagnostic tests that provide information that helps physicians detect disease, select appropriate treatments and monitor response to therapy. In addition, prior to clinical stages, researchers use the Company's antibodies and assays to better understand the cause of disease and to help discover and develop new treatments for significant medical conditions.

BioPorto's pioneering product portfolio features more than 150 highly specific monoclonal antibodies that the company has developed.

BioPorto serves customers such as hospitals and clinics, biopharmaceutical companies, laboratories and scientific research institutions globally through its own sales organization, as well as through distribution partnerships.

## The NGAL Test

### NGAL is a leading biomarker for acute kidney injury

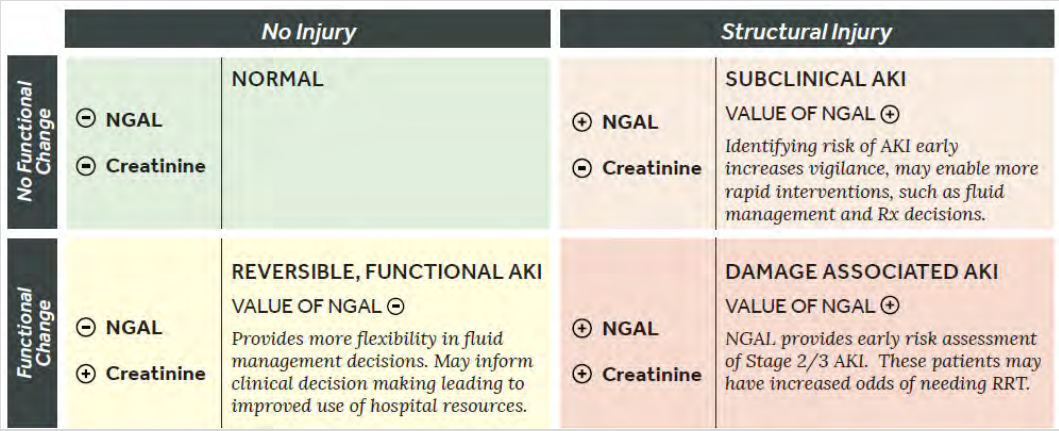
BioPorto's lead product is The NGAL Test, a particle-enhanced turbidimetric assay that measures Neutrophil Gelatinase-Associated Lipocalin (NGAL) and is designed for use on clinical chemistry analyzers.

The NGAL Test is available for in vitro diagnostic use in the European Union, Canada, Korea and Israel and is for research use only in all other territories.

### Acute kidney injury affects millions of lives each year

Acute kidney injury (AKI) is a sudden loss of kidney function typically caused by another serious illness, such as sepsis, or intervention, such as cardiac surgery.
Because pain and other symptoms do not often occur, AKI can be difficult to identify, but to preserve kidney function it is essential to detect and manage AKI promptly. AKI is common – occuring in 20-25% of hospitalized patients – and is associated with poorer outcomes, longer length of hospital stays, increased use of renal replacement therapy (dialysis), and higher risk of mortality. Because there is no AKI-specific therapy, rapid identification of patients who are at risk is critical to preserve kidney function.

**NGAL Biomarker Integrated with Creatinine**

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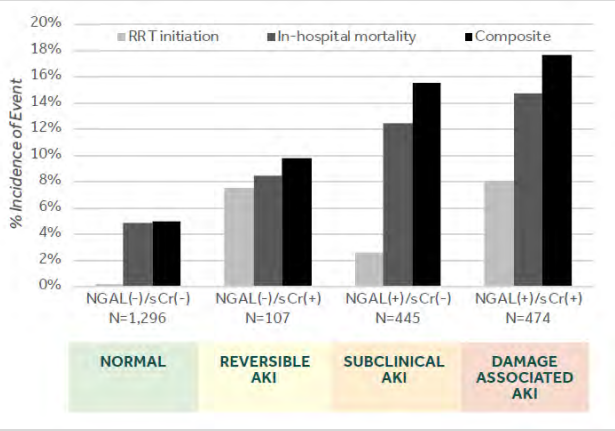
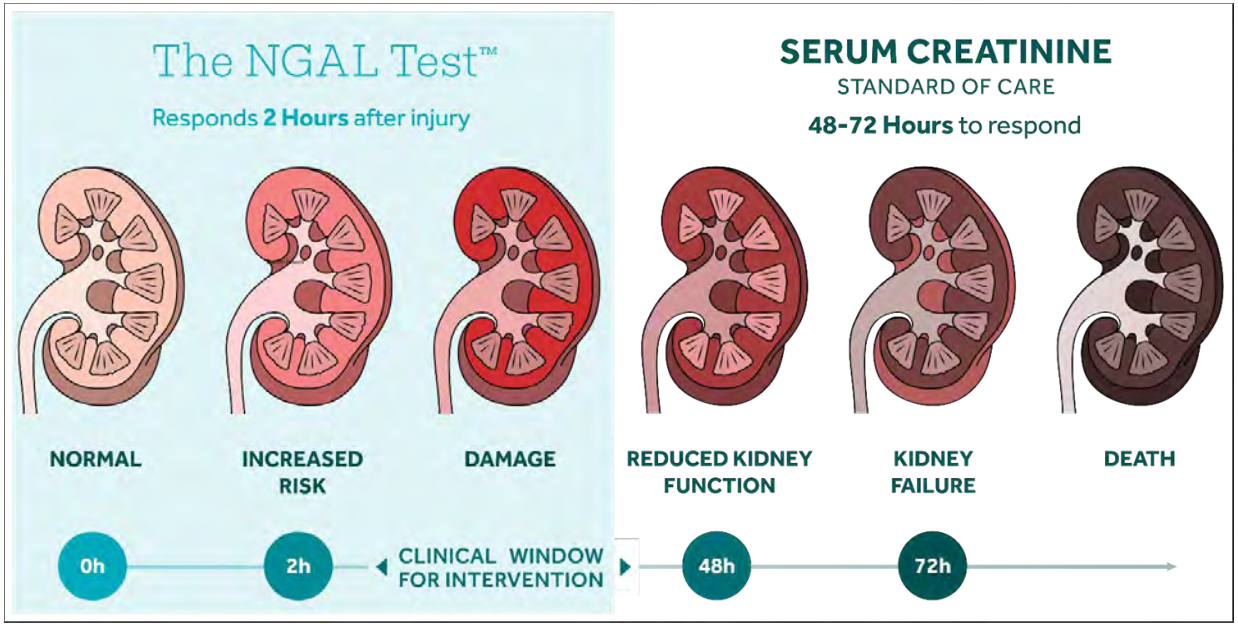



Adapted from: Haase M et al. J Am Coll Cardiol. 2011;57(17):1752–1761.

The use of NGAL as a marker of renal tubular injury supplements the standard of care test, serum creatinine, which is a measure of kidney function. Adding NGAL can refine the clinical picture and help physicians make better management decisions, particularly in those cases where NGAL differs from creatinine. For example, patients who are NGAL positive but creatinine negative may have kidney injury that has not yet caused a change in kidney function, called subclinical AKI. In these cases, without NGAL the diagnosis of AKI could be missed. Alternatively, when NGAL is negative and creatinine is positive, patients may be experiencing a reduction in function due to volume depletion but not structural injury, which is known as functional, or reversible, AKI. In these cases, the use of NGAL may allow physicians to maintain flexibility in fluid management and avoid overtreatment.




The NGAL Test is for in vitro diagnostic use in the European Union, Canada, Korea and Israel. For research use only in all other territories.

NGAL is a small protein expressed in the distal tubules of the nephron that binds and transports iron-carrying molecules. It is one of the most rapidly upregulated genes and overexpressed proteins in the kidney following ischemic or nephrotoxic injury. NGAL is detectable in both urine and plasma as quickly as 2 to 3 hours after injury, allowing for rapid identification of AKI, a condition characterized by rapid loss of renal function that can lead to a serious inability to maintain fluid, electrolyte and acid-base balance.

NGAL is well studied, and has been described in many scientific journals – over 2,000 papers in the last 10 years have been published on the biomarker and its myriad applications.

## The NGAL Test: an important step in early identification of AKI risk

The NGAL Test measures NGAL in either urine or plasma and runs on standard clinical chemistry analyzers. Results using The NGAL Test can be available just a few hours after a potential AKI incident.

By comparison, serum creatinine, the current standard of care measurement for AKI, is a late marker of kidney function. It generally peaks 48-72 hours after kidney injury, and may not rise until over half of a patient's kidney function has already been lost. Serum creatinine is also a marker influenced by many non-renal factors, such as age, gender, muscle mass, and nutritional status, making it even more challenging to interpret clinically.

Apart from serum creatinine, NEPHROCHECK® is the only CE-marked and FDA approved product available to aid in the detection of AKI. NEPHROCHECK is a test based on two cell-cycle arrest biomarkers (TIMP-2 and IGFBP7) and can only be measured in urine. The test is performed on a single-use cassette and requires a separate, stand-alone meter to complete the analysis. It is cleared for use in adult patients with acute cardiovascular and or respiratory compromise who are in the intensive care unit.

Using The NGAL Test to supplement serum creatinine and clinical evaluation will enable physicians to identify patients at risk of developing AKI earlier, take more appropriate action to manage fluid levels, avoid nephrotoxic agents, and potentially avoid permanent kidney damage. BioPorto believes that improved management of AKI can reduce hospital lengths of stay, minimize unnecessary interventions, inform treatment choices, and ultimately improve health and economic outcomes for patients, providers and healthcare systems.

## The NGAL Test addresses a significant market

Commercially, BioPorto focuses on four medical specialties: cardiac surgery, critical care, transplant and pharmacy through its own sales representatives, regional distributors as well as through distribution and licensing agreements with global partners.

A CE-marked and registered version of The NGAL Test is currently available for prediction of AKI risk in adults in Europe and Asia. In the US a Research Use Only (RUO) kit of The NGAL Test is available for scientific research.

The US market is the largest and most significant IVD market, representing approximately 44% of global diagnostic testing (Kalorama, August 2018 IVD Report; pg 115). BioPorto estimates that the addressable global market for The NGAL Test for risk prediction is approximately USD 2 billion annually, or about 100 million tests. Expansion to other markets is expected as the Company develops the test vertically into new clinical areas, such as for nephrotoxicity, for use in emergency departments to rule out AKI, for therapeutic monitoring and for triage of trauma victims. Addressing these additional opportunities, each of which would require clinical testing and regulatory applications, could expand the total addressable market for The NGAL Test to up to

250 million tests annually with an estimated value of more than USD 5 billion, assuming a price of USD 20 per test.

## NGAL ELISA kits

BioPorto also produces a CE marked NGAL ELISA kit for human use. It is widely used in research, and to a lesser extent in clinical practice, where real-time results using The NGAL Test on automated systems is preferred.

An important use of NGAL ELISA kits is in clinical trials in the biopharmaceutical industry, where NGAL is used in safety studies to evaluate the potential renal side effects from a drug candidate. BioPorto also provides NGAL ELISA kits for five different animal species that cover a broad spectrum of preclinical research testing.

As a result of BioPorto's pivot to focus on its own antibodies, rather than insourced products, MBL ELISA kits were phased out of the Company's portfolio in 2019.

## Antibodies

BioPorto's library of antibodies contains more than 150 of its own monoclonal antibodies, spanning different research disciplines such as microbiology, immune deficiency, peptide hormones and plasma proteins. New antibodies are frequently added to expand offerings in clinical areas of interest to customers.

One important area in the Company's antibody library is peptide hormones, such as GLP-1 (glucagon-like peptide-1), which is critical to the development of a new generation of products aimed at treating Type II diabetes and obesity.

BioPorto's antibodies are sold worldwide directly and through distributors. The competitive landscape for BioPorto's antibody portfolio varies significantly. For certain antibody targets competition is extremely limited, while other antibodies are available in similar versions by other manufacturers, and therefore face strong competition.

## Generic Rapid Assay Device (gRAD)

The gRAD is designed to speed up the development of customers' rapid assays.

The gRAD strip is an optimized standard lateral flow strip with a test line where a biotinylated capture antibody or other proteins will bind, and a control line that will capture any antibody. When a sample of interest is added to the antibody solution, the antibodies then react and can form a complex with the analyte in the sample.

With no specific antibodies initially immobilized on the strip, testing a variety of biomarkers and labeling systems will become much more flexible and easier, yielding a significantly faster development process.

BioPorto is currently testing and validating the gRAD platform for a NGAL ds in various countries and environments. The test is being sold for RUO in the US, where interest is building.

## Intellectual property rights

BioPorto has generated several patents within the area of NGAL. Together with additional NGAL patent families in-licensed on an exclusive basis from the Trustees of Columbia University, the patents constitute an important asset for optimizing future NGAL AKI market share, IP-protection of The NGAL Test and partnerships with diagnostic companies.

Two of BioPorto's patents are currently being challenged post grant: Before the European Patent Office (NGAL Exclusion) and in South Korea (NGAL Cutoff). The possible outcome is that the patents will be upheld; that the patents will be upheld in part; or that the patents will be revoked.

## Registration

For a diagnostic product to be marketed for clinical use, the product must undergo a registration process with the health authorities in each country. The NGAL Test has qualified for registration in several countries, including the European countries, South Korea, Canada, India and Israel. The company's human NGAL and ELISA kits are also registered in several countries, including east European countries, Canada, India, Iran, Chile and several north African countries (Algeria, Morocco and Tunisia), Israel and Australia (only ELISA kits in Australia).

| **BioPorto's NGAL patents & In-licensed NGAL patents** | **Europe** | **USA** | **Rest of the World** |
|---|---|---|---|
| NGAL Cut-off patent | Two patents issued. Divisional application pending | Application pending | Issued in Australia, Hong Kong, India, Japan, China, Singapore, South Korea. Pending in Canada |
| NGAL Exclusion patent | Issued, under opposition | Application pending | - |
| NGAL Ratio patent | Issued | Issued | - |
| NGAL Trauma patent | Issued | Issued (Radiation), continuing application pending | - |
| NGAL Forms patent | Issued | - | - |
| NGAL Serum/Plasma patent (In-licensed) | Two patents issued | Application pending | Issued in Australia, Canada, China, Japan |
| NGAL Blood patent (In-licensed) | Issued | - | - |
| NGAL Urine patent (In-licensed) | Three patents Issued | - | Issued in Australia, Brazil, China, Japan, Mexico, New Zealand, Hong Kong |
| NGAL Chronic patent (In-licensed) | Two patents issued | - | - |
| NGAL Kidney dysfunction (In-licensed) | - | Issued | - |

# Risk management

Risk management is an integrated part of BioPorto's operations. The Company identifies material risks that could affect revenues, development, production, future performance, or the interests of the shareholders with the purpose of running the Company in accordance with best practices in its industry.

All units in the Company participate in the identification and assessment of operational risk factors in order to address them properly. Risk Management is part of the Rules of Procedures for the Audit Committee. The Board of Directors receives updates and recommendations on initiatives, which then form part of the Board's overall assessment and decision on the Company's activities and future.

In 2019, the Company partly finalized its work on securing alternative manufacturing capabilities by identifying and validating a manufacturer for antibodies according to the Company's Quality procedures.

The work of securing alternative manufacturing options to ensure a reliable supply of actionable biomarkers will continue in 2020.

In November 2019, the Company received feedback on the US application for regulatory clearance of The NGAL Test for pediatric risk assessment of AKI. Following a dialogue with the FDA, BioPorto decided to supplement its application with additional data and plans to submit a revised application in the second quarter of 2020.

In June 2019, the Company concluded a financing round and issued approximately 9.3 million new shares in a private placement. The gross proceeds from the financing amounted to DKK 36.7 million.

In 2019, the Company continued its work with data protection and implemented the GDPR framework.

The primary risks in 2019 related to: the enrollment of patients in the US NGAL adult study; the submissions and clearances of The NGAL Test for adults and children; the preparation and launch of the test in US following regulatory clearances; antibody sales; and the establishment of alternative manufacturing sources. In 2019, antibody sales were impacted by a ceased collaboration with a supplier.

In 2020, the primary risks will be related to the gathering of additional data and filing the submission for FDA clearance of The NGAL Test in pediatrics as well in securing continued growth in NGAL revenues.

The design and execution of the protocol for the additional pediatric data collection and submission of the application is the single most important task in 2020.

As announced earlier the Company is currently pursuing financing. It was the ambition to finalize the financing prior to the announcement of the Annual Report 2019. However, the increased volatility and negative reactions in the financial markets caused by the global outbreak of the COVID-19 virus has pushed the timeline. The Company expects the financing to be finalized by mid-April.

## Risk Factors

Expectations and assumptions in the annual report concerning BioPorto's business – the market for diagnostics in AKI and antibodies – and the Company's revenue, accounting results and expected market share are subject to substantial uncertainty. There is no guarantee that the Company in whole or in part will achieve its expectations for revenue or the profit/loss for the year. The most significant operational risks are:

- The Company's cash preparedness and ability to obtain funding necessary to fulfill the Company's strategy
- Submission and clearance of application by FDA in US for The NGAL Test in children
- Preparation and launch of The NGAL Test in the US market
- Preparation of submission of application to FDA in US for The NGAL Test in adults
- Securing an alternative manufacturing option for the Company's actionable biomarkers
- Cyber attacks
- Warning letter from FDA and/or failed inspections from various regulatory authorities

Other short-to-medium-term uncertainties include, but are not limited to the following:

- Antibody sales
- Competing technologies adversely affecting the market roll-out of The NGAL Test
- Protection of patents and other intellectual property rights
- The ability to obtain the Freedom to Operate in commercially relevant markets
- The ability to prevent competing companies from having Freedom to Operate in commercially relevant markets
- The ability to attract and retain key personnel
- Performance and dependence of the Company's subcontractors; most significantly CMOs and CROs
- Collaborative agreements, including distribution agreements
- Duration and outcome of review processes by various regulatory authorities
- Clinical development and data from pipeline projects
- Risks relating to the Company's technologies, projects and products
- Risks relating to trade receivables and inventory
- Changes in the USD exchange rate and its impact on the free liquidity, future revenue and net finances
- Tax risks
- Risks related to IT in general

The Company's risks further include the ability to enter into collaborations with partners for development, manufacturing, marketing

and financial resources. There are additional risks related to sales contracts and the related production and logistics.

Currency risks include the risk arising from sales and production contracts being denominated in currencies other than Danish kroner. Contracts are primarily in USD and EUR, meaning that other currencies do not represent significant currency risks.

Revenues and contracts are still relatively modest and thus the Company is not hedging its USD exposure. However, the Company is monitoring its USD exposure and will be ready to use financial instruments to hedge this exposure if the need arises. As long as the DKK is linked to the EUR the Company's revenue and costs in EUR will not be hedged.

## Internal controls

The Board of Directors and the Management of BioPorto are responsible for the Company's control and risk management in connection with the financial reporting process, including compliance with rules and regulations that are relevant in reporting.

The Board of Directors has established an Audit Committee which reviews and discusses the accounting and audit practices with the Company's auditors and Management in accordance with the Rules of Procedures of the Audit Committee.

BioPorto's main focus in this area is to ensure that its financial statements are in compliance and give a correct and reliable view of the Company's operations and financial position.

The annual audit and reporting process include detailed planning of individual tasks and planning between investor relations, finance and the auditors. It is based on an audit strategy approved by the Audit Committee.

At least once a year the Audit Committee evaluates the risks connected with the financial reporting process, including the presence of internal controls and guidelines. The Audit Committee assesses the Company's organizational structure, including the risk of fraud and the measures to be taken to reduce and/or eliminate such risk.

In that regard, any incentive or motivation of Management to manipulate earnings or perform any other fraudulent action is discussed.

The Company's internal controls and guidelines provide a reasonable but not an absolute certainty that unlawful use of assets, loss and/or significant errors or deficiencies in relation to the financial reporting process can be avoided.

The Board of Directors has decided not to institute an internal audit at BioPorto, based on its assessment that the Company's size and complexity does not necessitate such a function.

# Corporate governance of BioPorto

In its corporate governance, BioPorto focuses on investor relations, and the Board of Directors gives priority to exercising good corporate governance as defined by the company's articles of association, values and policies, as well as relevant legislation and "Rules for issuers of shares" issued by NASDAQ Copenhagen A/S.

## Recommendations for Corporate Governance

BioPorto is covered by the recommendations of the Committee for Corporate Governance, which are available on:
www.corporategovernance.dk.

The Board of Directors regularly assesses how the Recommendations may contribute to strengthening the management of BioPorto and ensure maximum value creation for the Company's shareholders.

Once a year, the Board of Directors reviews the Recommendations and evaluates BioPorto's compliance with the Recommendations. The Board of Directors believes that BioPorto has complied with all but three of the Recommendations.

BioPorto has a vesting period or maturity period, of 24 months on all share-based compensation instead of 36 months as stipulated in the recommendations article 4.1.2 and 4.1.4. The Board of Directors has made the assessment that a vesting or maturing period in BioPorto's warrant programs should be 24 months, and should be below the recommended level, in order to motivate the recipient to implement the company's short-term goals that are relevant to the company's long-term value creation. In 2019 two warrant programs (June 2018 and August 2018) had the vesting period extended from 24 to 36 months. At the same time the exercise period for the two programs was reduced from 36 to 24 months.

Further, due to the size of BioPorto, the company does not have a Whistleblower Scheme as stipulated in the recommendations article 5.2.

The mandatory review of corporate governance, pursuant to Section 107b of the Danish Financial Statements Act, is found on the company's website.

## Work of the Management and Board of Directors

The Board of Directors defines BioPorto's objectives, policies and areas of activity. Furthermore, the Board of Directors makes decisions in all unusual matters or matters with far-reaching implications. In addition, the Board of Directors approves, monitors, evaluates and revises the Executive Board's business strategy and action plans.

The Board of Directors also ensures that BioPorto is properly managed as required by the Articles of Association, other guidelines, policies and applicable rules and regulations. The Board of Directors defines guidelines for the distribution of responsibilities between the Board of Directors and the Executive Board but does not participate in the day-to-day management of the Company.

The duties of the Board of Directors are described in the Rules of Procedure for the Board of Directors and the Executive Board. The Board of Directors held 16 Board meetings in 2019, including one full-day strategy meeting. Five (5) meetings are planned for 2020 in accordance with the Board of Directors' annual schedule, which may be changed at any time to allow for additional meetings, if necessary.

The Board of Directors appoints the Company's Executive Board and defines the working conditions and assignments to be undertaken by the Executive Board. BioPorto's Executive Board is responsible to the Board of Directors for ensuring that day-to-day operations are conducted in a commercially and legally responsible manner.

## Evaluation of the performance of the Board of Directors and the Executive Management

The Chairman of the Board of Directors is responsible for evaluating the Board of Directors and the Executive Board every year. The evaluation also includes the collaboration with the Executive Board and the composition and special qualifications of the Board of Directors, and it must produce an assessment of the results achieved during the year, which are subsequently presented and discussed at a Board meeting and accounted for in the management's review. External assistance is obtained at least every third year to conduct the survey.

In 2019, the Chairman of the Board concluded that the Board of Directors now has US experience and competencies among the Board members, due to the addition of two new US Board members.

## Composition of the Board

The general meeting, which is BioPorto's supreme authority, elects between three and seven members to the Board of Directors. The Board of Directors elects a Chairman and a Vice Chairman and currently consists of five members elected by the shareholders.

The members elected by the shareholders hold office for terms of one year at a time and may be re-elected. The members of the Board are nominated and stand for election on the basis of their specific qualifications and experience of relevance to BioPorto. Thus, the Board of Directors is composed with a view to ensuring an optimum combination of professional industry experience in general, in research and development, in IP rights and conclusion of contracts, in sales and marketing, as well as in finance and economics. All current Board members are considered independent persons, in order for the Board of Directors to be able to act independently. Each Board member's special qualifications may be found on the Company's website.

## Board committees

BioPorto's Board of Directors has set up a Remuneration and Nomination Committee, an Audit Committee, and a Business, Research and Development Committee. The Vice Chairman of the Board of Directors is Chairman of the Audit Committee and possesses the necessary professional qualifications and experience. A review of the terms of reference of the Board Committees and their composition is available on the Company's website.

## Amendments to the articles of association

The general meeting adopts amendments to the articles of association and takes all other decisions based on a simple majority, provided that a

specific majority or representation is not required pursuant to the provisions of the Danish Companies Act or the articles of association.

## Remuneration policy and Remuneration Report

This Section constitutes BioPorto's Remuneration Report for 2019.

Each year, the shareholder meeting approves the remuneration of Board members, and any remuneration for alternates, for the current fiscal year. The Board does not participate in the company's share-based compensation.

The basic fee of the Board is set at a level assessed as being competitive and reasonable compared to the sector in general and the company's current situation. Board members are paid a fixed annual remuneration, while the Chairman and Vice Chairman, according to a specific decision of the shareholder meeting, can be remunerated with a higher fee.

If a committee is established, or if Board members are charged with performing special tasks for the Board, the Board may submit a recommendation to the shareholder meeting that supplementary remuneration be provided. The Board may submit a recommendation to the shareholder meeting that alternates should also receive remuneration.

In 2019 the Annual General Meeting approved a fee of DKK 250,000 per ordinary Board member, and a fee of DKK 350,000 to the Vice Chairman and DKK 500,000 to the Chairman. Further it was approved that participation in a committee is remunerated with a supplementary fee of DKK 25,000 per committee, but with an overall cap of DKK 50,000 per ordinary Board member. The Chairman and Vice Chairman do not receive supplementary fees for committee participation.

BioPorto's remuneration policy can be found on the company's website.

The remuneration of the Executive Management is set at a level deemed competitive and reasonable compared to the sector in general and the company's current situation. The Executive Management does not receive remuneration for being a member of the Management or Board of BioPorto A/S's Danish subsidiaries. The Executive Management receives remuneration for management positions in US subsidiaries of BioPorto A/S.

The remuneration comprises a fixed salary, pension scheme, annual bonus and participation in share-based compensation. In the view of the Board, a combination of fixed and performance-dependent salary for the Executive Management helps to ensure that remuneration, which is in part incentive-based, motivates the Executive Management to create added value for the benefit of the shareholders.

The annual bonus may comprise 150% of the fixed yearly salary. This may also involve a retention bonus, loyalty bonus or similar. Whether a bonus is paid out, will depend on whether the terms, conditions and targets defined in the agreement were achieved in part or in full. This may involve personal targets associated with the specific director's own performance, BioPorto's results or the occurrence of relevant events.

In 2019, the Executive Management was made up of one person. In 2019, the Executive Management was paid DKK 4.9 million (in salary, including pension (contribution-based) and bonus, excluding share-based compensation.

| Remuneration<br>Executive Management<br>Covering BioPorto A/S and its subsidiaries<br><br>**Peter Mørch Eriksen, CEO** | 2017 | 2018 | 2019 |
|---|---|---|---|
| Base Salary | DKK 2,695,255 | DKK 3,025,529 | DKK 3,279,660x |
| Contribution based pension | DKK 420,000 | DKK 483,000 | DKK 528,000x |
| Bonus Agreement | Annual bonus: DKK 255,000 | Annual bonus: DKK 229,000<br>Long term incentive bonus plan: DKK 85,179 | Annual bonus: DKK 360,000<br>Long term incentive bonus plan: DKK 704,415 |
| - Explanation | Annual Bonus KPI: Based on revenue growth, EBIT target and certain must win battles that supports the goals for 2017 set forth in the Annual Report 2016. | Annual Bonus KPI: Based on revenue growth, EBIT target and certain must win battles that supports the goals for 2018 set forth in the Annual Report 2017.<br><br>LTI: In December 2018 a Long term incentive bonus plan was established with a value of up to DKK 3,000,000 if the following KPI's are fulfilled.<br>KPI: FDA clearance of NGAL (pediatric) 1/3 of bonus amount; and FDA approval of NGAL (adult) 2/3 of bonus amount. | Annual Bonus KPI: Based on revenue growth, EBIT target and certain must win battles that supports the goals for 2019 set forth in the Annual Report 2018.<br><br>LTI: FDA clearance of NGAL (pediatric) to be achieved no later than December 19, 2020 (extended from December 31, 2019). FDA clearance of NGAL (adult) to be achieved no later than December 31, 2021 (extended from December 31, 2019) |
| Warrant Agreement | Cost occurred in year DKK 1,250,398<br><br>2,400,000 warrants<br><br>2017 program: All warrants forfeited under the 2017 program – non-achievement of KPI. | Cost occurred in year DKK -240,805 as the 2017 warrants program was forfeited in 2018<br><br>New warrants programs<br><br>August 2018 program: 1,700,000 warrants<br><br>December 2018 program: 1,800,000 warrants | Cost occurred in year DKK 1,064,745<br><br>New warrants programs<br><br>April 2019 program: 1,350,000 Warrants |
| - Explanation | KPI: FDA clearance of The NGAL Test before December 31, 2018. | August 2018 program KPI: FDA clearance of The NGAL Test, 50 new sites in 2019, and 100% revenue growth in NGAL in 2019.<br><br>December 2018 program KPI: FDA clearance of NGAL (pediatric or adult) in 2019 and; 50 new hospital customer sites in the US are achieved no longer than 12 months after the clearance and; the company achieve NGAL revenue growth of 100 % (in local currency in the US) in the 12 months after the clearance compared to the 12 months before the clearance. | April 2019 program KPI: No KPI's associated with the warrant program.<br><br>December 2018 program KPI: FDA clearance of NGAL (pediatric or adult) no later than December 19, 2020 (extended from December 31, 2019). |
| Termination of employment relationship | 12 months' notice effective at the end of a calendar month. | 12 months' notice effective at the end of a calendar month. | 12 months' notice effective at the end of a calendar month. |
| Agreement regarding severance pay to the Executive Management | None | None | None |
| Agreement regarding severance pay entered into for the event of a change of control to the Executive Management | None | None | None |

| Remuneration Board of Directors | 2017 Base fee | 2017 Committee fee | 2018 Base fee | 2018 Committee fee | 2019 Base fee | 2019 Committee fee |
|---|---|---|---|---|---|---|
| Thomas Magnussen | 500,000 | - | 500,000 | - | 500,000 | - |
| Torben A. Nielsen | 350,000 | - | 350,000 | - | 350,000 | - |
| Kirsten Drejer | 173,611 | 34,722 | 250,000 | 50,000 | 250,000 | 50,000 |
| Christopher Lindop | - | - | - | - | 93,750 | - |
| Michael Singer | - | - | - | - | 93,750 | - |
| Britt Meelby Jensen[1)] | - | - | 177,083 | 35,417 | 53,572 | 10,714 |
| Niels Christian Nielsen[1)] | 219,444 | 50,000 | 72,917 | 14,583 | - | - |

[1)] Not a member of the board as of 31 December 2019.

## Review of the gender-based composition of the Management and Board, cf. Section 99b of the Danish Financial Statements Act

Diversity in the composition of the Board is endeavored, with a reasonable age composition, several nationalities and an equal gender ratio. The Board currently has five members, four of whom are men and one woman.
BioPorto has adopted a Diversity Policy, which is available on the company's website and reads as follows:

"BioPorto is committed to continue working towards ensuring and furthering equal opportunities for all employees in respect of differences, such as gender, age, religion, sexual orientation and ethnicity, as all – in our view – serve as key components in ensuring a better, more dynamic and healthier business. We believe that employees should be recognized because of – and not despite – their diversity. The view extended through this policy also includes maintaining equal opportunities for women and men at all management levels in the BioPorto group. The Board of Directors annually discusses the company's activities to ensure relevant diversity at management levels and evaluates the policy on diversity.

BioPorto has defined a target, that no later than in 2022, at least 25 % members of the Management of the company must be women. This target must not detract from other competency requirements in the nomination of members to the Management team of the company. With regards to diversity for the Board of Directors, the gender distribution is 80/20 at the end of 2019. As the defined target has not yet been reached, BioPorto will stay committed to reach the target within the set deadline."

The nominating committee has a clear policy for evaluating candidates of both genders for vacant Board positions, and for the election of a two new Board members in 2019, two male candidates was deemed to have the best competency profiles. For future vacant Board positions, the nomination committee will continue to evaluate candidates of both genders.

## Diversity in other layers of Management

The company does not have a policy for diversity in other layers of Management, as the company is below the minimum threshold (cf. guidelines from the Danish Business Authority).

## Gender diversity in BioPorto

The gender diversity in BioPorto at the end of 2019 is shown in the overview below:

| 2019 | Female | Male |
|---|---|---|
| Board of Directors | 20% | 80% |
| Executive Management (one person) | 0% | 100% |
| All Employees | 54% | 46% |

## Review of corporate social responsibility, cf. Section 99a of the Danish Financial Statements Act

BioPorto is aware of its corporate social responsibility and endeavors to improve social and environmental conditions. In addition to the corporate social responsibility report provided below, BioPorto has signed up to the UN Global Compact, and the latest Communication on Progress, which is available on the company's website.

In several areas, BioPorto fulfills its responsibility solely by complying with current law, but in other areas, the company's responsibility has been expanded to include preventive activities for optimizing various conditions. It is important to BioPorto to highlight these efforts vis-à-vis its customers, suppliers, stockholders, other stakeholders, etc., to ensure that the outside world trusts the company to live up to its social responsibility.

### BioPorto's business

BioPorto's business model seeks to utilize its unique library of monoclonal antibodies and its biomarker expertise to develop new clinical diagnostic products with attractive potential and bring them to the global market.

The NGAL Test is an example of how BioPorto has successfully taken an antibody from research and discovery phase to a commercial clinical product. Starting with the development of unique monoclonal NGAL antibodies, it was transformed into a microtiter plate assay. From there BioPorto developed The NGAL Test into its current format for automated testing on clinical chemistry systems and is now sold directly and via partners to hospital central laboratories across the world. BioPorto's other biomarker, Mannan-binding lectin (MBL), also started out as an antibody project and is now, in its present CE approved ELISA format, sold via distributors for analysis of immunodeficiencies.

BioPorto will, in 2020, complete clinical studies and submit regulatory applications for two separate indications of The NGAL Test with the FDA; one for risk use with AKI in adults based on plasma, and one for risk use with AKI in urine in children, which will enable BioPorto to sell The NGAL Test for diagnostic purposes in the US following FDA clearance.

For a detailed description of BioPorto's strategy and objectives, see page 8.

## Risks

The Group's risk of affecting the environment and climate, human rights and anti-corruption is assessed to be limited. The risk assessment has been carried out in such a way that selected topics have been analyzed for their potential risk for BioPorto and the Group's stakeholders, respectively. Risk is in this context, a product of the subject's proportional role in the daily business, and the likely negative impact the topic has on the group or stakeholders. To the extent that risks have been identified, the individual areas are described together with the relevant policies.

For a detailed description of BioPorto's additional risks, see Risk management on page 14.

## Human rights

1. Businesses should support and respect the protection of internationally proclaimed human rights; and
2. make sure that they are not complicit in human rights abuses.

BioPorto supports and respects internationally recognized human rights. BioPorto has no external suppliers in countries that do not respect human rights. In 2017, BioPorto established a Code of Conduct covering the above. BioPorto's employees are bound by BioPorto's Code of Conduct and the company has initiated a process of implementing the Code of Conduct into supplier contracts to ensure that the company's suppliers respect human rights. Again in 2019 BioPorto's employees have been trained on Human Rights and a training session has been conducted for all new employees to raise the public awareness on human rights.

BioPorto's executive management monitor and evaluates the performance annually. Any alleged incidents of Human Rights abuses would be reported to the executive management and the executive management would take prompt action.

## Labor rights

3. Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;
4. the elimination of all forms of forced and compulsory labor;
5. the effective abolition of child labor; and
6. the elimination of discrimination in respect of employment and occupation.

Danish and American traditions, culture and law mean that labor rights are naturally supported and complied with by BioPorto, both in Denmark and the United States. BioPorto has no external suppliers in countries that use child labor or forced and compulsory labor, and BioPorto deems that there is a very low risk of this taking place in areas where BioPorto might be expected to operate. In 2017, BioPorto established a Code of Conduct covering the above. BioPorto's employees are bound by BioPorto's Code of Conduct and the company has initiated a process of implementing the Code of Conduct into supplier contracts to ensure that suppliers comply with these labor rights.

The BioPorto group has fair and equal employment terms and working conditions, including equality and non-discrimination. BioPorto's employee handbook covers policies concerning the employee rights. BioPorto works consistently to maintain a safe and healthy work environment. Many procedures are in place. Both the physical and mental working environment are monitored and continually improved to avoid accidents, injury and illness. Management ensures that employees are trained to handle hazardous goods and chemicals correctly.

In the composition of its staff, BioPorto endeavours to achieve an equal gender breakdown as well as a diversity of educational backgrounds, nationalities and cultures. This diversity provides a dynamic workday and encourages fine interplay for the benefit of staff and company efforts alike.

Any incidents of violations of Labor principles would be reported to the executive management. The executive management would investigate the violation.

BioPorto monitors and evaluates performance yearly by looking at working related injurie, employee related cases with the union etc. BioPorto had zero employee related cases with the union in 2019 and BioPorto had no working related injurie in 2019.

## Environment

7. Businesses should support a precautionary approach to environmental challenges;
8. undertake initiatives to promote greater environmental responsibility; and
9. encourage the development and diffusion of environmentally friendly technologies.

BioPorto's in-house production is limited in scope and of such a nature that it has an insignificant environmental impact. BioPorto is continuously seeking to reduce its environmental impact as much as possible and to be compliant with environmental legislation. An ongoing effort will be made in an environmentally conscious way in order to minimize any other possible environmental impact, including the consumption of water and electricity, which will cut costs at the same time. BioPorto's activities are primarily knowledge-based and employees are encouraged to be mindful of the environment and climate, and to produce as little waste as possible. BioPorto's employees are bound by BioPorto's Code of Conduct and the company has initiated a process of implementing the Code of Conduct into supplier contracts to ensure the above. BioPorto use less paper due to double-sided printing in 2019 than in 2018. Management will continually encourage employees to do environmental and climate friendly initiatives

Any incident would be reported to the executive management and they would take prompt action to make sure the incident would not happen again.

## Anti-corruption

10. Businesses should work against corruption in all its forms, including extortion and bribery.

BioPorto has a zero-tolerance policy regarding corruption, bribery and similar methods and BioPorto's activities must always be in compliance with existing anti-corruption legislation and the UN Convention against Corruption. Suppliers and partners are chosen with care and are included

in BioPorto's quality system. Also in 2019 Corruption problems have not affected BioPorto's activities up to now and BioPorto has not been involved in any legal cases, rulings or other events related to corruption and bribery.

In 2017, BioPorto established a Code of Conduct covering the above. BioPorto's employees are bound by BioPorto's Code of Conduct and the company has initiated a process of implementing the Code of Conduct into supplier contracts to ensure that suppliers comply with the above.

Any incidents of corruption would be reported to the Executive Management and they would prompt take action to ensure that a similar incident would not happen again.

# Shareholder matters

## Investor relations

BioPorto aims to give the market transparent and adequate information about the group's strategy, operations and results with a view to ensuring fair pricing of its shares. BioPorto operates in a highly complex sector in terms of both products and market conditions. Insofar as possible, the group endeavors to strike a balance so that the information it communicates is both technically correct and understandable to laypeople. All stakeholders should have rapid, equal access to important information about BioPorto's development and growth. This means, among other things, that relevant information is published in company announcements via NASDAQ Copenhagen A/S and is made available on the group's website: www.bioporto.com.

Other published information, including general company and investor presentations, are made available to everyone on the company's website. The investor section of the website also includes an email service where shareholders and others can subscribe to receive news by email immediately after the publication of company announcements, press releases and other news.

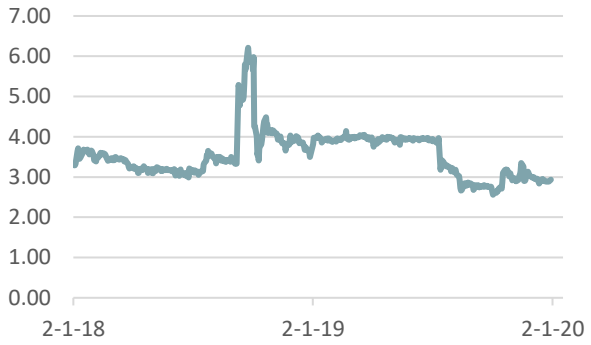
To ensure an efficient, expedient dialogue with shareholders, BioPorto encourages its shareholders to let their shareholding be registered and to participate in BioPorto's shareholder meetings. The Investor Relations (IR) department is also responsible for ensuring that information from the group's IR stakeholders is passed on to Management and the Board of Directors. For more relevant details relating to BioPorto, investors are referred to the company's website: www.bioporto.com.

## Shares

### ISIN, capital stock and price trends

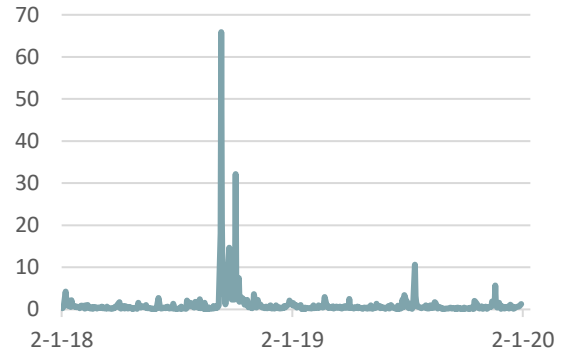
BioPorto's capital stock has a nominal value of DKK 174,944,375 divided into 174,944,375 shares with a nominal value of DKK 1 each, equivalent to 174,944,375 votes. BioPorto A/S's shares are listed on NASDAQ Copenhagen under the symbol "BIOPOR". The ISIN is DK0011048619. BioPorto had a market value of DKK 513 million at the end of 2019 (end of 2018: DKK 580 million).

BioPorto share, Closing price (DKK)




The closing price of BioPorto shares was DKK 2.93 on December 30, 2019, which equals a decrease of 16% in the fiscal year.

BioPorto share, Volume (DKK million)




The value of traded shares was DKK 159 million in 2019 (2018: DKK 394 million), equivalent to average daily trading of DKK 0.6 million (2018: DKK 1.6 million) and a daily volume of 187,912 shares (2018: 363,740 shares).

### Capital increase

On June 17, 2019, the Board of BioPorto A/S decided to exercise part of the authority stipulated in article 16b of the company's articles of association to carry out a private placement cash issue for a limited number of selected institutional and financial investors. As a result of the implementation of the issue, the capital stock of BioPorto A/S was increased in the nominal amount of DKK 9,256,577, after which it nominally amounts to DKK 174,944,375. The subscription price of DKK 3.97 was the closing price of BioPorto shares traded on NASDAQ Copenhagen A/S on June 17, 2019.

The private placement generated gross proceeds of DKK 37 million for BioPorto. The new shares equated to 5.59% of BioPorto's registered capital stock before the implementation of the capital increase.

### Ownership

As of December 31, 2019, BioPorto had 8,478 registered shareholders (2018: 8,544), who in the aggregate owned 87.67% of the capital stock. On December 31, 2019, the following shareholders state that they own 5% or more of the company's shares/voting rights:

| | |
|---|---|
| Ejendomsselskabet Jano ApS, Copenhagen | 11.83 % |
| Media-Invest Danmark A/S, Copenhagen | 10.09 % |

## Warrant program

The Board established three warrant programs in 2019 for the purpose of creating a long-term incentive for retaining and motivating Management and employees. At the end of the fiscal year, a total of 16,532,500 warrants remained, which amounted to 9.5 % of the existing nominal capital stock.

## Dividend policy

BioPorto's policy is that shareholders should receive a return on their investment in the form of a share price increase based on the group's growth. Because of the group's need for capital to implement new strategic initiatives and ensure the basis for higher sales, no dividend is expected to be paid in 2020. In the long term and as the company generates profits, the company wishes to be able to give shareholders direct returns in the form of dividends and/or share buybacks in addition to a return on the share price.

## Equity analysts and investor meetings

BioPorto has ongoing contacts with investors and equity analysts and, in this context, holds regular presentations and meetings where strategy, pipeline development and risks are discussed. BioPorto usually holds investor meetings after the publication of the annual report and interim reports and quarterly announcements.

The following analysts are covering BioPorto:

| | |
|---|---|
| Edison Group, US | Nat Calloway |
| Maxim Group, US | Jason McCarthy |

## Annual Shareholder Meeting

BioPorto A/S will hold its annual shareholder meeting on April 14, 2020, at 3.00 pm at the company's address Tuborg Havnevej 15, ground fl., DK-2900 Hellerup.

## IR contact

Ole Larsen, Chief Financial Officer
Tel.: +45 4529 0000
E-mail: investor@bioporto.com

## Financial calendar for 2020

| Date | Description |
|---|---|
| March 2, 2020 | Deadline for shareholder proposals for the annual general meeting |
| March 11, 2020 | Annual Report 2019 |
| April 14, 2020 | Annual General Meeting |
| May 7, 2020 | Interim financial report – 3 months 2020 |
| August 19, 2020 | Interim financial report – 6 months 2020 |
| November 18, 2020 | Interim financial report – 9 months 2020 |

## Company announcements

| Date | No. | Description |
|---|---|---|
| Feb 26, 2020 | 2 | Updated financial calendar for 2020 |
| Feb 26, 2020 | 1 | BioPorto announces preliminary Financial Result for 2019, guidance for 2020 and postpones publication of audited annual report for 2019 to March 11, 2020. A private placement of new shares are being pursued to strengthen financial position. |
| Dec 30, 2019 | 22 | Grant of Warrants |
| Nov 21, 2019 | 21 | BioPorto Announces Q3 2019 Report |
| Nov 18, 2019 | 20 | BioPorto to provide additional patient information in support of its US application for regulatory clearance of The NGAL Test™ for pediatric risk assessment of Acute Kidney Injury |
| Oct 17, 2019 | 19 | BioPorto submits answers to the FDA regarding The NGAL Test™ for risk assessment for AKI in pediatric patients |
| Sep 6, 2019 | 18 | Updated Financial calendar for 2019 and Financial calendar for 2020 |
| Aug 15, 2019 | 17 | Grant of Warrants |
| Aug 15, 2019 | 16 | BioPorto – Extraordinary General Meeting |
| Aug 15, 2019 | 15 | BioPorto Announces Q2 2019 Report |
| Jul 13, 2019 | 14 | BioPorto to redraw U.S. application for regulatory clearance of The NGAL Test™ for risk assessment for AKI in patients under the age of 22 with the intend to resubmit in Q4 2019 |
| Jul 12, 2019 | 13 | Notice Convening the Extraordinary General Meeting |
| Jul 2, 2019 | 12 | Adjustment of timeline for FDA decision regarding application for pediatric clinical use of The NGAL Test™ |
| Jun 28, 2019 | 11 | Managers' transactions |
| Jun 28, 2019 | 10 | Changes in number of shares and votes |
| Jun 17, 2019 | 9 | Private placement fully subscribed |
| Jun 17, 2019 | 8 | BioPorto A/S to Increase its Share Capital through a Cash Issue, Private Placement |
| May 15, 2019 | 7 | BioPorto Submits Pediatric Application to FDA for The NGAL Test™ Under Breakthrough Designation |
| May 9, 2019 | 6 | BioPorto Announces Q1 2019 Report |
| Apr 15, 2019 | 5 | Grant of Warrants |
| Mar 18, 2019 | 4 | BioPorto A/S Annual General Meeting |
| Feb 22, 2019 | 3 | Notice Convening the Annual General Meeting |
| Feb 22, 2019 | 2 | BioPorto Announces Annual Report 2018 |
| Jan 8, 2019 | 1 | Corrected Financial Calendar 2019 |

# Company information

## Bank

Nordea Bank Danmark A/S
Strandgade 3
DK-0900 Copenhagen C

## Lawyers

Gorrissen Federspiel
Axeltorv 2
DK-1609 København V

## Independent accountants

PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab
Strandvejen 44
DK-2900 Hellerup

## Locations

BioPorto A/S, BioPorto Diagnostics A/S,

Veterinary Diagnostics A/S

Tuborg Havnevej 15, ground floor
2900 Hellerup
Denmark

(Headquarter)

BioPorto Inc.

BioPorto Diagnostics Inc.

444 N. Michigan Avenue, Suite 3350
Chicago, IL 60611
USA

# Board of Directors

Thomas Magnussen
(M) (1953)

**Chairman of the board**
Joined the Board in 2013, must be re-elected in 2020
Independent board member
Participation in 16 board meetings in 2019 & participation in 9 committee meetings in 2019

## Qualifications of relevance for BioPorto

Thomas Magnussen has been a member of the Board of Directors for BioPorto since 2013 and is Chairman of the Board of Directors. Thomas Magnussen is CEO of Therazone ApS. Thomas Magnussen is an entrepreneur within high-tech start-up companies with a global business reach. Thomas Magnussen has experience in commercialization strategies and within nanotechnology, ICT and Medtech industries and has previously been chairman of QuantumWise A/S and Zylinc A/S. Thomas Magnussen holds an MBA from INSEAD as well as a Ph.D. and MSc from DTU.

## Current directorships in other companies

Chairman of the Board for Therazone ApS, Usertribe A/S, BioPorto Diagnostics A/S and Veterinary Diagnostics A/S.
Director in Therazone ApS.

Torben A. Nielsen
(M) (1960)

**Vice-chairman**
Joined the Board in 2013, must be re-elected in 2020
Independent board member
Participation in 16 board meetings in 2019 & participation in 6 committee meetings in 2019

## Qualifications of relevance for BioPorto

Torben Arnth Nielsen has been a member of the Board of Directors for BioPorto since 2013 and is Vice Chairman of the Board of Directors. Torben Arnth Nielsen has over the past 25 years held senior positions in the financial sector, most recently as a member of the executive management at Sydbank, among others being responsible for asset management and capital markets, and as CEO of BankInvest. Concurrently, he has held several national and international board directorships, as well as previously for Nasdaq Copenhagen A/S. Over the last 30 years, of which 5 years were in New York and London, Torben Arnth Nielsen has built and managed businesses in Denmark and abroad in all relevant commercial business areas in the financial sector and has been involved in and responsible for several mergers and acquisitions. Torben Arnth Nielsen holds DIEU's top management education VL (2006) as well as a degree in banking.

## Current directorships in other companies

Partner at Linde & Partners Kapitalrådgivning A/S and Board member at Wavepiston A/S, BioPorto Diagnostics A/S and Veterinary Diagnostics A/S.
CEO at Arnth Advice ApS.

Kirsten Drejer
(F) (1956)

**Board member**
Joined the Board in 2017, must be re-elected in 2020
Independent board member
Participation in 16 board meetings in 2019 & participation in 4 committee meetings in 2019

## Qualifications of relevance for BioPorto

Kirsten Aarup Drejer has been a member of the Board of Directors for BioPorto since 2017. Kirsten Aarup Drejer is co-founder of Symphogen, a biopharmaceutical company focused on the innovative therapeutic utilization of antibodies. In the period 2000-2016, Kirsten Aarup Drejer was CEO of Symphogen and in the period 2016-2018 she was a member of the Board of Directors at Symphogen. Prior to this, Kirsten Aarup Drejer held a number of scientific and managerial positions within Novo Nordisk as well as directorships of, among others, Danisco. Kirsten Aarup Drejer is a member of numerous advisory boards at the University of Copenhagen and the Copenhagen Business School. Kirsten Aarup Drejer won the prize of "BiotechBuilder of the Year" in 2003 and "Entrepreneur of the Year, Biotech" in 2007. Kirsten Aarup Drejer holds a MSc (pharm) and Ph.D. in pharmacology from the University of Copenhagen.

## Current directorships in other companies

Kirsten Aarup Drejer is chairman of Antag Therapeutics ApS, ResoTher Pharma and Bioneer A/S, deputy chairman of Zealand Pharma A/S as well as a member of the board of directors at Lyhne & Company A/S and Alligator Bioscience.

Christopher Lindop
(M) (1957)

**Board member**
Joined the Board in 2019, must be re-elected in 2020
Independent board member
Participation in 5 board meetings in 2019

## Qualifications of relevance for BioPorto

Christopher James Lindop has been a member of the Board of directors for BioPorto since 2019. Christopher James Lindop qualified as a CA and CPA and was previously a partner with Arthur Andersen and E&Y. In 2003, Christopher Lindop took the position as Chief Financial Officer (CFO) in Inverness Medical Ltd., before he became CFO and EVP Business Development at Haemonetics Corporation Ltd. (HAE) in 2007. Since 2017, Christopher Lindop has been CFO at Quotient Limited (QTNT) until February 2020 and he is EVP until he retires in May 2020. From 2007 until 2018 Mr. Lindop was a member of the board of directors of Parexel International (PRXL) where he served as Chairman of the Audit Committee and member of the Nominating and Governance Committee. He has considerable experience in management of US listed health care and diagnostic companies and within finance and reporting, corporate governance, mergers & acquisitions, funding and strategy development and execution.

Michael Singer
(M) (1973)

**Board member**
Joined the Board in 2019, must be re-elected in 2020
Independent board member
Participation in 6 board meetings in 2019

## Qualifications of relevance for BioPorto

Michael Singer has been a member of the Board of directors for BioPorto since 2019. Michael Singer has since 2016 served as Chief Scientific Officer (CSO) and co-founder of Cartesian Therapeutics, Inc., a US biotech company with clinical candidates for novel immunotherapies to cure cancer. Since 2019, he has been Chief Medical Officer and Investor at Neutrolis Inc. Before this he was co-founder and CSO of Topokine Therapeutics, Inc. where he was responsible for pre-clinical and clinical development of the company's topical medicine candidates for fat reduction. Topokine was sold to Allergan in 2016. Early in his career, Michael S. Singer was a physician and surgeon, among other places at Brigham and Women's Hospital in Boston, MA, before in the period 2006-2012 founding and divesting Health Honors Corporation and leading Translational Medicine at Novartis Institutes for Biomedical Research as a director. Michael S. Singer possess significant experience and skills in designing and executing pre-clinical and clinical development processes in biotech and health care companies. He is MD cum laude and Ph.D. (neurosciences) from Yale University, CT.

## Current directorships in other companies

Member of the Board of Directors at Cartesian Therapeutics and Pykus Therapeutics.

# Executive Management

Peter Mørch Eriksen
(M) (1960)

**Chief Executive Officer**

Joined BioPorto as CEO in 2013

## Qualifications of relevance for BioPorto

Peter Mørch Eriksen has served as CEO of BioPorto since July 2013 and has spent more than 20 years in the medtech/life science industries, including CEO of Sense A/S and VP of Medtronic. From these positions, Peter Mørch Eriksen brings extensive experience in creating growth, restructuring and funding in technology-intensive and complex companies. He is an experienced leader with a record of business within the medical device industry, and has broad experience selling and developing medical devices for both small and large medtech companies. Peter Mørch Eriksen has an accounting background, supplemented with management experience.

## Current directorships in other companies

Member of the Board of BioPorto Diagnostics A/S, BioPorto Inc., BioPorto Diagnostic Inc. and Veterinary Diagnostics A/S.

Member of the Board of Fluo Guide.

Member of the Advisory Board at Lund University Diabetes Centre.

Peter Mørch Eriksen also serves on the Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Center in Cincinnati, Ohio (US).

Peter Mørch Eriksen is Director in PME Holding ApS.

| Shareholdings of the Board of Directors & Executive Management | December 31, 2018 | Purchased | Sold | December 31, 2019 |
|---|---|---|---|---|
| Thomas Magnussen, Chairman of the board<br>(Thomas Magnussen & Therazone ApS) | 866,953 | 150,000 | - | 1,016,953 |
| Torben A. Nielsen, Vice-chairman | 301,925 | - | - | 301,925 |
| Kirsten Drejer, Board member | 15,000 | - | - | 15,000 |
| Christopher Lindop, Board member | - | 334,866 | - | 334,866 |
| Michael Singer, Board member | - | 167,433 | - | 167,433 |
| Peter M. Eriksen, CEO<br>(PME Holding ApS) | 69,239 | - | - | 69,239 |

# Financial review 2019

## Income Statement

The financial review is based on the Group's consolidated financial information for the year ended December 31, 2019, with comparative figures for 2018 in brackets. There is no significant difference in the development of the Group and the Parent Company.

In 2019, BioPorto generated revenues of DKK 26.6 million (DKK 26.0 million). Earnings before interest and taxes (EBIT) showed a loss of DKK 74.3 million (DKK 41.8 million). The cash position as of December 31, 2019 amounted to DKK 18.1 million (DKK 46.7 million).

### Revenue

Revenue for 2019 was DKK 26.6 million (DKK 26.0 million).

Revenue from The NGAL Test was DKK 11.6 million (DKK 10.6 million) and was composed of DKK 4.9 million (DKK 4.5 million) from RUO sales in the US, DKK 5.5 million (DKK 4.7 million) from sales in the EU and the rest of the world and DKK 1.2 million (DKK 1.4 million) in NGAL related fees and licenses.

Revenue from sale of antibodies amounted to DKK 9.4 million (DKK 9.4 million).

Revenue from ELISA kits was DKK 4.8 million (DKK 4.8 million).

Revenues from other products, royalties and licenses amounted to DKK 0.8 million (DKK 1.2 million).

### Production costs

Production costs amounted to DKK 9.3 million (DKK 8.2 million) bringing the gross profit for 2019 to DKK 17.3 million (DKK 17.8 million) and the gross margin to 65% (69%). The increase in production costs is primarily related to a write-down of antibody inventory (DKK 0.6 million), staff-related costs (DKK 0.5 million) and consumed goods (DKK 0.3 million).

### Sales and marketing costs

Sales and marketing costs totaled DKK 39.3 million (DKK 20.9 million). The increase in costs is mostly due to additional staff-related costs of DKK 9.4 million following a strengthening of the US organization. In addition costs of consultants have increased by DKK 3.1 million and one-time costs related to a ceased collaboration with a vendor total DKK 5.4 million.

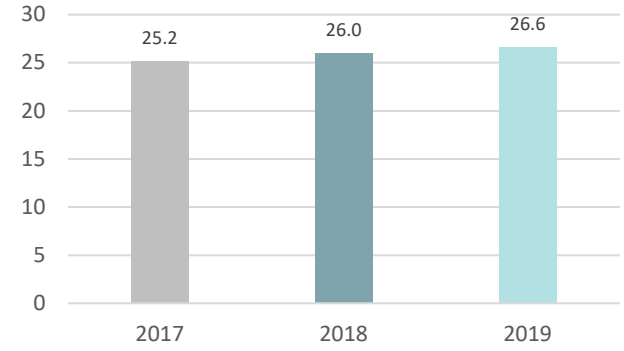
### Research and development costs

Research and development costs amounted to DKK 24.6 million (DKK 18.7 million). Clinical study costs increased in 2019 by DKK 1.6 million compared to 2018 due to activities for the NGAL pediatric study and the additional enrollment of patients for the NGAL adult study. In addition the staff-related costs increased by DKK 3.5 million in 2019 compared to 2018 following additions in US based R&D staff.

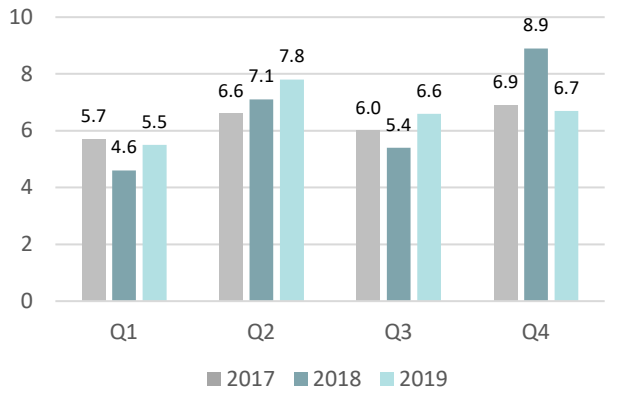
### Administrative costs

Administrative expenses were DKK 27.8 million (DKK 20.0 million). In 2019 staff-related costs increased by DKK 5.4 million, consultancy cost increased by DKK 1.7 million and fees to lawyers increased by DKK 0.5 million compared to 2018.

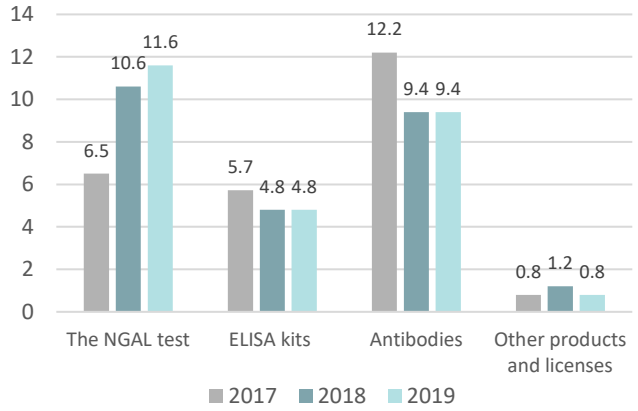
Revenue (DKK million)




Revenue by quarter (DKK million)




Revenue by product category (DKK million)



## Financial income and expenses

Financial income was DKK 0.5 million (DKK 0.3 million) and consisted of positive exchange rate adjustments of DKK 0.4 million (DKK 0.3 million) and interest from banks DKK 0.1 million (DKK 0.0 million).

Financial expenses amounted to DKK 0.5 million (DKK 0.1 million) and consists of bank charges and interest. The increase is due to interest on leasing liabilities DKK 0.3 million (DKK 0.0 million).

## Tax on income of the year

Tax on income of the year was an income of DKK 4.6 million (income of DKK 3.6 million) which is primarily related to refunded tax losses originating from research and development costs.

## Liquidity

As of December 31, 2019, BioPorto had a cash position of DKK 18.1 million (DKK 46.7 million). The Company has funded cash requirements for 2019 with a combination of revenue from product sales and a capital increase through a private placement.

As announced earlier the Company is currently pursuing financing. The Company expects the financing to be finalized by mid-April.

## Cash flow

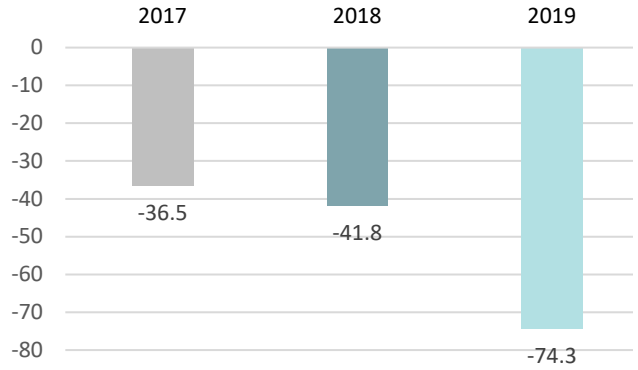
Net cash expenditure from operating activities amounted to DKK 60.2 million (DKK 38.0 million) mainly driven by an increase in the loss of the year before financial items of DKK 32.5 million partly off-set by amortization and depreciation of DKK 2.3 million, warrant expenses of DKK 4.0 million and changes in working capital of DKK 5.1 million.

Net cash used in investing activities was DKK 2.1 million (DKK 1.5 million) of which the vast majority was investment in financial assets.

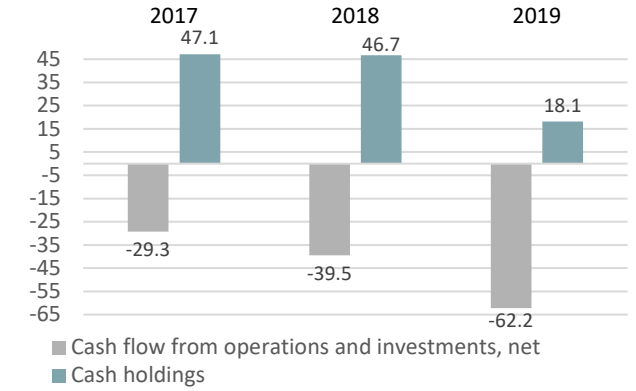
Net cash provided by financing activities totaled DKK 33.6 million (DKK 39.1 million) primarily from a capital increase through a private placement securing net proceeds of DKK 36.0 million (DKK 39.3 million).

The net cash flow for 2019 was negative by DKK 28.6 million (DKK 0.4 million negative).

EBIT (DKK million)




Cash flows and Cash holdings (DKK million)




# Balance Sheet

The balance sheet total was DKK 42.7 million as of December 31, 2019 (DKK 66.2 million).

## Assets

Intangible assets in 2019 were DKK 1.3 million (DKK 1.4 million). The decrease is due to the amortization of intangible assets, partly offset by an investment in software.

Fixtures and fittings, tools and equipment stood at DKK 1.7 million (DKK 1.4 million). The increase is primarily due to the investment in leasehold improvements and lab equipment, partly off-set by depreciation.

Right-of-use assets have been recognized as of January 1, 2019 as part of implementing IFRS 16. Right-of-use assets consists of the group leases of office space and vehicles and total DKK 3.5 million as of December 31, 2019. No right-of-use assets were recognized in 2018.

Financial assets stood at DKK 1.7 million (DKK 0.8 million) and consists of deposits in connections to leasing of office space. The increase is primarily related to a new lease of office space.

The Company has no tax asset in the balance sheet. As of December 31, 2019, the total write-down of the tax asset amounted to DKK 55.0 million (DKK 44.4 million). The Company retains the right to use the tax loss carry forward of DKK 53.5 million (DKK 43.0 million) and the other tax assets of net DKK 1.5 million (DKK 1.4 million) that were written down.

Inventories stood at DKK 4.2 million (DKK 3.6 million) of which finished goods consisted of DKK 2.1 million (DKK 2.2 million).

Receivables stood at DKK 12.2 million (DKK 12.3 million), of which trade receivables amounted to DKK 5.7 million (DKK 8.0 million). The reduction is mainly due to a reduction in outstanding balances more

than 90 days overdue and due to slower sales in December 2019 compared to December 2018.

Income tax receivables totaled DKK 4.7 million (DKK 3.7 million) and other receivables DKK 1.2 million (DKK 0.6 million).

As of December 31, 2019, the cash position was DKK 18.1 million (DKK 46.7 million). BioPorto's cash is primarily invested in deposit accounts with two Nordic banks.

### Equity

After the transfer of the loss of the year, equity stood at DKK 25.3 million (DKK 56.2 million).

### Liabilities

Non-current liabilities stood at DKK 2.5 million (DKK 0.8 million).

Current liabilities stood at DKK 14.9 million (DKK 9.2 million) of which trade payables amounted to DKK 3.2 million (DKK 4.5 million) and other payables amounted to DKK 9.2 million (DKK 4.6 million).

## Capital structure

The Management continuously assesses whether the consolidated capital structure conforms to the interests of the group and the shareholders. The overarching goal is to ensure a capital structure which underpins long-term financial growth and at the same time maximizes the returns for the group's stakeholders by optimizing the relationship between equity capital and borrowed capital.

## Change of control

The Danish Financial Statements Act, Section 107 a, contains rules relating to listed companies with respect to certain disclosures in relation to disclosure of change of control provisions.

BioPorto has entered into agreements with external parties, which may be subject to renegotiation in case of a change of control event in BioPorto. However, detailed information is not provided here, as it may be restricted from disclosure due to confidentiality or is not expected to have significant influence on the Company's financial position.

# Income statement and statement of comprehensive income

## Income statement

| Note | | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|---|
| 3 | Revenue | 26,622 | 26,016 |
| 4,6,14 | Production costs | (9,293) | (8,181) |
| | **Gross profit/loss** | **17,329** | **17,835** |
| 4,6 | Sales and marketing costs | (39,268) | (20,935) |
| 4,6 | Research and development costs | (24,556) | (18,676) |
| 4,6,7 | Administrative expenses | (27,804) | (20,005) |
| | **Profit/loss before financial items (EBIT)** | **(74,299)** | **(41,781)** |
| 8 | Financial income | 503 | 277 |
| 8 | Financial expenses | (451) | (113) |
| | **Profit/loss before tax** | **(74,247)** | **(41,617)** |
| 9 | Total income tax benefits | 4,605 | 3,569 |
| | **Profit/loss for the year** | **(69,642)** | **(38,048)** |
| | | DKK | DKK |
| 10 | Profit/loss per share (EPS & DEPS) | (0.41) | (0.24) |

## Statement of comprehensive income

| Note | | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|---|
| | **Profit/loss for the year** | **(69,642)** | **(38,048)** |
| | Amounts which will be re-classified to the income statement: | | |
| | Adjustment of foreign currency fluctuations on subsidiaries | (325) | (277) |
| | **Total comprehensive income** | **(69,967)** | **(38,325)** |

# Balance sheet

| Note | ASSETS | 2019 December 31 DKK thousand | 2018 December 31 DKK thousand |
|---|---|---|---|
| | **Non-current assets** | | |
| | **Property, plant and equipment and intangible assets** | | |
| 11 | Rights and software | 1,262 | 1,374 |
| 12 | Fixtures and fittings, tools and equipment | 1,710 | 1,437 |
| 13 | Right-of-use assets | 3,537 | - |
| | **Total property, plant and equipment and intangible assets** | **6,509** | **2,811** |
| | **Financial assets** | | |
| | Deposits | 1,709 | 752 |
| | **Total financial assets** | **1,709** | **752** |
| | **Total non-current assets** | **8,218** | **3,563** |
| | **Current assets** | | |
| 14,19 | Inventories | 4,155 | 3,631 |
| 15,18,19 | Trade receivables | 5,695 | 8,036 |
| | Income tax receivable | 4,742 | 3,656 |
| 15,18,19 | Other receivables | 567 | - |
| 15,19 | Prepayments | 1,183 | 606 |
| | **Total inventories and receivables** | **16,342** | **15,929** |
| 18 | Cash | 18,122 | 46,709 |
| | **Total current assets** | **34,464** | **62,638** |
| | **Total assets** | **42,682** | **66,201** |

| Note | LIABILITIES | 2019 December 31 DKK thousand | 2018 December 31 DKK thousand |
|---|---|---|---|
| | **Equity** | | |
| 16 | Share capital | 174,944 | 165,688 |
| 17 | Treasury shares | - | - |
| | Exchange-rate adjustments | (672) | (347) |
| | Retained earnings | (148,950) | (109,144) |
| | **Total equity** | **25,322** | **56,197** |
| | **Liabilities** | | |
| | **Non-current liabilities** | | |
| 18 | Lease obligation | 1,545 | - |
| 18,19 | Other non-current liabilities | 957 | 787 |
| | **Non-current liabilities** | **2,502** | **787** |
| | **Current liabilities** | | |
| 18 | Current portion of non-current liabilities | 2,306 | 141 |
| 18,19 | Trade payables | 3,237 | 4,451 |
| | Tax payables | 78 | 47 |
| 18,19 | Other payables | 9,237 | 4,578 |
| | **Current liabilities** | **14,858** | **9,217** |
| | **Total liabilities** | **17,360** | **10,004** |
| | **Total equity and liabilities** | **42,682** | **66,201** |

# 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 January 1, 2019 | 165,688 | - | (347) | (109,144) | **56,197** |
| Comprehensive income: | | | | | |
| Net Profit/loss for the year | - | - | - | (69,642) | **(69,642)** |
| Adjustment of foreign currency fluctuations on subsidiaries | - | - | (325) | - | **(325)** |
| Transactions with owners: | | | | | |
| Issue | 9,256 | 27,493 | - | - | **36,749** |
| Issue costs | - | (766) | - | - | **(766)** |
| Share-based compensation | - | - | - | 3,109 | **3,109** |
| Transferred to retained earnings | - | (26,727) | - | 26,727 | **-** |
| **Equity at December 31, 2019** | **174,944** | **-** | **(672)** | **(148,950)** | **25,322** |

| | Share capital DKK thousand | Share premium DKK thousand | Exchange-rate adjustments DKK thousand | Retained earnings DKK thousand | Total DKK thousand |
|---|---|---|---|---|---|
| Equity at January 1, 2018 | 155,510 | - | (70) | (99,372) | **56,068** |
| Comprehensive income: | | | | | |
| Net Profit/loss for the year | - | - | - | (38,048) | **(38,048)** |
| Adjustment of foreign currency fluctuations on subsidiaries | - | - | (277) | - | **(277)** |
| Transactions with owners: | | | | | |
| Issue | 10,178 | 29,822 | - | - | **40,000** |
| Issue costs | - | (681) | - | - | **(681)** |
| Share-based compensation | - | - | - | (865) | **(865)** |
| Transferred to retained earnings | - | (29,141) | - | 29,141 | **-** |
| **Equity at December 31, 2018** | **165,688** | **-** | **(347)** | **(109,144)** | **56,197** |

| | 2019 DKK thousand | 2018 DKK thousand | 2017 DKK thousand | 2016 DKK thousand | 2015 DKK thousand |
|---|---|---|---|---|---|
| Share capital at January 1 | 165,688 | 155,510 | 142,494 | 129,599 | 117,874 |
| Issue of new shares | 9,256 | 10,178 | 13,016 | 12,895 | 11,725 |
| **Share capital at December 31** | **174,944** | **165,688** | **155,510** | **142,494** | **129,599** |

# Cash flow statement

| Note | | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|---|
| | Profit/loss before financial items | (74,299) | (41,781) |
| | | | |
| 6 | Amortization and depreciation | 2,857 | 543 |
| 4 | Warrant expenses | 3,109 | (865) |
| | Other non-cash adjustments | 194 | - |
| | **Cash generated from operations before working capital** | **(68,139)** | **(42,103)** |
| 19 | Changes in working capital | 4,453 | (631) |
| | **Cash generated from operations** | **(63,686)** | **(42,734)** |
| | Financial income, received | 591 | 1,692 |
| | Financial expenses, paid | (626) | (1,766) |
| | Tax refund, net | 3,557 | 4,799 |
| | **Cash flows from operating activities** | **(60,164)** | **(38,009)** |
| 12 | Purchase of operating equipment | (646) | (1,410) |
| 11 | Purchase of rights and software | (460) | (52) |
| | Purchase of financial assets | (957) | (21) |
| | **Cash flows from investing activities** | **(2,063)** | **(1,483)** |
| 20 | Issue, gross proceeds | 36,749 | 40,000 |
| 20 | Issue costs | (766) | (681) |
| | Reduction of non-current liabilities | (164) | (158) |
| 13 | Reduction of lease obligation | (2,211) | (40) |
| | **Cash flows from financing activities** | **33,608** | **39,121** |
| | **Net cash flow from operating, investing and financing activities** | **(28,619)** | **(371)** |
| | Cash and cash equivalents at January 1 | 46,709 | 47,080 |
| | Currency adjustments | 32 | - |
| | **Cash and cash equivalents at December 31** | **18,122** | **46,709** |

# Notes - Group

# Note 1

## Accounting policies

The financial statements of the BioPorto Group are presented in accordance with the International Financial Reporting Standards (IFRS) as adopted by the EU and additional Danish disclosure requirements for annual reports of accounting class D (listed) enterprises, cf. the Danish Statutory Order on Adoption of IFRS issued in pursuance of the Danish Financial Statements Act.

The financial statements are presented in Danish kroner (DKK), which is considered the primary currency of the Group's activities and the functional currency of the parent company as well as of the most significant subsidiary.

The accounting policies for the Group are otherwise as described in the following.

### Implementation of new and amended standards and interpretations

All new and amended Standards (IFRS/IAS) and the new Interpretations (IFRIC) issued by IASB and adopted by EU effective as of January 1, 2019 has been adopted by the group. This includes IFRS 16 'Leases' which was implemented using the modified retrospective approach on January 1, 2019. The implementation has not affected comparatives.

At initial recognition, right-of-use assets are measured as an amount equal to the lease liability, which is measured at the present value of future lease payments. The lease liability is measured using the average marginal borrowing rate of the BioPorto Group, 6.0%.

In applying IFRS 16 for the first time, the group has used the following practical methods permitted by the standard:

- the use of a single discount rate to a portfolio of leases with reasonably similar characteristics, and
- the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application.

The implementation has had the following impact on the balance sheet for the numbers of the BioPorto Group:

| | Group<br>DKK thousand |
|---|---|
| Rental and operating lease commitments at 31 December, 2018 | 5,225 |
| Discounting (6%) [1] | (456) |
| Consumption expenditure included in operating lease commitments at 31 December 2018 [1] | (427) |
| Lease commitments not recognized at 31 December 2018 [1] | 982 |
| **Lease liability recognized in statement of financial position at 1 January, 2019** | **5,324** |

[1] The specification has been updated after publication of the interim report covering the first three months of 2019.

### Standards and interpretations not yet in force

At the time of publishing this Annual Report, there are several new or modified standards and interpretations which have yet to come into effect and which are therefore not implemented into 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.

### Consolidated financial statements

The consolidated financial statements comprise the parent company BioPorto A/S and subsidiaries in which BioPorto A/S has control over the company's financial and operating policies to obtain returns or other benefits from its activities. Control is obtained when the Company directly or indirectly holds more than 50% of the voting rights in the subsidiary or controls the subsidiary in some other way.

The consolidated financial statements have been prepared consolidating the financial statements of the parent company and the individual subsidiaries using the Group's accounting policies, eliminating intra-group income and expenses, intra-group shareholdings, intra-group balances and dividends as well as realized and unrealized gains on intra-group transactions. Unrealized gains on transactions with associates are eliminated in proportion to the Group's share of the company. Unrealized losses are eliminated in the same way as unrealized gains, to the extent that no impairment has occurred.

# Note 1, continued

### Translation of foreign currency

For each of the reporting entities in the Group, a functional currency is determined. The functional currency is the currency used in the primary financial environment in which the reporting entity operates. Transactions in currencies other than the functional currency are considered foreign-currency transactions.

On initial recognition, transactions denominated in foreign currencies are translated to the functional currency at the exchange rates ruling at the transaction date. Exchange differences arising between the exchange rate ruling at the transaction date and the exchange rate ruling at the date of actual payment are recognized in the income statement under financial income or financial expenses.

Receivables, payables and other monetary items in foreign currencies are translated to the functional currency at the exchange rates ruling at the balance sheet date. The difference between the exchange rate applying at the balance sheet date and the exchange rate at the time when the receivable or payable arose or was recorded in the most recent annual report is recognized in the income statement under financial income or expenses.

### Incentive programs

The company has issued warrants (options) to Management and employees. Share based incentive programs in which employees only have the option of choosing to subscribe for new shares in the parent company (equity-settled share-based payment transactions) are measured at the equity instrument's fair value on the date of issue and are recognized in the income statement over the vesting period. The counter entry for this is recognized directly in equity. The fair value per warrant is specified based on the Black-Scholes equation on the date of issue and is not adjusted subsequently. Warrants restricted by vesting conditions are forfeited if the vesting conditions are not met.

### Segment information

The segmentation reflects the primary use of the company's products across the product groups. The company distinguishes between the following segments:

The NGAL Test
ELISA kits
Antibodies
Other products, royalties and licenses

The segments are measured primarily in terms of revenue as distribution, sales and marketing, research and development and administration concern all segments. There are no intra-segment balances.

As in previous years, information is provided on the breakdown of revenue into geographical areas.

80.0% of non-current assets are placed in Denmark (100% in 2018).

## Income statement and statement of comprehensive income

### Revenue

Revenue from the sale of finished goods is recognized on the income statement if delivery and transfer of control to the buyer have taken place before year-end and if the income can be reliably measured and is expected to be received.

Revenue from development and collaboration contracts is recognized on the income statement if the general recognition criteria are met.

This is the case when:

- delivery has taken place before the end of the year;
- a binding sales agreement has been made;
- the selling price has been determined; and
- payment has been received or may reasonably be expected to be received

Revenue is measured at the transaction price excluding VAT and net of discounts related to sales. Typical payment terms are 30 days.

### Production costs

Production costs comprise costs incurred to generate the revenue, including direct and indirect costs for raw materials and consumables, wages and salaries, freight and packaging material, rent and leasing and depreciation of production equipment.

### Sales and marketing costs

Sales and marketing costs include royalties and costs incurred for the marketing of goods sold during the year and for sales campaigns, etc. This includes costs related to sales staff, advertising, exhibitions and depreciation and amortization.

# Note 1, continued

### Research and development costs

Research and development costs include wages and salaries, laboratory materials, patent costs, clinical studies, rent, leasing and other costs relating to the Group's research and development activities.

### Administrative expenses

Administrative expenses comprise expenses incurred during the year for management and administration, including expenses for administrative staff, office premises and office expenses and depreciation.

### Financial income and expenses

Financial income and expenses include interest, capital gains and losses and impairment on debt, securities and transactions in foreign currencies, amortization of financial assets and liabilities, and additions and remunerations under the Danish tax on account tax scheme, etc.

### Income tax

Income tax comprises current tax and changes in deferred tax for the year. The tax expense relating to the results for the year is recognized on the income statement, and the tax expense relating to changes directly recognized in equity or other comprehensive income is recognized in equity.

To the extent the Group benefits from a deduction in the determination of taxable income due to share-based compensation, the tax effect of such programs is included in income tax. Any tax deduction exceeding the accounting cost is recognized directly in equity.

## Balance sheet
## Non-current assets

### Development projects

In accordance with IAS 38 Intangible Assets, intangible assets arising from development projects must be recognized on the balance sheet when the development project is clearly defined and identifiable, when the technical feasibility has been demonstrated and adequate resources to complete the development work and market or use the project have been documented, the project has received FDA clearance and company Management has declared its intention to manufacture and market or use the product.

Finally, it must be adequately demonstrated that future income from the development project will exceed the costs of production and development and costs used to sell and administer the product. Development costs concerning individual projects are only capitalized if there is adequate documentation that the future income from the individual projects will exceed not only the production, selling and administrative expenses, but also the actual development costs relating to the product.

### Rights and software

Rights and software are measured at cost less accumulated depreciation and impairment.

The cost comprises the purchase price as well as costs directly related to the purchase until the date on which the asset is ready for use. In addition, the cost comprises future minimum royalty payments to which the company is bound, discounted back to present value.

Assets are depreciated on a straight-line basis over their estimated useful lives based on the following assessment of the expected lives of the assets:

Rights and software; 3– 10 years

The basis of depreciation is cost less expected residual value at the end of the useful life. The cost of a total asset is split into smaller parts that are depreciated separately if such components have different useful lives. Depreciation methods, useful lives and residual values are reassessed annually.

Depreciation is recognized on the income statement under sales and marketing costs and administrative expenses.

### Fixtures and fittings, tools and equipment

Other plant, operating equipment and fixtures and fittings are measured at cost less accumulated depreciation and impairment losses. Cost comprises the purchase price and any costs directly attributable to the acquisition until the date when the asset is ready for use.

Assets are depreciated on a straight-line basis over their estimated useful lives based on the following assessment of the expected lives of the assets:

Other fixtures and fittings, tools and equipment; 3–5 years

The basis of depreciation is cost less expected residual value at the end of the useful life. The cost of a total asset is split into smaller parts that are depreciated separately if such components have different useful lives. Depreciation methods, useful lives and residual values are reassessed annually.

To the extent that depreciation is not reflected in the cost of inventories as production overhead depreciation is recognized on the income statement under production costs, sales and marketing costs, research and development costs and administrative expenses respectively.

# Note 1, continued

### Right-of-use assets

Right-of-use assets are initially measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments. Lease liabilities are initially measured as the net present value of the future lease payments discounted by the incremental borrowing rate.

The right-of-use asset is depreciated over the shorter of the asset's useful life or the lease term on a straight-line basis.

Depreciation is recognized on the income statement under administrative expenses.

### Deferred tax assets

Deferred tax is measured using the balance sheet liability method on temporary differences between the carrying amount and tax base of assets and liabilities. However, no deferred tax is recognized on temporary differences regarding non-deductible goodwill or other items for which temporary differences, with the exception of acquisitions, have arisen at the acquisition date without affecting either the profit/loss for the year or the taxable income. If the tax base may be calculated according to several sets of tax regulations, deferred tax is measured in accordance with the regulations that apply to the use of the asset or settlement of the liability as planned by Management.

Deferred tax assets, including the tax base of tax loss carry-forwards, are recognized under other non-current assets at the expected value of their utilization, either as an off-set against tax on future income or as an off-set against deferred tax liabilities within the same legal tax entity or jurisdiction (joint taxation).

Deferred tax related to elimination of unrealized intra-group profits and losses is adjusted on consolidation.

Deferred tax is measured based on the tax regulations and rates that, according to the rules in force at the balance sheet date, will apply at the time the deferred tax is expected to crystallize as current tax. Changes in deferred tax due to changes in the tax rate are recognized on the income statement.

### Impairment of assets

Deferred tax assets are reviewed annually and recognized only to the extent that it is probable that they will be utilized in the foreseeable future.

The carrying amounts of other non-current assets are tested annually to determine whether there is any indication of impairment. If such an indication exists, the recoverable amount of the asset is calculated. The recoverable amount is the higher of an asset's fair value less expected costs to sell and its value in use.

An impairment loss is recognized when the carrying amount of an asset or a cash generating unit exceeds the recoverable amount of the asset or the cash generating unit. Impairment losses are recognized in the income statement as production costs, sales and distribution costs or administrative expenses.

Impairment of assets is reversed to the extent changes have occurred to the assumptions and estimates leading to the impairment. Impairment is only reversed to the extent the new carrying amount of an asset does not exceed the carrying amount the asset would have had net of depreciation, had the asset not been impaired.

## Current assets

### Inventories

Inventories are measured at cost in accordance with the FIFO method. Where the net realizable value is lower than cost, inventories are written down to this lower value.

The cost of raw materials and consumables comprises the purchase price plus delivery costs.

The cost of finished goods and work in progress comprises the cost of raw materials, consumables, direct labor and production overheads. Production overhead comprises indirect material and labor costs as well as costs of maintenance and depreciation of the machinery and equipment used in the manufacturing process as well as costs of production administration and management.

The net realizable value of inventories is calculated as the selling price less costs of conversion and costs incurred to execute the sale and is determined having regard to marketability, obsolescence and expected losses.

### Receivables

Trade receivables are measured at amortized cost less allowance for lifetime expected credit losses. To measure the expected credit losses, trade receivables have been grouped based on business area and the days past due.

Trade receivables are written of when there is no reasonable expectation of recovery.

The cost of allowances for expected credit losses and write-offs for trade receivables are included in sales and distribution costs.

# Note 1, continued

### Income tax receivables

Current tax receivables are recognized on the balance sheet as calculated tax on the taxable income for the year, adjusted for tax on prior years' taxable income and for tax paid under the on-account tax scheme.

Companies covered by the Danish tax credit scheme (Skattekreditordningen) may obtain payment of the base of losses originating from research and development expenses of up to DKK 25 million.

### Prepayments

Prepayments are measured at cost Prepayments comprise costs incurred relating to subsequent financial years.

## Equity

### Treasury shares

Cost and selling prices of treasury shares as well as dividends are recognized directly in equity. A capital reduction effected by the cancellation of treasury shares will lower the share capital by an amount equal to the nominal value of the shares.

### Issue costs

Issue costs include costs legal fees, placement fees, finders fees and other costs associated with the issuing of new shares.

### Warrants

Proceeds received from the exercise of warrants are taken directly to equity.

## Financial liabilities

### Lease liabilities

The group leases office space and vehicles. Until January 1, 2019, leases were classified as operating leases. Payments made under operating leases were charged to profit or loss on a straight-line basis over the period of the lease.

From January 1, 2019, leases, except for short term assets in which the lease term is 12 months or less, or low value assets, are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the group.

Short term leases and leases of low value are recognized as an expense in the profit or loss on a straight-line basis over the lease term.

Lease liabilities are initially recognized at the present value of future lease payments. At initial recognition each leasing contract is assessed individually to determine the likelihood of exercising any potential extension options in the contract. The option to extend the contract period will be included in the calculation of the lease liability if it is reasonably certain that the extension option will be exercised.

Lease costs are not split into service components and rental costs but are accounted for as a single lease component. Variable service components invoiced separately are expensed as operational costs.

The lease liability is measured using a discount rate equal to the incremental borrowing rate.

If a lease contract is modified, the lease liability is remeasured.

Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit or loss over the lease period to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

### Tax payable

Current tax payables are recognized on the balance sheet as calculated tax on the taxable income for the year, adjusted for tax on prior years' taxable income and for tax paid under the on-account tax scheme.

### Other financial liabilities

Debt to banks is recognized at the raising of a loan at fair value less transaction costs. In the subsequent periods, financial liabilities are measured at amortized cost, applying the "effective interest rate method", to the effect that the difference between the proceeds and the nominal value is recognized on the income statement under financial expenses over the term of the loan.

Other liabilities are measured at amortized cost.

## Cash flow statement

The cash flow statement is presented according to the indirect method and cash flows from operating, investing and financing activities for the year, the year's changes in cash and cash equivalents as well as the company's cash and cash equivalents at the beginning and end of the year.

# Note 1, continued

Cash flows from operating activities are calculated as EBIT adjusted for non-cash operating items, working capital changes as well as financial income, financial expenses, establishment cost (subsidiaries) and income taxes paid.

Cash flows for investing activities comprise acquisitions and disposals of intangible assets, property, plant and equipment and financial assets.

Cash flows from financing activities comprise changes in the size or composition of the share capital of BioPorto A/S and related costs as well as the raising of loans, repayment of interest-bearing debt and payment of dividends to shareholders.

Cash and cash equivalents comprise cash at bank and in hand.

## Financial ratios

Earnings per share (EPS) and diluted earnings per share (DEPS) are calculated in accordance with IAS 33. Financial ratios have been calculated in accordance with the guidelines from the Danish Society of Financial Analysts from 2018.

The ratios listed in the key figures and ratios section were calculated as follows:

| | |
|---|---|
| Revenue growth | (Revenue year 1 - Revenue year 0) x 100 / Revenue year 0 |
| Gross margin | Gross profit x 100 / Net revenue |
| Equity ratio | Equity, closing x 100 / Total liabilities, closing |
| Earnings per share (EPS) | Result for the year / Average number of shares |
| Net asset value per share at year end | Capital and reserves, closing / No. of shares, closing |

# Note 2

## Significant accounting estimates and judgments

The calculation of the carrying amounts of certain assets and liabilities requires an estimate of how future events will affect the value of such assets and liabilities at the balance sheet date. Estimates material to the financial reporting are made in the calculation of, inter alia, development costs, incentive schemes, inventories and deferred tax.

The estimates made are based on assumptions that Management finds reasonable given the circumstances but which are inherently uncertain and unpredictable. The assumptions may be incomplete or imprecise and unexpected events or circumstances may arise. In addition, the company is subject to risks and uncertainties that may cause actual results to deviate from the estimates. Special risks to BioPorto are described in the Management's review.

### Development projects

In the opinion of Management, the development of the Group's products generally involves a high degree of risk, and therefore there is currently no adequate documentation for the future income. The future economic benefits in relation to the product development cannot be estimated with sufficient certainty until the development activities have been completed and received FDA clearance. As a result, development costs are expensed as incurred.

### Tax assets

The Group has a significant deferred tax asset (see note 9). However, Management has found that, in accordance with IFRS, it is not sufficiently probable that the tax asset can be utilized in the foreseeable future. Management has therefore decided not to recognize the calculated tax asset on the balance sheet.

# Note 3

## Segment reporting

| GEOGRAPHIC DISTRIBUTION | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Europe | 9,956 | 11,005 |
| North America | 12,936 | 12,161 |
| Asia | 3,182 | 2,445 |
| Other countries | 548 | 405 |
| **Revenue** | **26,622** | **26,016** |

The geographic distribution is based on the customer's registered office.

| PRODUCT GROUPS | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| NGAL revenue: | | |
| Product sales | 10,476 | 9,195 |
| Other NGAL revenue | 1,168 | 1,439 |
| Total NGAL revenue | 11,644 | 10,634 |
| Other products and licenses: | | |
| ELISA kits | 4,752 | 4,826 |
| Antibodies | 9,417 | 9,369 |
| Royalty | 142 | 41 |
| Other products and licenses | 667 | 1,146 |
| Total other products and license revenue | 14,978 | 15,382 |
| **Revenue** | **26,622** | **26,016** |

Product groups are defined as sale of goods, royalties and licenses.

No customer is responsible for more than 10% of BioPorto's revenue in 2019. One customer was responsible for more than 10% of BioPorto's revenue in 2018: The customer is based in Europe and made purchases amounting to DKK 3,116 thousand in 2018. The customer primarily purchases antibodies and ELISA kits. Out of net revenue, 48% was invoiced to customers based in the US (2018: 45%) and 11% to customers based in the UK (2018: 14%).

# Note 4

## Staff costs

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Wages and salaries | 38,943 | 25,948 |
| Defined contribution pension plans | 2,485 | 1,874 |
| Share-based compensation expenses | 3,109 | (865) |
| Other social security costs | 2,070 | 842 |
| Other staff costs | 566 | 436 |
| **Staff costs** | **47,173** | **28,235** |
| Average number of employees | 34 | 28 |

| SPECIFICATION OF STAFF COSTS | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Production costs | 3,554 | 3,005 |
| Sales and marketing costs | 19,282 | 10,881 |
| Research and development costs | 8,358 | 4,549 |
| Administrative expenses | 15,979 | 9,800 |
| **Staff costs** | **47,173** | **28,235** |

# Note 4, continued

| SPECIFICATION OF RENUMERATION FOR KEY MANAGEMENT PERSONNEL | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|
| **Executive Management** | | |
| **Peter Mørch Eriksen** | | |
| Salary | 3,280 | 3,026 |
| Bonus | 360 | 229 |
| LTI bonus[1)] | 704 | 85 |
| Contribution based pension | 528 | 483 |
| **Renumeration, Total** | **4,872** | **3,823** |
| Share-based compensation expenses | 1,065 | (241) |
| **Executive Management, Total** | **5,937** | **3,582** |
| **Management** | | |
| **Ole Larsen (Employment started at August 1, 2018)** | | |
| Salary | 2,811 | 1,114 |
| Bonus | 300 | 292 |
| Contribution based pension | 277 | 110 |
| Other employee benefits | 159 | 85 |
| **Renumeration, Total** | **3,547** | **1,601** |
| Share-based compensation expenses | 537 | 171 |
| **Jan Kuhlmann** | | |
| Salary | 2,276 | 2,130 |
| Bonus | 270 | 88 |
| LTI bonus[1)] | 352 | 43 |
| Contribution based pension | 225 | 201 |
| Other employee benefits | 84 | - |
| **Renumeration, Total** | **3,207** | **2,462** |
| Share-based compensation expenses | 546 | (158) |

| SPECIFICATION OF RENUMERATION FOR KEY MANAGEMENT PERSONEL | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|
| **Amy Morse Winslow (Employment started at March 1, 2019)** | | |
| Salary | 1,926 | - |
| Contribution based pension | 84 | - |
| **Renumeration, Total** | **2,010** | **-** |
| Share-based compensation expenses | 715 | - |
| **Chris Bird (Employment started at August 1, 2019)** | | |
| Salary | 981 | - |
| Bonus | 1,143 | - |
| Contribution based pension | 79 | - |
| **Renumeration, Total** | **2,203** | **-** |
| Share-based compensation expenses | 138 | - |
| **Board of Directors** | | |
| Remuneration | 1,402 | 1,450 |
| **TOTAL RENUMERATION FOR KEY MANAGEMENT PERSONNEL** | **20,242** | **9,108** |

[1)] A Long term incentive bonus plan was established in December 2018. The LTI has been expensed since it was established in 2018 and will be paid out once the KPI's are fulfilled (2020 and 2021).

In April 2019 Executive Management was granted 1,350,000 warrants. In 2018 Executive Management was granted 1,700,000 warrants in August and 1,800,000 warrants in December. Milestones for the issued warrant programs in 2019 and 2018 are described in note 5. In 2017 Executive Management was granted 2,400,000 warrants depending up receiving FDA-clearance of The NGAL Test in 2018. As the milestone was not achieved, the warrant program was subsequently forfeited in 2018.

# Note 5

## Incentive schemes

For the purpose of motivating and retaining Management and key staff, BioPorto A/S uses warrants as an incentive and bonus scheme. The arrangements, which may only be exercised by the issuance of new shares (equity-settled share-based payment transaction), entitle the recipient to subscribe for a number of new shares in the parent company at a price agreed in advance.

The share-based payment compensation expenses amounted to DKK 3.1 million in 2019 (2018: DKK -0.9 million). In 2018 the expenses for the issued programs were DKK 1.6 million, however, this was more than off-set by warrants forfeited due to resigned employees and the cancellation of the warrant program from 2017 totaling DKK -2.5 million.

The detailed warrant terms are found in the company's articles of association which can be found on www.bioporto.com under Investor Relations > Governance > Company Articles.

In 2019 the Board of Directors in BioPorto used its authorization and issued a total of 6,600,000 warrants to the Management and certain employees in three different programs. Each warrant entitles the recipient to subscribe for one share in BioPorto A/S.

### April 2019 program

In the first program from April a total of 5,100,000 warrants were issued. The exercise price was set at DKK 3.92 per share. The warrants can only be exercised in the period beginning on April 16, 2021 until April 15, 2024.

### August 2019 program

In the second program from August a total of 1,500,000 warrants were issued. The exercise price was set at DKK 2.88 per share. The warrants can only be exercised in the period beginning on August 16, 2021 until August 15, 2024. In December a total of 250,000 warrants was forfeited due to an employee resignation.

### December 2019 program

In the third program from December a total of 250,000 warrants were issued. The exercise price was set at DKK 2.90 per share. The warrants can only be exercised in the period beginning on December 30, 2021 until December 29, 2024.

### June 2018 program

In the first program from June a total of 900,000 warrants were issued. The exercise price was set at DKK 3.12 per share. In 2019 the vesting period of the program was extended from 24 to 36 months. At the same time the exercise period for the program was reduced from 36 to 24 months. The warrants can only be exercised in the period beginning on June 15, 2021 until June 14, 2023. Conditions for cancellation of all warrants in the program apply in case the Company does not achieve FDA approval of The NGAL Test within the vesting period.

### August 2018 program

In the second program from August a total of 4,100,000 warrants were issued. The exercise price was set at DKK 3.44 per share. In 2019 the vesting period of the program was extended from 24 to 36 months. At the same time the exercise period for the program was reduced from 36 to 24 months. The warrants can only be exercised in the period beginning on August 20, 2021 until August 19, 2023. Conditions for exercising of all warrants apply in case the Company achieves FDA approval of The NGAL Test before the subscription period, if 50 new hospital customer sites in the USA are achieved before December 31, 2019, and if the company achieve NGAL revenue growth of 100 % (in local currency in the USA) in 2019 compared to 2018.

### December 2018 program

In the third program from December a total of 2,500,000 warrants were issued. The exercise price was set at DKK 3.75 per share. The warrants can only be exercised in the period beginning on December 20, 2020 until December 19, 2023. Conditions for exercising of all warrants apply in case the Company achieves FDA approval of The NGAL Test before December 19, 2020, if 50 new hospital customer sites in the USA are achieved no longer than 12 months after the approval, and if the company achieves NGAL revenue growth of 100 % (in local currency) in the USA in the 12 months after the approval compared to the 12 months before the approval.

Within the exercise period, warrants can be exercised within ordinary trading windows. The program also includes conditions on claw-back in case of erroneous financial information and on accelerated vesting in case of e.g. takeover bid, resolution and business transfer.

All the warrants issued in 2018 and 2019 are restricted by terms concerning total or partial forfeiture. The theoretical market value of the warrants issued amounted to DKK 6,005,884. The specification is based on the Black-Scholes equation, using 2-year interest rate and the historical volatility of BioPorto A/S' shares over 24 months.

In 2016 and 2017 the Board of Directors issued two warrant programs.

### 2017 program

The program was forfeited in Q4 2018.

# Note 5, continued

## 2016 program

In 2016 a total of 6,368,696 warrants were issued to BioPorto's Management and certain employees. Each warrant entitles the recipient to subscribe for one share in BioPorto A/S. The exercise price is set at DKK 4.58 per share. The warrants can only be exercised in the period beginning on April 8, 2018 and ending on April 7, 2021. Within the exercise period, warrants can be exercised within ordinary trading windows. Roughly half of the warrants issued are restricted by terms concerning total or partial forfeiture. The theoretical market value of the warrants issued amounted to DKK 6,987,129 on the date of issue. The specification is based on the Black-Scholes equation, using a 2 year interest rate and the historical volatility of BioPorto A/S' shares over 24 months. By the end of 2019 the program had 2,432,500 outstanding warrants of which all are exercisable.

## Overview of exercise periods for the various programs

| | |
|---|---|
| April 2016 | April 8, 2018 to April 7, 2021 |
| June 2018 | June 15, 2021 to June 14, 2023 |
| August 2018 | August 20, 2021 to August 19, 2023 |
| December 2018 | December 20, 2020 to December 19, 2023 |
| April 2019 | April 16, 2021 to April 15, 2024 |
| August 2019 | August 16, 2021 to August 15, 2024 |
| December 2019 | December 30, 2021 to December 29, 2024 |

# Note 5, continued

## Overview of outstanding warrants at December 31, 2019

| | Outstanding at January 1 | Granted | Exercised | Expired | Forfeited | Outstanding at December 31 | Can be exercised at December 31 |
|---|---|---|---|---|---|---|---|
| April 2016 | 2,432,500 | - | - | - | - | 2,432,500 | 2,432,500 |
| June 2018 | 900,000 | - | - | - | - | 900,000 | - |
| August 2018 | 4,100,000 | - | - | - | - | 4,100,000 | - |
| December 2018 | 2,500,000 | - | - | - | - | 2,500,000 | - |
| April 2019 | - | 5,100,000 | - | - | - | 5,100,000 | - |
| August 2019 | - | 1,500,000 | - | - | (250,000) | 1,250,000 | - |
| December 2019 | - | 250,000 | - | - | - | 250,000 | - |
| **Total** | **9,932,500** | **6,850,000** | **-** | **-** | **(250,000)** | **16,532,500** | **2,432,500** |

| | Outstanding at January 1 | Granted | Exercised | Expired | Forfeited | Outstanding at December 31 | Can be exercised at December 31 |
|---|---|---|---|---|---|---|---|
| Executive Management | 4,410,000 | 1,350,000 | - | - | - | 5,760,000 | 910,000 |
| Management | 3,600,000 | 4,750,000 | - | - | - | 8,350,000 | - |
| Other employees | 1,922,500 | 750,000 | - | - | (250,000) | 2,422,500 | 1,522,500 |
| **Total** | **9,932,500** | **6,850,000** | **-** | **-** | **(250,000)** | **16,532,500** | **2,432,500** |

# Note 5, continued

## Overview of outstanding warrants at December 31, 2018

| | Outstanding at January 1 | Granted | Exercised | Expired | Forfeited | Outstanding at December 31 | Can be exercised at December 31 |
|---|---|---|---|---|---|---|---|
| April 2016 | 2,782,500 | - | - | - | (350,000) | 2,432,500 | 2,432,500 |
| April 2017 | 4,350,000 | - | - | - | (4,350,000) | - | - |
| June 2018 | - | 900,000 | - | - | - | 900,000 | - |
| August 2018 | - | 4,100,000 | - | - | - | 4,100,000 | - |
| December 2018 | - | 2,500,000 | - | - | - | 2,500,000 | - |
| **Total** | **7,132,500** | **7,500,000** | **-** | **-** | **(4,700,000)** | **9,932,500** | **2,432,500** |

| | Outstanding at January 1 | Granted | Exercised | Expired | Forfeited | Outstanding at December 31 | Can be exercised at December 31 |
|---|---|---|---|---|---|---|---|
| Executive Management | 3,310,000 | 3,500,000 | - | - | (2,400,000) | 4,410,000 | 910,000 |
| Management | 1,000,000 | 3,600,000 | - | - | (1,000,000) | 3,600,000 | - |
| Other employees | 2,822,500 | 400,000 | - | - | (1,300,000) | 1,922,500 | 1,522,500 |
| **Total** | **7,132,500** | **7,500,000** | **-** | **-** | **(4,700,000)** | **9,932,500** | **2,432,500** |

## Specification of parameters for Black-Scholes model

| | Apr 2016 | Jun 2018 | Aug 2018 | Dec 2018 | Apr 2019 | Aug 2019 | Dec 2019 |
|---|---|---|---|---|---|---|---|
| Exercise price at grant | 4.58 | 3.11 | 3.44 | 3.75 | 3.92 | 2.88 | 2.90 |
| Expected volatility rate | 59.8% | 37.6% | 37.3% | 50.1% | 47.3% | 47.2% | 50.1% |
| Expected life (months) | 24 | 36 | 36 | 24 | 24 | 24 | 24 |
| Expected dividend per share | - | - | - | - | - | - | - |
| Risk-free interest rate p.a. | -0.429% | -0.556% | -0.578% | -0.514% | -0.604% | -0.87% | -0.69% |
| Fair value at grant (thousands) | 7,509 | 575 | 2,868 | 2,561 | 5,151 | 1.102 | 197 |

# Note 6

## Amortization and depreciation

| RIGHTS AND SOFTWARE | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| **Total amortization** | **377** | **307** |
| **Specification of amortization:** | | |
| Sales and marketing costs | 331 | 291 |
| Administrative expenses | 46 | 16 |
| **Total amortization** | **377** | **307** |

| PROPERTY, PLANT AND EQUIPMENT | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| **Total depreciation** | **373** | **236** |
| **Specification of depreciation:** | | |
| Production costs | 88 | 84 |
| Sales and marketing costs | 1 | 1 |
| Research and development costs | 268 | 149 |
| Administrative expenses | 16 | 2 |
| **Total depreciation** | **373** | **236** |

| RIGHT-OF-USE ASSETS | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| **Total depreciation** | **2,107** | **-** |
| **Specification of depreciation:** | | |
| Administrative expenses | 2,107 | - |
| **Total depreciation** | **2,107** | **-** |

# Note 7

## Fees to auditors appointed by the general meeting

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| **Fees to auditors appointed by the general meeting** | **829** | **849** |
| **Breakdown of fees:** | | |
| Fees for statutory audit | 355 | 260 |
| Fees for tax consulting | 413 | 398 |
| Other services | 61 | 191 |
| **Total fees to auditors appointed by the general meeting** | **829** | **849** |

Fees for services in addition to the statutory audit of the financial statements which were provided by the statutory auditor PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab amounted to DKK 0.6 million. Non-audit services in addition to the statutory audit of the financial statements comprise services relating to tax compliance, other assurance opinions as well as other general accounting consultancy services.

# Note 8

## Financial income and expenses

| FINANCIAL INCOME | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Interest income from bank | 75 | 27 |
| **Interest income from financial assets measured at amortized cost** | **75** | **27** |
| Exchange rate adjustments, net | 428 | 250 |
| **Total financial income** | **503** | **277** |

| FINANCIAL EXPENSES | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Interest expenses, other debt | (42) | (38) |
| Interest expenses, leasing debt | (284) | - |
| **Interest expenses on financial liabilities measured at amortized cost** | **(326)** | **(38)** |
| Other financial expenses | (125) | (75) |
| **Total financial expenses** | **(451)** | **(113)** |

# Note 9

## Deferred tax

The Group has a significant deferred tax asset. However, Management has found that, regarding IFRS, it is not sufficiently probable that the tax asset can be utilized in the foreseeable future. Management has therefore decided not to recognize the calculated tax asset on the balance sheet, cf. note 2. The tax asset is of indefinite duration.

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Calculated tax asset | **55,043** | 44,382 |
| Write down to assessed value | **(55,043)** | (44,382) |
| **Carrying amount** | **-** | **-** |

| DEFERRED TAX ASSETS NOT RECOGNIZED IN THE BALANCE SHEET | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Intangible assets | 614 | 488 |
| Property, plant and equipment | 805 | 761 |
| Right-of-use assets | (656) | - |
| Current assets | 58 | 182 |
| Leasing liabilities | 682 | - |
| Tax losses carried forward | 53,540 | 42,951 |
| **Deferred tax at December 31, net** | **55,043** | **44,382** |

| INCOME TAX BENEFITS | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Net result before tax | (74,247) | (41,617) |
| **Computed, 22%** | **(16,334)** | **(9,156)** |
| Valuation allowance | 16,334 | 9,156 |
| Tax credit for research and development cost | 4,764 | 3,632 |
| Tax foreign subsidiaries | (319) | (38) |
| Adjustment of tax from previous years | 160 | (25) |
| **Total income tax benefits** | **4,605** | **3,569** |

In accordance with the Danish tax credit scheme (Skattekreditordningen) BioPorto is eligible to receive DKK 4,764 thousand (2018: DKK 3,632 thousand) in cash relating to the surrendered tax loss for 2019 of DKK 21,657 thousand (2018: DKK 16,511 thousand) based on qualifying research and development expenses.

# Note 10

## Earnings per share

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Profit/loss for the period | (69,642) | (38,048) |
| **BioPorto Group's share of profit/loss** | **(69,642)** | **(38,048)** |
| Average number of shares | 170,405 | 156,653 |
| Average number of treasury shares | (13) | (13) |
| Average number of shares in circulation | 170,392 | 156,640 |
| Diluted average number of shares in circulation | 170,392 | 156,640 |
| Earnings per share (EPS) | (0.41) | (0.24) |

There is no difference between earnings per share (EPS) and diluted earnings per share (DEPS) because the company incurred a loss for the year. The warrants are not included in the calculation of earnings per share (EPS) or diluted earnings per share (DEPS).

# Note 11

## Rights and software

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Cost at January 1 | 2,363 | 2,311 |
| Additions during the year | 460 | 52 |
| Disposals during the year | (234) | - |
| **Cost at December 31** | **2,589** | **2,363** |
| Amortization at January 1 | (989) | (682) |
| Amortization during the year | (377) | (307) |
| Disposals during the year | 39 | - |
| **Amortization at December 31** | **(1,327)** | **(989)** |
| **Carrying amount at December 31** | **1,262** | **1,374** |

# Note 12

## Fixtures and fittings, tools and equipment

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Cost at January 1 | 3,464 | 2,054 |
| Additions during the year | 646 | 1,410 |
| **Cost at December 31** | **4,110** | **3,464** |
| Depreciation at January 1 | (2,027) | (1,791) |
| Depreciation during the year | (373) | (236) |
| **Depreciation at December 31** | **(2,400)** | **(2,027)** |
| **Carrying amount at December 31** | **1,710** | **1,437** |

# Note 13

## Right-of-use assets

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Cost at January 1 | 5,324 | - |
| Additions during the year | 294 | - |
| Currency adjustments | 21 | - |
| **Cost at December 31** | **5,639** | **-** |
| Amortization at January 1 | - | - |
| Amortization during the year | (2,107) | - |
| Currency adjustments | 5 | - |
| **Amortization at December 31** | **(2,102)** | **-** |
| **Carrying amount at December 31** | **3,537** | **-** |

| LEASE LIABILITIES | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Current | 2,165 | - |
| Non-current | 1,545 | - |
| **Lease liabilities at December 31** | **3,710** | **-** |

| 2019 | Less than 1 year<br>DKK thousand | Between 1 and 5 years<br>DKK thousand | More than 5 years<br>DKK thousand | Total<br>DKK thousand |
|---|---|---|---|---|
| Lease liabilities | 2,165 | 1,545 | - | 3,710 |
| **Total** | **2,165** | **1,545** | **-** | **3,710** |

| AMOUNTS RECOGNIZED IN THE INCOME STATEMENT | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Depreciation charge of right-of-use assets | 2,107 | - |
| Interest expense (included in financial expenses) | 284 | - |
| Expense related to short-term leases | 34 | - |
| | **2,425** | **-** |

BioPorto has had no low-value lease contracts in 2019 or 2018.

The total cash outflow for leases in 2019 was DKK 2,211 thousand.

Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased assets may not be used as security for borrowing purposes.

# Note 14

## Inventories

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Finished goods | 2,144 | 2,246 |
| Raw materials and consumables | 2,011 | 1,385 |
| **Inventories** | **4,155** | **3,631** |
| Write-down of slow-moving items | 591 | 248 |
| Cost of sales included in production cost | 3,304 | 3,151 |

All product groups have been individually assessed in terms of historical marketability and future sales potential. Inventories have been written down to the extent it is believed that the product group will not contribute substantially to the company's future revenue. Inventories assessed to be non-marketable within the next three years are written off.

# Note 15

## Receivables

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Trade receivables | 5,959 | 8,417 |
| Other receivables | 567 | - |
| Prepayments | 1,183 | 606 |
| Provision for bad debts | (264) | (381) |
| **Total receivables** | **7,445** | **8,642** |

For receivables that mature within one year after the end of the financial year, the nominal value is considered to correspond to the fair value.

A provision for bad debts is recognized to reduce the carrying amount of trade receivables by the value which is impaired due to risk of loss. As of January 1, 2018 the provision for bad debts has been calculated based on the simplified expected credit loss model.

An overview of trade receivables is included in note 18.

# Note 16

## Share capital

| NUMBER OF SHARES | 2019 Number | 2018 Number |
|---|---|---|
| January 1 | 165,687,798 | 155,509,681 |
| Issue | 9,256,577 | 10,178,117 |
| **December 31** | **174,944,375** | **165,687,798** |

| CAPITAL INCREASES IN 2019 | Number of shares | Nominal value DKK | Share price DKK/share |
|---|---|---|---|
| Issue | 9,256,577 | 1.00 | 3.97 |

| CAPITAL INCREASES IN 2018 | Number of shares | Nominal value DKK | Share price DKK/share |
|---|---|---|---|
| Issue | 10,178,117 | 1.00 | 3.93 |

The share capital consists of 174,944,375 shares of DKK 1.00 each. The share capital has been paid up in full. The shares have not been divided into classes and carry no special rights.

The Board of Directors is authorized until March 18, 2022 to increase the company's capital stock on one or more occasions by a total of DKK 110,743,423. Further details are available in Article 16 of the Company Articles.

# Note 17

## Treasury shares

| NOMINAL VALUE | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|
| January 1 | 13 | 13 |
| December 31 | **13** | **13** |

| NUMBER | No. | No. |
|---|---|---|
| January 1 | 13,000 | 13,000 |
| December 31 | **13,000** | **13,000** |

| % OF SHARE CAPITAL | % | % |
|---|---|---|
| January 1 | 0.01% | 0.01% |
| December 31 | **0.01%** | **0.01%** |

At present, BioPorto A/S is not authorized to acquire treasury shares.
BioPorto A/S did not acquire treasury shares in 2019 or 2018.

# Note 18

## Financial risks and financial instruments

| FINANCIAL INSTRUMENT CATEGORIES | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|
| Trade receivables | 5,695 | 8,036 |
| Other receivables | 567 | - |
| Cash and cash equivalents | 18,122 | 46,709 |
| **Financial assets at amortized cost** | **24,384** | **54,745** |

| | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|
| Lease liabilities | 3,710 | - |
| Other non-current liabilities | 1,098 | 928 |
| Trade payables | 3,237 | 4,451 |
| **Financial liabilities at amortized cost** | **8,045** | **5,379** |

| | Currency | Effective rate of interest | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|---|---|
| Floating-rate deposits | DKK | -0.5% to 0.5% | 18,122 | 46,709 |
| Sensitivity to change in interest rates | | 0.01 | 324 | 135 |

### Financial liabilities

Liabilities under trade payables and other payables fall due within one year after the end of the financial year. For these liabilities, the carrying amount is assumed to equal the fair value.

## Financial risks

### Currency risk

Currency risks include the risk arising from sales and production contracts being denominated in currencies other than Danish kroner. Contracts are primarily in USD and EUR, meaning that exposure in other currencies represents an insignificant currency risk.

With current revenue and contract-sizes the Company assess that it is not feasible to hedge its USD exposure. However, the Company is monitoring the USD exposure and will be ready to use financial instruments to hedge its USD exposure. As long as the DKK is linked to the EUR the Company's revenue and costs in EUR will not be hedged.

| | Currency | Exchange rate | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|---|---|
| Trade receivables settled in | EUR | 7.47 | 4,477 | 3,894 |
| Sensitivity to change in exchange rates | 1.00% | 0.07 | 45 | 39 |
| Trade receivables settled in | USD | 6.67 | 1,344 | 3,628 |
| Sensitivity to change in exchange rates | 10.00% | 0.67 | 134 | 363 |

### Interest rate risk

The Group's cash is placed in a flexible savings account on high-interest terms, and a lesser amount is subject to a variable interest rate on market terms. The company's risk is limited (see the statement in this note under financial instruments).

# Note 18, continued

## Credit risk

The Group's credit risk is primarily associated with trade receivables. Cash and cash equivalents are deposited with major Danish banks and the credit risk estimated to be immaterial. The financial situation and ability to pay of entities with trade receivables are continuously evaluated, with payment upon placement of an order required if ability-to-pay is evaluated to be low. To measure expected credit losses, trade receivables are grouped by business area and days past due. The expected loss percentage is calculated based on historical credit losses. Trade receivables are written of when there is no reasonable expectation of recovery. The maximum credit risk of the group as of December 31, 2019 is estimated to be DKK 5,695 thousand (DKK 8,036 thousand).

| 2019 | Expected credit loss rate | Trade receivables DKK thousand | Expected loss DKK thousand | Total DKK thousand |
|---|---|---|---|---|
| Not due | 0.0% | 3,680 | - | 3,680 |
| 1-30 days overdue | 4.5% | 593 | 27 | 566 |
| 31-60 days overdue | 2.8% | 269 | 8 | 261 |
| 61-90 days overdue | 7.0% | 106 | 7 | 99 |
| More than 90 days overdue | 16.9% | 1,311 | 222 | 1,089 |
| **December 31, 2019** | | **5,959** | **264** | **5,695** |

The majority of the 'More than 90 days overdue' are receivables from distributors, where the credit risk is considered low.

| 2018 | Expected credit loss rate | Trade receivables DKK thousand | Expected loss DKK thousand | Total DKK thousand |
|---|---|---|---|---|
| Not due | 1.2% | 5,075 | 61 | 5,014 |
| 1-30 days overdue | 3.7% | 422 | 16 | 406 |
| 31-60 days overdue | 5.2% | 344 | 18 | 326 |
| 61-90 days overdue | 7.3% | 345 | 25 | 320 |
| More than 90 days overdue | 11.7% | 2,231 | 261 | 1,970 |
| **December 31, 2018** | | **8,417** | **381** | **8,036** |

BioPorto has recognized a bad debt provision of DKK 0.3 million (DKK 0.4 million in 2018) based on the simplified expected credit loss model.

## Liquidity risk

In connection with BioPorto's ongoing financing of operations, efforts are made to ensure adequate and flexible liquidity. As of December 31, 2019, BioPorto's liquid assets amounted to DKK 18.1million. Provided that the presented guidance for 2020 is achieved, that the processing times usually seen with the US registration-application process are followed and the current financing expected finalized in mid-April is secured the liquid assets and capital resources are deemed sufficient for collecting the additional data and submitting the application for the FDA clearance of The NGAL Test™ in children in 2020, and preparing initiation of commercialization of The NGAL Test™ in the US market. Flexibility is guaranteed by placing free funds in deposits.

Maturity dates for financial liabilities are specified below broken down by the time intervals applied in the Group's cash management. The amounts specified represent the amounts falling due including interest, etc.

## Capital structure

Management regularly assesses whether the Group's capital structure properly serves the interests of the Group and the shareholders. The overarching goal is to secure a capital structure that underpins long-term financial growth while maximizing returns to the Group's stakeholders by optimizing the debt/equity ratio.

## Financial risks and financial instruments

| 2019 | Less than 1 year DKK thousand | Between 1 and 5 years DKK thousand | More than 5 years DKK thousand | Total DKK thousand |
|---|---|---|---|---|
| Lease liabilities | 2,165 | 1,545 | - | 3,710 |
| Other non-current liabilities | 141 | 807 | 150 | 1,098 |
| Trade payables and other payables | 12,474 | - | - | 12,474 |
| **Financial liabilities** | **14,780** | **2,352** | **150** | **17,282** |

| 2018 | Less than 1 year DKK thousand | Between 1 and 5 years DKK thousand | More than 5 years DKK thousand | Total DKK thousand |
|---|---|---|---|---|
| Other non-current liabilities | 141 | 488 | 299 | 928 |
| Trade payables and other payables | 9,029 | - | - | 9,029 |
| **Financial liabilities** | **9,170** | **488** | **299** | **9,957** |

# Note 19

## Change in working capital

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Change in inventories | (524) | (197) |
| Change in receivables | 1,197 | (1,039) |
| Change trade payables | (1,214) | 1,039 |
| Change in non-current liabilities | 335 | - |
| Change in other payables | 4,659 | (434) |
| **Total change in working capital** | **4,453** | **(631)** |

# Note 20

## Capital increase

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Issue, gross proceeds | 36,749 | 40,000 |
| Issue costs | (766) | (681) |
| **Total net proceeds** | **35,983** | **39,319** |

# Note 21

## Contingent liabilities and events after the end of the period

BioPorto has in the fourth quarter of 2019 entered into a lease agreement for offices. The lease is not recognized as a lease liability as the leased office space is not available for use at December 31, 2019. No lease payments have been made in 2019 regarding the new lease.

The total commitment of the lease agreement is DKK 12,274 thousand.

The company is regularly involved in disputes but does not currently expect such disputes to impose any obligations on the company.

BioPorto has entered into development, distribution and licensing agreements with external parties that can be subject to renegotiation in the event of a change of ownership in BioPorto A/S. Possible changes to the agreements that would have a significant impact on the Group's financial position is not expected.

### Events after the end of the period

The Board and Management are not aware of any reporting events occurring after the end of the financial year of significance to the group's economic or financial position that are not described in this annual report.

# Note 22

## Cash preparedness and cash position during 2020

The Board of Directors and Management regularly assess whether BioPorto has an adequate capital structure, adequate capital resources and liquidity resources available. Such assessment has also been carried out in relation to preparing the 2019 Annual Report. The Board of Directors will together with Management monitor the development of the cash position throughout 2020 ensuring appropriate financial readiness at all times.

The guidance for 2020 and the expected cash position on December 31, 2020 are based on assumptions of financing with net proceeds of DKK 65 million and a 10% increase in revenues of The NGAL Test in 2020 and a slight decrease in revenue generated by antibodies compared to 2019. No sales of a FDA-cleared The NGAL Test in the US is assumed in 2020. As announced earlier the Company is currently pursuing financing. The Company expects the financing to be finalized by mid-April.

Budgets and plans are based on best estimates of the future at the time of approving the Annual Report. However, budgets and financing plans relate to future events and the fulfilment of such are by nature prone to uncertainty.

If against expectations, BioPorto do not complete the financing or raises a lower cash amount than expected in the financing and/or performs below budget, the Board of Directors and Management will take mitigating actions to secure sufficient cash until December 31, 2020. These mitigating actions could include a capital increase with pre-emptive rights for shareholders later in 2020.

Although the Board of Directors and Management based on this assessment considers that BioPorto will have adequate and enough liquidity resources available to finance the operations of the Group for the coming year, the above indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern.

# Note 23

## Related parties and ownership

BioPorto - The Group's related parties are:

### Board of Directors and Executive Management

Thomas Magnussen, Chairman (elected February 26, 2013)

Torben A. Nielsen, Vice Chairman (elected April 02, 2013)

Kirsten Drejer (elected April 21, 2017)

Christopher Lindop (elected August 15, 2019)

Michael Singer (elected August 15, 2019)

Peter Mørch Eriksen, CEO (appointed July 18, 2013)

### Group-owned companies

BioPorto Diagnostics A/S, Tuborg Havnevej 15, 2900 Hellerup. Ownership: 100%

BioPorto Diagnostics Inc, Chicago, Illinois, USA. Ownership: 100%

BioPorto Inc, Chicago, Illinois, USA. Ownership: 100%

Veterinary Diagnostics A/S, Tuborg Havnevej 15, 2900 Hellerup. Ownership: 100%

### Related party transactions

Intercompany transactions are made under arm’s length conditions.

In 2019, BioPorto purchased consultancy services in the amount of DKK 240,000 from Therazone ApS in conjunction with recruitment of new board members. Therazone ApS is owned by Chairman Thomas Magnussen.

# Income statement

| Note | | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|---|
| 2 | Revenue | 9,600 | 9,600 |
| | **Gross profit** | **9,600** | **9,600** |
| 3 | Sales and marketing cost | (3,357) | (2,577) |
| 3,4 | Administrative expense | (25,028) | (17,450) |
| | **Profit/loss before financial items (EBIT)** | **(18,785)** | **(10,427)** |
| 5 | Income from investments in subsidiaries | (70,144) | (43,686) |
| 6 | Financial income | 20,406 | 17,440 |
| 6 | Financial expenses | (266) | (18) |
| | **Profit/loss before tax** | **(68,789)** | **(36,691)** |
| 7 | Total income taxes | (853) | (1,357) |
| | **Profit/loss for the year** | **(69,642)** | **(38,048)** |

# Balance sheet

| Note | ASSETS | 2019 December 31 DKK thousand | 2018 December 31 DKK thousand |
|---|---|---|---|
| | **Financial assets** | | |
| | Right-of-use assets | 2,980 | - |
| 5 | Investments in subsidiaries | - | 3,183 |
| | Receivables from subsidiaries | 40,035 | 20,038 |
| | Deposits | 774 | 752 |
| | **Total financial assets** | **43,789** | **23,973** |
| | **Total non-current assets** | **43,789** | **23,973** |
| | **Current assets** | | |
| | Income tax receivables | 4,764 | 3,632 |
| | Prepayments | 798 | 285 |
| | **Total receivables** | **5,562** | **3,917** |
| | Cash | 12,864 | 41,363 |
| | **Total current assets** | **18,426** | **45,280** |
| | **Total assets** | **62,215** | **69,253** |

| EQUITY AND LIABILITIES | 2019 December 31 DKK thousand | 2018 December 31 DKK thousand |
|---|---|---|
| **Equity** | | |
| Share capital | 174,944 | 165,688 |
| Exchange rate adjustments | (672) | (347) |
| Retained profit/loss | (148,950) | (109,144) |
| **Total equity** | **25,322** | **56,197** |
| **Provisions** | | |
| Investments in subsidiaries with negative equity | 28,065 | 9,531 |
| **Total provisions** | **28,065** | **9,531** |
| **Liabilities** | | |
| **Non-current liabilities** | | |
| Lease obligation | 1,332 | - |
| Other non-current liabilities | 61 | - |
| **Non-current liabilities** | **1,393** | **-** |
| **Current liabilities** | | |
| Current portion of non-current liabilities | 1,769 | - |
| Trade payables | 923 | 635 |
| Payables to subsidiaries | 60 | - |
| Other payables | 4,683 | 2,890 |
| **Current liabilities** | **7,435** | **3,525** |
| **Total liabilities** | **8,828** | **3,525** |
| **Total equity and liabilities** | **62,215** | **69,253** |

# Statement of changes in equity

| | Share capital DKK thousand | Share premium DKK thousand | Exchange rate adjustment DKK thousand | Retained earnings DKK thousand | Total DKK thousand |
|---|---|---|---|---|---|
| Equity at January 1, 2019 | 165,688 | - | (347) | (109,144) | **56,197** |
| | | | | | |
| Comprehensive income | | | | | |
| Profit/loss for the year | - | - | - | (69,642) | **(69,642)** |
| Adjustment of foreign currency fluctuations on subsidiaries | - | - | (325) | - | **(325)** |
| | | | | | |
| Transactions with owners | | | | | |
| Issue | 9,256 | 27,493 | - | - | **36,749** |
| Issue costs | - | (766) | - | - | **(766)** |
| Share-based compensation | - | - | - | 3,109 | **3,109** |
| Transferred to Retained earnings | - | (26,727) | - | 26,727 | **-** |
| **Equity at December 31, 2019** | **174,944** | **-** | **(672)** | **(148,950)** | **25,322** |

| | Share capital DKK thousand | Share premium DKK thousand | Exchange rate adjustment DKK thousand | Retained earnings DKK thousand | Total DKK thousand |
|---|---|---|---|---|---|
| Equity at January 1, 2018 | 155,510 | - | (70) | (99,372) | **56,068** |
| | | | | | |
| Comprehensive income | | | | | |
| Profit/loss for the year | - | - | - | (38,048) | **(38,048)** |
| Adjustment of foreign currency fluctuations on subsidiaries | - | - | (277) | - | **(277)** |
| | | | | | |
| Transactions with owners | | | | | |
| Issue | 10,178 | 29,822 | - | - | **40,000** |
| Issue costs | - | (681) | - | - | **(681)** |
| Share-based compensation | - | - | - | (865) | **(865)** |
| Transferred to Retained earnings | - | (29,141) | - | 29,141 | **-** |
| **Equity at December 31, 2018** | **165,688** | **-** | **(347)** | **(109,144)** | **56,197** |

# Notes - Parent

# Note 1

## Accounting policies

The financial statements of the parent company BioPorto A/S have been prepared in accordance with the provisions of the Danish Financial Statements Act for large reporting class D enterprises.

The annual report is presented in Danish kroner (DKK), which also is the functional currency of the company.

### Changes in accounting policies

At group level IFRS 16 'Leases' was implemented using the modified retrospective approach on January 1, 2019. Reference is made to note 1 in BioPorto's consolidated financial statements for further description.

The implementation has had the following impact on the balance sheet of BioPorto A/S

| | Dec. 31, 2019 DKK thousand | Jan. 1, 2019 DKK thousand |
|---|---|---|
| Increase of assets | 2,980 | 4,417 |
| Increase of liabilities (Short term and long term) | 3,101 | 4,417 |
| Increase of interest costs | 235 | - |

BioPorto A/S has implemented IFRS 15 on January 1, 2019. The application of IFRS 15 has had no impact on BioPorto A/S's financial statements.

Other than this, the accounting policies are consistent with those applied last year.

### Differences relative to the Group's accounting policies

The parent company's accounting policies for recognition and measurement are in accordance with the Group's policies with the exceptions set out below:

## Income statement

### Income from investments in subsidiaries.

Income from investments in subsidiaries are recognized in the parent company's income statement.

## Balance sheet

### Investments in subsidiaries.

Investments in subsidiaries are recognized and measured under the equity method. Subsidiaries with a negative net asset value are recognized at DKK nil, and any receivable amount from these companies is written down by the negative net asset value to the extent it is deemed to be irrecoverable.

### Cash flow statement

As allowed under section 86 (4) of the Danish Financial Statements Act, no cash flow statement has been prepared, as this is included in the consolidated cash flow statement.

### Taxation

The parent company is taxed jointly with its domestic subsidiaries. The jointly taxed Danish enterprises are taxed under the Danish on-account tax scheme. Current tax for jointly-taxed companies is recognized in each individual company. All jointly-taxed companies are covered by the joint-taxation liability.
See "Deferred tax assets and Tax payable" in the consolidated financial statements.

# Note 2

## Revenue

| GEOGRAPHIC DISTRIBUTION | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|
| Denmark | 9,600 | 9,600 |
| **Revenue** | **9,600** | **9,600** |

The sale of services in BioPorto A/S exclusively concerns intra-group selling of services. The revenue is recognized over time in the accounting period in which the services are rendered.

# Note 3

## Staff costs

| | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|
| Wages and salaries | 13,527 | 11,133 |
| Share-based compensation expenses | 3,109 | (865) |
| Defined contribution pension plans | 1,231 | 991 |
| Other social security costs | 69 | 58 |
| Other staff costs | 61 | 85 |
| **Staff costs** | **17,997** | **11,402** |
| Average number of employees | 6 | 6 |

| SPECIFICATION OF STAFF COSTS | 2019 DKK thousand | 2018 DKK thousand |
|---|---|---|
| Sales and marketing costs | 3,357 | 2,304 |
| Administrative expenses | 14,640 | 9,098 |
| **Staff costs** | **17,997** | **11,402** |

Reference is made to note 4 in the consolidated financial statements concerning remuneration of the Executive Management and Board of Directors and share-based payment.

# Note 4

## Fees to auditors appointed by the general meeting

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Fees for statutory audit | 355 | 260 |
| Fees for tax consulting | 42 | 108 |
| Other services | 61 | 191 |
| **Total fees to auditors appointed by the shareholders** | **458** | **559** |

# Note 5

## Investments in subsidiaries

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Cost at January 1 | 51,364 | 51,364 |
| Additions | - | - |
| **Cost at December 31** | **51,364** | **51,364** |
| Revaluation at January 1 | (343,666) | (299,703) |
| Income from investments in subsidiaries | (70,144) | (43,686) |
| Exchange rate adjustments investments in subsidiaries | (325) | (277) |
| Equity changes in subsidiaries | - | - |
| **Revaluation at December 31** | **(414,135)** | **(343,666)** |
| **Value at December 31** | **(362,771)** | **(292,302)** |
| Negative value of investments set off against receivables from group | 334,706 | 285,954 |
| Negative value of investments recognized as a provision | 28,065 | 9,531 |
| **Value at December 31** | **-** | **3,183** |

BioPorto A/S regularly contributes capital to the subsidiary BioPorto Diagnostics A/S to support the subsidiary's operating activities. The receivable amount carries interest at an annual rate of 6%, which accrues once a year on December 31. The Management members of BioPorto A/S and BioPorto Diagnostics A/S are identical. As BioPorto Diagnostics A/S activities account for the bulk of the Group's activities, reference is made to the Management's review, including the description of risks. Management believes that some uncertainty attaches to BioPorto Diagnostics A/S possibility of repaying the part of the parent company's receivable from the subsidiary which corresponds to the subsidiary's negative equity. Accordingly, a write-down has been made to reflect this.

## List of subsidiaries

BioPorto Diagnostics A/S, Tuborg Havnevej 15, 2900 Hellerup. Ownership: 100%

BioPorto Inc, Chicago, Illinois, USA. Ownership: 100%

BioPorto Diagnostics Inc, Chicago, Illinois, USA. Ownership: 100%

Veterinary Diagnostics A/S, Tuborg Havnevej 15, 2900 Hellerup. Ownership: 100%

# Note 6

## Financial income and expenses

| FINANCIAL INCOME | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Interest income from subsidiaries | 19,883 | 16,618 |
| Interest income from bank | 75 | 27 |
| Exchange rate adjustments, net | 448 | 795 |
| **Total financial income** | **20,406** | **17,440** |

| FINANCIAL EXPENSES | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Interest expense to subsidiaries | (4) | - |
| Interest expenses, leasing debt | (235) | - |
| Interest expenses, other debt | (27) | (16) |
| Exchange rate adjustments, net | - | (2) |
| Other financial expenses | - | - |
| **Total financial expenses** | **(266)** | **(18)** |

# Note 7

## Deferred tax

A deferred tax asset has been calculated. However, Management has found that it is not sufficiently probable that the tax asset can be utilized. Management has therefore decided not to recognize the calculated tax asset on the balance sheet. Reference is made to note 2 in BioPorto's consolidated financial statements.

| | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Calculated tax asset | 26 | 52 |
| Write-down to assessed value | (26) | (52) |
| **Carrying amount** | **-** | **-** |

| DEFERRED TAX ASSETS NOT RECOGNIZED IN THE BALANCE SHEET | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Property, plant and equipment | 656 | 52 |
| Leasing liabilities | (682) | - |
| **Deferred tax at December 31, net** | **(26)** | **52** |

| TOTAL INCOME TAXES | 2019<br>DKK thousand | 2018<br>DKK thousand |
|---|---|---|
| Net result before tax | (68,789) | (36,691) |
| **Computed 22%** | **(15,134)** | **(8,072)** |
| | | |
| Valuation allowance | 15,134 | 8,072 |
| Taxation contribution, group companies | (1,013) | (1,357) |
| Adjustment of tax from previous years | 160 | - |
| **Total income taxes** | **(853)** | **(1,357)** |

# Note 8

## Contingent liabilities

BioPorto A/S has acknowledged towards the subsidiaries BioPorto Diagnostics A/S, Veterinary Diagnostics A/S BioPorto Inc. and BioPorto Diagnostics Inc. that it will finance its operations in 2020. The contingent liability is estimated to DKK 68 million.

# Note 9

## Distribution of the year's result

The Board of Directors proposes that BioPorto A/S's loss for the year 2019 of DKK 69,642 thousand (2018: loss of DKK 38,048 thousand) to be transferred to retained earnings.

# Note 10

## Other notes

Reference is made to notes 16 and 17 in BioPorto's consolidated financial statements with respect to share capital and treasury shares.

Reference is made to note 23 in BioPorto's consolidated financial statements with respect to matters relating to related parties and the section on directorships held by members of the Board of Directors and Management Board.

# Statement by Management

The Board of Directors and Executive Management have today considered and adopted the Annual Report of BioPorto A/S for the financial year January 1 – December 31, 2019.

The Consolidated Financial Statements have been prepared in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act, and the Parent Company Financial Statements have been prepared in accordance with the Danish Financial Statements Act. Management's Review has been prepared in accordance with the Danish Financial Statements Act.

In our opinion, the Consolidated Financial Statements and the Parent Company Financial Statements give a true and fair view of the financial position at December 31, 2019 of the Group and the Parent Company and of the results of the Group and Parent Company operations and consolidated cash flows for the financial year January 1 - December 31, 2019.

In our opinion, Management's Review includes a true and fair account of the development in the operations and financial circumstances of the Group and the Parent Company, of the results for the year and of the financial position of the Group and the Parent Company as well as a description of the most significant risks and elements of uncertainty facing the Group and the Parent Company.

We recommend that the Annual Report be adopted at the Annual General Meeting.

Hellerup, March 11, 2020

**Executive Management**:

**Peter Mørch Eriksen**
CEO

**Board of Directors**:

**Thomas Magnussen**
Chairman

**Torben A. Nielsen**
Vice Chairman

**Kirsten Drejer**

**Christopher Lindop**

**Michael Singer**

# Independent auditor's report

**To the shareholders of BioPorto A/S**

## Our opinion

In our opinion, the Consolidated Financial Statements give a true and fair view of the Group's financial position at December 31, 2019 and of the results of the Group's operations and cash flows for the financial year January 1 to December 31, 2019 in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act.

Moreover, in our opinion, the Parent Company Financial Statements give a true and fair view of the Parent Company's financial position at December 31, 2019 and of the results of the Parent Company's operations for the financial year January 1 to December 31, 2019 in accordance with the Danish Financial Statements Act.

Our opinion is consistent with our Auditor's Long-form Report to the Audit Committee and the Board of Directors.

### What we have audited

The Consolidated Financial Statements and the Parent Company Financial Statements of BioPorto A/S for the financial year January 1 to December 31, 2019 comprise income statement, balance sheet, statement of changes in equity and notes, including summary of significant accounting policies for the Group as well as for the Parent Company and statement of comprehensive income and cash flow statement for the Group. Collectively referred to as the "Financial Statements".

## Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and the additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the *Auditor's responsibilities for the audit of the Financial Statements* section of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Independence

We are independent of the Group in accordance with the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants (IESBA Code) and the additional requirements applicable in Denmark. We have also fulfilled our other ethical responsibilities in accordance with the IESBA Code.

To the best of our knowledge and belief, prohibited non-audit services referred to in Article 5(1) of Regulation (EU) No 537/2014 were not provided.

### Appointment

We were first appointed auditors of BioPorto A/S on 10 April 2014 for the financial year 2014. We have been reappointed annually by shareholder resolution for a total period of uninterrupted engagement of 6 years including the financial year 2019.

## Material Uncertainty Related to Going Concern

We draw attention to Note 22 in the consolidated financial statements, which describe that the budgeted liquidity may be tight during 2020 and is dependent on both the completion and the amount of cash from the planned capital increase later in 2020. This indicates that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern.

Our opinion is not modified in respect of this matter.

## Key audit matters

Except for the matter described in the Material Uncertainty Related to Going Concern section, we have determined that there are no other key audit matters to communicate in our report.

## Statement on Management's Review

Management is responsible for Management's Review.

Our opinion on the Financial Statements does not cover Management's Review, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the Financial Statements, our responsibility is to read Management's Review and, in doing so, consider whether Management's Review is materially inconsistent with the Financial Statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

Moreover, we considered whether Management's Review includes the disclosures required by the Danish Financial Statements Act.

Based on the work we have performed, in our view, Management's Review is in accordance with the Consolidated Financial Statements and the Parent Company Financial Statements and has been prepared in accordance with the requirements of the Danish Financial Statements Act. We did not identify any material misstatement in Management's Review.

## Management's responsibilities for the Financial Statements

Management is responsible for the preparation of consolidated financial statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the EU and further

requirements in the Danish Financial Statements Act and for the preparation of parent company financial statements that give a true and fair view in accordance with the Danish Financial Statements Act, and for such internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the Financial Statements, Management is responsible for assessing the Group's and the Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless Management either intends to liquidate the Group or the Parent Company or to cease operations, or has no realistic alternative but to do so.

## Auditor's responsibilities for the audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the Financial Statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these Financial Statements.

As part of an audit in accordance with ISAs and the additional requirements applicable in Denmark, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the Financial Statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's and the Parent Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of Management's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's and the Parent Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the Financial Statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group or the Parent Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the Financial Statements, including the disclosures, and whether the Financial Statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the Consolidated Financial Statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with those charged with governance, we determine those matters that were of most significance in the audit of the Financial Statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Hellerup, March 11, 2020
PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab
CVR No 3377 1231

Torben Jensen
State Authorised Public Accountant
mne18651

Allan Knudsen
State Authorised Public Accountant
mne29465

# Glossary

| | |
|---|---|
| Biomarker | Theoretically, any analyzable phenomenon that can be used for indicating a biological condition (e.g. pulse, body temperature). Most often used for a molecule whose level in a patient sample (blood, tissue) indicates the existence of a disease and possibly its seriousness. |
| Diagnostics | Diagnostics is the process whereby a disease and possibly its cause are identified. Fast, accurate diagnostics are decisive for the subsequent treatment (therapy). Certain diagnostic tests can be used for monitoring the patient's response to treatment and possible needs for changing the treatment. |
| ELISA kit | "Enzyme-linked immunosorbent assay" kit, a laboratory assay format that can determine the content of a biomarker in body fluids such as blood or urine samples. |
| FDA | The "Food and Drug Administration", is the US authority that authorizes the use of medicines, including diagnostic products. |
| IVD | "In vitro diagnostic(s)", a diagnostic procedure that takes place outside the body, e.g. by analyzing blood and urine samples in a laboratory, as opposed to "in vivo diagnostics", which are performed on the patient, such as a prick test in the skin or an X-ray. |
| MBL | "Mannan-binding lectin", a blood protein that binds to foreign organisms and contributes to congenital (innate) immune response. |
| Monoclonal | Derived from a single "clone", in this case a single cell line. A monoclonal antibody thus consists of antibody molecules which are all identical, whereas a polyclonal antibody consists of many different antibody molecules produced by many different cell lines in the body. |
| NGAL | "Neutrophil gelatinase-associated lipocalin", a biomarker that can indicate renal injury at an early stage. |
| RUO | Products that are for Research Use Only. |
| Sensitivity | In medical diagnosis, test sensitivity is the ability of a test to correctly identify those with the disease (true positive rate). |
| Specificity | In medical diagnosis, test specificity is the ability of the test to correctly identify those without the disease (true negative rate). |
| Therapy/therapeutic products | Treatment of diseases and the products used for this, typically medicines. |
| Turbidimetry | A homogeneous analysis method by which a fluid sample from the patient mixed with a reagent fluid containing substances, often antibodies, that react with the biomarker in the sample to form a haze in the liquid (turbidity), which can be measured through diffraction of light. |

BioPorto is an in vitro diagnostics company that provides 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.

www.bioporto.com

bioporto

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