

***“Early prediction  
is half the cure”***

# Annual Report 2018



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## About BioPorto

BioPorto is an in-vitro diagnostics company with a product portfolio of highly specialized monoclonal antibodies and antibody-based diagnostic assays, some of which are used in the management of critically ill patients.

The 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 detects acute kidney injury (AKI) far earlier and more reliably than other tests on the market. AKI is a well-known complication resulting from injury to the kidney, commonly after surgeries such as kidney transplants and heart bypass surgery. The NGAL Test™ enables doctors to plan a care pathway more quickly and effectively thereby reducing the risk of life-threatening renal failure and mortality. The test helps to optimize the use of resources to benefit patients, hospitals and health authorities.

## Focus on U.S. clearances 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 potential growth inherent in the global market penetration of The NGAL Test™. In 2019, BioPorto expects to submit two separate U.S. regulatory applications with the U.S. Food and Drug Administration (FDA) for use of the test in both adults and children. Upon receiving clearance, BioPorto will commence commercialization of the test in the U.S., which is regarded as the biggest and most important market for biomarkers.

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# Financial highlights 2014 - 2018

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

	2018	2017	2016	2015	2014
	DKK million				
Revenue	26.0	25.2	20.7	20.4	18.7
Production costs	(8.2)	(6.9)	(5.0)	(4.9)	(5.5)
Sales and marketing costs	(20.9)	(18.5)	(18.0)	(8.9)	(9.4)
Research and development costs	(18.7)	(21.9)	(9.7)	(9.9)	(8.6)
Administrative costs	(20.0)	(14.3)	(13.0)	(9.4)	(10.4)
Operating profit/loss (EBIT)	(41.8)	(36.5)	(25.0)	(12.8)	(15.3)
Net financials	0.2	(0.6)	0.1	(0.3)	0.2
Operating profit/loss before tax	(41.6)	(37.1)	(24.9)	(13.0)	(15.1)
Profit/loss for the year	(38.0)	(32.2)	(22.8)	(10.7)	(12.9)
Total comprehensive income	(38.3)	(32.0)	(23.1)	(10.7)	(12.9)
Non-current assets	3.6	2.6	3.1	1.7	1.5
Current assets	62.6	63.0	47.6	47.3	35.8
Total assets	66.2	65.6	50.6	49.0	37.2
Equity	56.2	56.1	44.3	44.5	28.7
Non-current liabilities	0.8	0.9	1.2	0.1	0.1
Current liabilities	9.2	8.7	5.1	4.4	8.5
Total equity and liabilities	66.2	65.6	50.6	49.0	37.2

	2018	2017	2016	2015	2014
	DKK million				
Cash flows from operating activities	(38.0)	(29.2)	(19.7)	(16.6)	(16.1)
Cash flows from investing activities, net	(1.5)	(0.1)	(0.4)	(0.5)	(1.2)
Of which investment in property, plant and equipment	(1.4)	(0.0)	(0.2)	(0.1)	(0.5)
Cash flows from financing activities	39.1	40.7	20.8	26.5	(0.0)
Total cash flows	(0.4)	11.4	0.8	9.4	(17.4)
Revenue growth	3%	21%	2%	9%	13%
Gross margin	69%	73%	76%	76%	71%
Equity ratio (solvency)	85%	85%	87%	91%	77%
Average number of employees	28	25	27	22	24
Number of shares by the end of year (1,000)	165,688	155,510	142,494	129,599	117,874
Earnings per share (EPS), DKK	(0.24)	(0.22)	(0.17)	(0.09)	(0.11)
Net asset value per share, year-end, DKK	0.34	0.36	0.31	0.34	0.24
Share price, year-end, DKK	3.50	3.31	2.10	4.82	1.69

## To BioPorto's shareholders



Peter Mørch Eriksen

CEO

### Full speed ahead in 2019

Once again, we have closed the books on an eventful year in BioPorto. 2018 was characterized by a very high level of activity to boost our NGAL momentum – most of it centered on increasing awareness, performance and potential of The NGAL Test™.

And indeed, we have both celebrated successes and dealt with disappointments. In July 2018, we submitted a U.S. application for FDA clearance of The NGAL Test™ for AKI in adults based on comprehensive clinical data from more than 500 patients and the allocation of substantial internal and external resources to the process. The FDA, however, in October 2018 required further data to support the application, which to our regret postponed the clinical U.S. commercialization we had planned. Since then, we have initiated an additional 150-200 patient study to complement the original prevalence data. Together, the clinical trials conducted will form the basis of a revised application, which we will submit this year and expect clearance of by second half 2019.

While the postponement of a FDA clearance was a disappointment to us all, the encouragement and increasing support we have experienced from regulatory bodies, patient organizations and physicians for our NGAL platform has by far outweighed the temporary setback.

This support is the result of the last year's successful investments in changing perceptions of NGAL in the entire health care system from patients, to clinicians, to politicians – first and foremost in the U.S. Through targeted dialog and relentless effort to engage with all stakeholders, we have demonstrated and confirmed the substantial unmet need for the NGAL technology in today's health care environment to provide safer and more efficient diagnosis and treatment of AKI for the benefit of patients and health care economics alike.

We have recorded success on two important parameters in 2018; First, a sharp increase in Research Use Only (RUO) sales of The NGAL Test™ in the U.S. up 80% due to increasing awareness and interest. This provides a solid basis for clinical commercialization. Second, a strong encouragement from external partners and parties to further utilize our technology to improve treatment of critically ill patients. This was a major driver behind the decision to initiate a clinical study for a separate FDA application for The NGAL Test™ for AKI in children under the age of 21 in October 2018. Based on a retrospective study, we will be able to complete the study very efficiently and apply for U.S. clearance with the FDA in the first half of 2019.

Looking ahead, 2019 will be yet another exciting year for BioPorto where we will focus on strategic execution. Resources will be allocated to push progress in the U.S., where we will submit the two separate FDA applications for clearance and add further resources to our commercial organization to continue to influence, build awareness and grow sales of The NGAL Test™. These will be decisive factors in growing turnover by 50% in 2019.

Following the expected FDA clearances, we will continue to pursue further vertical development of our NGAL platform for new indications and commence exploration of the additional product opportunities provided by our other biomarker candidates to fully realize the huge potential of BioPorto.

Peter Mørch Eriksen

CEO

# Main events in 2018 and financial guidance for 2019

## Renewed application for regulatory clearance for The NGAL Test™ for adults in 2019

Having submitted an application to the FDA for U.S. regulatory clearance of The NGAL Test™ for risk use with AKI in adults in Summer 2018, BioPorto received feedback from the FDA in October 2018 requiring additional data to continue the clearance process for the test.

A subsequent dialogue with FDA has since established the foundation for a revised application. It will be based on an updated dataset compiled from original data and results from an additional clinical study enrolling 150-200 patients from 3-5 of the U.S. hospitals and clinics already participating in the clinical trial program. BioPorto expects this new study will provide additional prevalence data to support statistical elements of the application. The study will commence in the first quarter 2019. Subject to timing of the FDA process, BioPorto expects clearance of The NGAL Test™ in adults by second half 2019 following submission of a renewed application.

## Clinical study for urine-based NGAL test in children initiated – separate FDA application expected to be submitted in first half of 2019

Use of urine NGAL as an early biomarker for risk of developing AKI in critically ill children has experienced growing clinical attention. With more than 200 dedicated pediatric hospitals in the U.S. and robust interest from pediatric departments in general hospitals, a high unmet need and significant potential for The NGAL Test™ clearly exists.

BioPorto has therefore initiated a U.S. pivotal clinical pediatric NGAL study for AKI in children under the age of 21. The clinical study is retrospective using a set of samples of urinary NGAL in children originally tested with the BioPorto NGAL ELISA test in 2014 which can therefore be concluded quickly and cost effectively.

This is the first step in BioPorto's strategy of expanding the product portfolio vertically to penetrate and capitalize on a massive global market opportunity for the proprietary and leading NGAL technology. BioPorto expects to submit the separate FDA application for regulatory clearance of The NGAL Test™ in patients under 21 in the first half of 2019.

## Considerable resources allocated to pave the road for U.S. post-clearance launch

Throughout 2018 BioPorto has allocated significant resources to increasing knowledge and awareness of NGAL among Key Opinion Leaders (KOLs) to build a strong foundation for U.S. commercialization of The NGAL Test™ upon FDA clearance.

Activities have included discussions with leading clinical experts and engagement with patient organizations such as the U.S. National Kidney Association. Furthermore, BioPorto has held Grand Round Presentations by physicians in the U.S. and been working with KDIGO, an organization issuing evidence-based clinical practice guidelines for AKI, with the intent of including NGAL in future guidelines.

Participation at medical conferences, such as the 2018 International Symposium on AKI in Children held in Cincinnati, Ohio in October 2018 has garnered strong interest in The NGAL Test™ from over 100 participating physicians. These meetings have been a major part of engaging KOLs in the successful discussions regarding NGAL and a successful uptake in RUO sales.



## NGAL platform used to evaluate toxicity from ICU prescribed drugs

A group of U.S. based scientists and clinicians have initiated a study to assess the potential of NGAL as a biomarker in Intensive Care Unit (ICU) medication.

The study consists of more than 120 patients enrolled in 2018 at several participating sites in the U.S. and enrollment will continue through 2019 until a total of 150 patients is reached.

The study will test the toxicity and negative side effects on the kidney from prescribing specific and often used medications in the ICU.

To assess the potential kidney damage from these drugs, researchers will compare results from BioPorto's full NGAL product range, i.e. The NGAL Test™, ELISA NGAL kits and NGAL dip stick (ds). In total, a series of 5-6 tests per patient will be used to monitor the status of the patients' kidneys. The study is expected to be concluded mid-year, with results from the study to be published and presented at a medical conference later in 2019.

BioPorto expects to use the results from the study to assess the potential of the NGAL platform, both in regard to ongoing monitoring of patients' health in the ICU, but also to engage in further dialogue with pharmaceutical companies on benefits of applying the tests in preclinical and clinical development of new drug candidates to evaluate negative side effects.

### NGAL distribution agreement with Roche signed in 2018

In February 2018, BioPorto and Roche Diagnostics entered into a global exclusive distribution agreement for a customized version of The NGAL Test™ for adults on Roche's Cobas c501/c502 systems. Along with the distribution agreement with Siemens Healthcare from 2016, the agreement with Roche Diagnostics is of high strategic importance for BioPorto to ensure global awareness, reach and availability of The NGAL Test™ following FDA clearance.



### Multiple indications as a next step in BioPorto's strategy

In 2018 BioPorto continued discussions with potential partners for the NGAL technology, both the existing indications of The NGAL Test™ and new potential areas such as inflammation, toxicity, urinary tract infection and drug toxicity monitoring in cancer patients.

Also in 2018, BioPorto has entered into partnerships with both public research organizations and global pharmaceutical companies, which will be using The NGAL Test™ for kidney related side effects in their clinical development programs for new drugs. New partnerships of this kind are currently being evaluated and will add to the increasing awareness and growth of the test going forward.

### Strengthening of IP portfolio with divisional NGAL cutoff patent in Europe

In 2018, The European Patent Office granted BioPorto a patent covering monitoring the onset of a renal disorder in a human being by measuring NGAL in subsequent samples obtained within 24 hours or less and detecting a rise in NGAL of 50 ng/ml or more. The patent is part of BioPorto's IP rights in the NGAL area and will further strengthen BioPorto's overall patent portfolio.

### Strong additions to management and board of directors

In April 2018, BioPorto announced the appointment of Ole Larsen as Chief Financial Officer of BioPorto A/S. Ole joined BioPorto with more than 17 years of CFO experience from large companies, the last 10 years as Executive Vice President and CFO at Bavarian Nordic A/S, a NASDAQ Copenhagen listed company. Ole represents a strong addition to the management team with comprehensive international experience and health care industry knowledge. In BioPorto he is responsible for finance, IR and IT functions.

At the Annual General Meeting held in April 2018, Britt Meelby Jensen, CEO of NASDAQ-listed Zealand Pharma A/S, was nominated and elected to the Board of Directors of BioPorto A/S. Her extensive global commercial and general management experience in life science, which also includes tenures at Novo Nordisk and Dako, has since been a strong asset on the Board, complementing existing insights.

### Successful share capital increase with proceeds of DKK 40 million

In 2019, BioPorto will complete clinical studies and submit two separate 510K applications to the FDA for The NGAL Test™ for risk assessment in acute kidney injury.

In November 2018, BioPorto completed a private placement cash issue, which will go to support the two clinical studies and FDA applications for The NGAL Test™, to continue activities preparing for U.S. commercialization, support growing sales and strengthen the company's overall liquidity.

In total, 10,178,117 new shares at nominally DKK 1 each equivalent to 6.55% of BioPorto's registered share capital prior to the capital increase, were offered at a subscription price of DKK 3.93 per share to a limited number of selected investors. The private placement was fully subscribed yielding net proceeds of DKK 39.3 million after deduction of transaction costs.

Following the issue, BioPorto's share capital amounts to DKK 165,687,798 divided into 165,687,798 shares of nominally DKK 1 each carrying one vote.

### Financial results for 2018

BioPorto grew revenue in 2018 by 3.4% to a total of DKK 26 million compared to DKK 25 million in 2017. The all-important driver was a continued strong performance in RUO sales of The NGAL Test™ in the U.S., which increased by 80%. In total, revenue growth from The NGAL Test™ was 43% in 2018 over 2017.

Revenue from antibodies and ELISA kits, however, fell in 2018 compared to 2017 by 23% and 16%, respectively, which was mainly due to a decline in market conditions which led to fewer large bulk orders. This was also the primary reason why we did not meet our financial guidance for 2018 with revenues of approximately DKK 30 million and a loss before interest and tax (EBIT) of DKK 32-37 million. Our expectations for revenues were lowered in August 2018 from approximately DKK 35 million as we saw the first signs of a decrease in larger bulk orders in antibodies.

The operating loss (EBIT) of DKK 42 million in 2018 was DKK 5 million higher than in 2017. BioPorto incurred higher cost related to administration and sales due to new hiring and a slightly lower gross margin, primarily attributable to exchange rate fluctuations and differences in product mix.

### Financial Guidance for 2019

In 2019, BioPorto's focus will remain on executing on our strategic initiatives centered on securing FDA clearances for The NGAL Test™. Meanwhile, our operational focus will be to grow revenues considerably to approximately DKK 40 million, primarily from increased RUO sales of

The NGAL Test™ in the U.S., from higher activity in rest of the world (ROW) and from sales upon anticipated FDA clearances.

In 2019, the expected cost associated with the two NGAL applications to the FDA are estimated to DKK 6 million, considerably lower than earlier submissions.

In 2019, BioPorto will engage in building a strong U.S. sales organization, and additionally expects capacity cost to be influenced by the full year impact of the new hires in 2018. In total, BioPorto expects to incur an operating loss (EBIT) of approximately DKK 45 million with a cash impact of DKK 41 million.

The guidance for 2019 and the expected cash position at 31 December 2019 are based on assumptions of FDA clearance of The NGAL Test™ for children and/or adults in 2019 and a significant increase in RUO sales of the NGAL Test™ mainly in the U.S. in 2019 and a slight decrease in revenue generated by antibodies compared to 2018.

The Board of Directors will together with Management monitor the development in the cash position through out 2019 ensuring an at all time appropriate financial readiness.

If against our expectations, FDA delays the approval or do not provide approval of our U.S. regulatory application for The NGAL Test™ for AKI in children, the Board of Directors and Management will take corrective actions to secure sufficient cash until 31 December 2019 and beyond.

	2018 financial guidance	2018 actual	2019 financial guidance
Revenue	Approximately DKK 30 million	DKK 26 million	Approximately DKK 40 million
EBIT	Loss of DKK 32-37 million	Loss of DKK 42 million	Loss of approximately DKK 45 million

# Strategy and objectives

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 which is now sold both 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 is sold worldwide via distributors for analysis of immunodeficiencies.

## R&D and product maturing as core competencies

BioPorto's core value creation is based on research and development of assays and biomarkers from its antibody library. Once developed, products are quality assessed and, if appropriate, taken through relevant regulatory approval processes driven by inhouse capabilities.

In the commercialization phase of a biomarker, assay or antibody, BioPorto will manage the initial commercialization via its own dedicated sales force to build value propositions and develop unified product knowledge among key opinion leaders and customers. Once this has been established, BioPorto will take on the role as medical liaison and partner with distributors to leverage their collective access to end-user customers, gain global momentum and increase the scale of market penetration.

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



## Vertical and horizontal pipeline

The company's strategy is established on a horizontal and a vertical pipeline of product development.

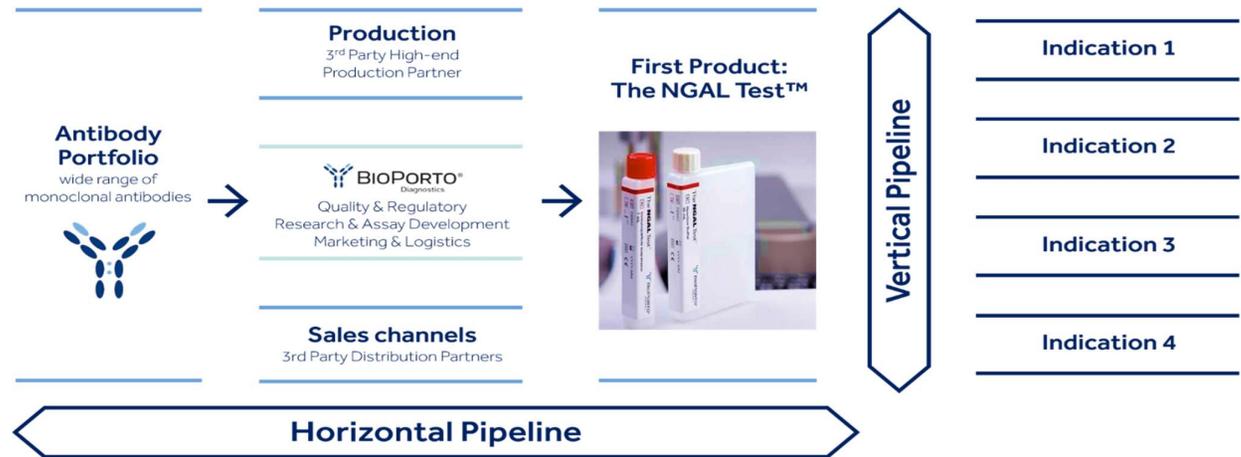
The horizontal pipeline is defined by the individual biomarker candidates which BioPorto derives from research and development activities based on its antibody portfolio. In addition to the NGAL biomarker for early detection of AKI, and MBL for immune response, BioPorto evaluates targets in antibiotics, immune defense and other areas.

The vertical pipeline is defined by the opportunities BioPorto seeks to leverage and maximize for each biomarker, by uncovering, registering and marketing for the biomarker for different indications. In 2018 BioPorto initiated the application process for U.S. regulatory clearance of The NGAL Test™ in pediatrics, which will complement the current CE approved version of the test, and the upcoming U.S. registration application for predictive risk use with AKI in adults. Further opportunities to be explored for The NGAL Test™ are within monitoring and exclusion of AKI and on other indications such as trauma, cancer treatment etc., which will ensure that the full potential of the test and technology is addressed for the benefit of patients.

## Strategy and execution for 2019 is centered on the U.S. market

In 2019, BioPorto will take critical steps to execute on vertical elements of its strategy and secure further penetration of the market for The NGAL Test™. While sales activities in Europe and Asia will be intensified, focus will be centered on establishing a strong foothold in the U.S. for clinical commercialization of the test. By allocating more resources with strong structural and financial incentives to introduce new tools to manage critically ill patients, BioPorto will continue to build a strong position and presence in the U.S. with the NGAL platform and The NGAL Test™.

Prioritization of our initiatives to execute on the U.S. elements of our strategy falls into two categories; obtaining two separate regulatory clearances for The NGAL Test™ and continuing to grow sales, presence and awareness of the test and the NGAL technology.



## BioPorto will submit two U.S. registration applications in 2019

In 2019, BioPorto will complete clinical studies and submit regulatory applications for two separate indications of The NGAL Test™ with the FDA; a renewed one for risk use with AKI in adults based on plasma and one for risk use with AKI in urine in children.

The key element in the clinical studies for the FDA application for The NGAL Test™ in adults is to obtain an additional dataset with high AKI prevalence to supplement the data which has been collected from patients in 2017 and 2018. Patient enrollment in the 2019 study will take place in U.S. hospitals and clinics that have had the highest prevalence of AKI in prior studies.

The clinical study for the pediatric application is based on a retrospective set of samples collected in 2014, allowing for a fast and cost-effective process. BioPorto's application for FDA clearance for use in children

under 21 will allow more than 200 dedicated pediatric U.S. hospitals and clinics to adopt the test much faster than if they had to conduct their own studies and internal approvals to use the test for clinical decision making, as is normal practice.

## Execution of market strategy to accelerate growth and prepare clinical launch of The NGAL Test™ in the U.S.

Since 2016, BioPorto has cultivated the U.S. market for RUO sales and as a result, sales grew considerably in 2018. This is due to significant efforts in building market awareness and acceptance of The NGAL Test™ as an improvement to the current standard of care through dialogue with patient organizations, KOLs and politicians as well as publications in scientific journals and participation in scientific conferences.

### U.S. regulatory application for The NGAL Test™

	Adults	Children
Indication	Risk use with AKI	Risk use with AKI
Based on measurements in	Plasma	Urine
Clinical study	Enrolment of up to 200 patients with AKI from 3-5 sites in the US	Retrospective study based on existing U.S. data
Key dates	Expected clearance in 2H 2019	Application expected to be submitted in 1H 2019
Estimated study and application costs in 2019	Approx. DKK 3.5 million	Approx. DKK 2.5 million

In 2019, BioPorto will strengthen its U.S. presence through increasing its medical liaison team and further expanding its sales force to broaden its customer base among cardiac and kidney transplant centers. This will accelerate the strong momentum in awareness and lead to an uptake in RUO sales as well as the development of product ambassadors prior to regulatory clearance and commercial launch.

Finalizing the applications and obtaining FDA clearance in 2019 will enable BioPorto to begin the commercialization of the clinical NGAL test, both through our own channels and through our distribution partners Roche Diagnostics and Siemens Healthcare.

#### Ongoing review of our antibody library for identification of new biomarkers

In 2019, BioPorto will continue reviewing and building on our comprehensive library of antibodies to create a pipeline of potential new assays and biomarkers. Focus will however remain on submitting and obtaining FDA clearance for the pediatric and adult use The NGAL Test.

#### 2019 OBJECTIVES

- Submit renewed FDA application for The NGAL Test™ in adults with additional and required data
- Submit FDA application for The NGAL Test™ in children
- Increase RUO sales and the number of new customers in the U.S.
- Expand the U.S. organization
- Review new opportunities for NGAL and the antibody library
- Grow total revenues by 50%

# Products and markets

BioPorto's product portfolio and pipeline includes highly specialized and unique diagnostic tests for analyzing blood and urine samples in laboratories.

The tests provide information critical to physicians in detecting disease, selecting appropriate treatments and monitoring patients responses to treatment. In addition, scientists can use our tests to better understand the causes of disease and to help discover and develop new treatments for critically ill patients.

Furthermore, BioPorto's pioneering product portfolio features more than 400 highly specific monoclonal antibodies used in pharmaceutical research.

We service global customers such as hospitals and clinics, pharmaceutical companies, laboratories and scientific research institutions directly through our own sales organization and through partnerships.

## Product portfolio and pipeline

### The NGAL Test™

BioPorto's lead product, The NGAL Test™, is a particle-enhanced turbidimetric test that measures neutrophil gelatinase-associated lipocalin (NGAL) that is used on industry standard clinical chemical analyzers.

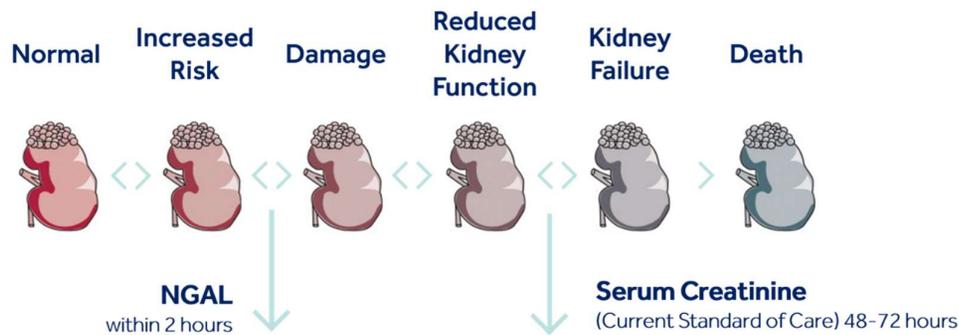
NGAL is a biomarker that can indicate renal injury at an early stage and can therefore be used in the diagnosis of AKI. AKI is a rapid deterioration of renal function, resulting in an inability to maintain fluid, electrolyte and acid-base balance. It represents a medical emergency with an estimated 13 million yearly incidents worldwide, of which 4 million will be fatal (Lameire NH, Bagga A, Criz D. et al. "Acute kidney injury: an increasing global concern". Lancet 2013). Research shows that 1 in 5 adults and 1 in 3 children will be affected by AKI during a hospital episode of care (Susantitaphong, et al. "World Incidence of AKI: A Meta-Analysis), and that the number of U.S. AKI hospitalizations, according to CDC historically has grown by more than 10% per annum, making it a massive and increasing challenge.

The NGAL Test™ can measure NGAL in either urine or plasma and can be run on most automated clinical chemistry analyzers already available in laboratories and clinical practices. Importantly, results using The NGAL Test™ can be available in as little as two hours after a potential AKI incident.

The current standard of care in AKI diagnosis, measurement of serum creatinine, has numerous deficiencies; it will not identify renal dysfunction until 48 to 72 hours after an injury to the kidney, it can only be measured in plasma and it must be interpreted using an established baseline. Furthermore, it is a non-specific marker and its concentration depends on several factors such as medication, age, gender, fluid and food in-take.

## BioPorto's primary customer segments





### Measurement of NGAL:

- Earlier risk of AKI diagnosis, within 2 hours of injury
- Earlier initiation of appropriate management
- Risk stratification of AKI
- Improved prediction of clinical outcomes
- Better ability to monitor response to therapy
- Lower hospitalization costs
- Better quality of life for patients

VS.

### Measurement of Serum Creatinine:

- Does not identify renal dysfunction until 48-72 hours after the kidney is injured, which could result in permanent damage
- Is a non-specific marker of kidney function

Apart from serum creatinine, there is only one competing product in the market which is CE-marked and approved by the FDA, NephroCheck® developed by Astute Medical. NephroCheck® is a kidney-injury test based on two cell-cycle arrest biomarkers (TIMP-2 and IGFBP7) and can only be measured in urine. Astute Medical sells its kidney injury test only for use with its own analyzer, the Astute 140 Meter. The analysis of one urine sample can determine whether the patient has a higher risk of developing moderate to severe kidney failure within the next 12 hours.

Using The NGAL Test™ will make it possible for physicians to make crucial decisions in diagnosis and treatment before a kidney injury causes significant morbidity or mortality, and before initiating a potentially unnecessary and costly or invasive treatment. Hence, The NGAL Test™ can reduce mortality rates, improve management of the disease for

patients and dramatically reduce the length of hospitalization and associated health care costs.

In its sales efforts, BioPorto focuses on penetrating three medical segments: coronary artery bypass surgery, kidney transplants and intensive care units via its own sales channels, local distributors and through distribution and licensing agreements.

A CE-approved and registered version of The NGAL Test™ is currently available for clinical use for prediction of AKI risk in adults in Europe and Asia. The NGAL Test™ is also sold for RUO in the U.S. while clinical FDA clearance is pending. The U.S. is the largest and most important market representing approximately 44% of the global IVD testing market (Kalorama, August 2018 IVD Report; pg 115). BioPorto estimates that the addressable global market for The NGAL Test™ for prediction is worth

approximately USD 1.5 billion in 2019. However, an even larger market is addressable according to BioPorto's vertical strategy by obtaining additional approvals for monitoring and ruling out AKI to be used in emergency and pediatric settings.

BioPorto also expects the test to be applicable in other indications, such as trauma and cancer treatment, as an early biomarker to optimize the diagnostic process. Addressing these additional opportunities, which will require further clinical testing and registrations, will expand the total addressable market for The NGAL Test™ to 250+ million tests annually

### Estimated Tests Per Year & Potential Global Market size

Research Use Current applications	5 million+ tests \$100 million
Prediction of AKI Risk On the market in Europe and Asia. Under FDA review in U.S.	150 million+ tests \$3 billion
Pediatric use Retrospective trial initiated Q4 2018	5-10 million+ tests \$100-200 million
Exclusion of AKI Label expansion	
Monitoring of AKI Label expansion	100 million+ tests \$2 billion
Trauma, Cancer Treatment, etc. New Indications	

Source: CDC, AHA, Ciccia 2017 and company estimates

## A unique and ready-to-use lateral flow platform speeds up the development of new assays

In 2018, BioPorto launched their proprietary and novel lateral flow assay development platform, called, the generic Rapid Assay Device (gRAD), which 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.

### Large potential market

Implementation of gRAD has proven to be very effective with many potential applications. It can be used as an attractive option for research facilities, companies and NGOs to facilitate a low-cost production with highly accurate results using most bodily fluids. Furthermore, gRAD could work as a home-test, which would be valuable in developing countries where access to quality care is limited or difficult.

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 U.S., where interest is building and is expected to further intensify in 2019.



with an estimated value of more than USD 5 billion, assuming a price of USD 20 per test and an estimated 4-5 tests per diagnosis of AKI.

BioPorto is currently preparing the FDA application for The NGAL Test™ in adults in plasma, which is expected to be submitted in 2019. Additionally, BioPorto is conducting trials in the retrospective urine-based clinical NGAL study for AKI in children under the age of 21. This will be part of a separate application to FDA which will be submitted in first half of 2019. BioPorto expects FDA decisions on both applications in 2019, subject to standard review times for U.S. registration applications.

### NGAL ELISA kits

BioPorto produces a CE marked NGAL ELISA kit for human use. It is widely used in research, and to a lesser extent in clinical practice, as real-time results are not as easy to obtain with this kit as with the automated NGAL test.

An important use of NGAL ELISA kits is in clinical trials in the pharmaceutical industry, where NGAL is used to evaluate the potential side effects of a drug candidate on the kidneys. In addition, BioPorto provides NGAL ELISA kits for five different animal species which are also used in research.

### MBL ELISA kits

MBL is an important molecule in the innate immune response. MBL deficiency can affect a patient's ability to combat a foreign organism, such as a virus or bacterium.

It is estimated that 5-10 percent of people globally have an MBL deficiency, which can cause recurrence of severe or unusual infections. MBL deficiency can also be problematic for organ-transplant patients, patients with cystic fibrosis and persons suffering from other genetic defects of the immune response.

BioPorto's ELISA kit is based on one of the most widely used monoclonal MBL antibodies, which has been the subject of many scientific paper. BioPorto is the only vendor of this specific assay, which has been the "gold standard" for quantitative measurement of MBL levels since 2002.

## Antibodies

BioPorto's library of antibodies contains more than 400 monoclonal antibodies, spanning different research disciplines such as microbiology, immune deficiency, renal, peptide hormones and plasma proteins. New antibodies are frequently added to the library to expand our offerings in key clinical areas of interest to customers and our biomarker program.

One additional area of focus for BioPorto is in antibodies to peptide hormones, like GLP-1 (glucagon-like peptide-1), which is key 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 via distributors. The competitive landscape for the products in BioPorto's antibody portfolio varies significantly. For certain antibody targets the competition is limited, as similar products are unavailable. Other antibodies are available from competitors in similar versions, and hence face strong competition.

## 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 in an opposition before the European Patent Office (NGAL Exclusion) and South Korean Patent Office (NGAL Cutoff), where the possible outcomes in the case is that the patent will be upheld; that the patent will be upheld in part; or that the patent will be revoked.

On January 28, 2019 the European Patent Office made the decision to uphold BioPorto's NGAL Cutoff Patent in Europe after an opposition was made in October 2017.

## 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, Russia, India and Israel. The company's human NGAL and MBL 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 MBL ELISA kits in Australia).

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

# Risk management

Risk management is an integrated part of BioPorto's operations. The Company is identifying material risks that could affect sales, development, production, future performance or goals, or the interests of the shareholders with the purpose of running the Company in accordance with best practices in the Company's area of business.

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 2018, the Company continued its work on securing alternative manufacturing options to ensure a reliable supply of our products.

In October 2018, the Company received feedback on the 510K submission to the FDA for clearance of The NGAL Test™ in adults. The main feedback from FDA was that they wanted a higher prevalence – i.e. a larger part of the patient population with AKI stage 2-3. In order to mitigate the risk of not getting clearance of the test for adults in US, the Company will enroll a further 150-200 patients in the study. The enrollment will be done at 3-5 sites and include hospitals and doctors who enrolled patients with the highest prevalence in the original study.

To ensure the quality of the enrollment and secure that patients are enrolled according to the inclusion and exclusion criteria the Company will manage the trial monitoring and not outsource this service.

In November 2018, the Company concluded a financing round and issued approximately 10 million new shares in a private placement. The gross proceeds from the financing amounted to DKK 40 million. This addition to BioPorto's cash preparedness enables the Company to continue the development and the awareness build of NGAL.

The primary risk to the revenue in 2018 was the clearance of The NGAL Test™ for adults as well as the antibody sales. Despite the delay in the approval BioPorto has managed to grow revenues from The NGAL Test™ in the U.S. and increase the number of hospitals using the test under its RUO labeling.

In 2018, antibody sales experienced a difficult year with fewer larger contracts than prior years.

The primary risks in 2019 relate to the enrollment of patients in the U.S. NGAL adult study, the submissions and clearances of The NGAL Test™ for adults and children, the preparation and launch of the test in U.S. once clearances have been obtained, the antibody sales, and the establishment of an alternative manufacturing source.

## 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:

- Submission and clearance of 510K by FDA in U.S. for The NGAL Test™ in adults
- Submission and clearance of 510K by FDA in U.S. for The NGAL Test™ in children
- Preparation and launch of The NGAL Test™ in the U.S. market
- The Company's cash preparedness and ability to obtain funding necessary to fulfil the Company's strategy
- Securing an alternative manufacturing option
- Cyber attacks
- Warning letter from FDA and/or failed inspections from various authorities
- Antibody sales

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

- Securing new sites in U.S. using The NGAL Test™ for research use
- Competing technologies adversely affecting the market roll-out of The NGAL Test™
- Protection of patents and other intellectual property rights
- The ability to obtain 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 and most significantly CMOs and CROs
- Collaborative agreements, including distribution agreements
- Disputes concerning contractual relations where the company may risk losing the rights to products marketed by the company
- Duration and outcome of review processes by various 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
- Risks relating to a U.S. Government shutdown
- 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 the 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 the 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](http://www.corporategovernance.dk).

BioPorto's Board of Directors continuously assesses how its recommendations can help strengthen the Management of BioPorto and maximize value creation for the company's shareholders.

The Board evaluates the recommendations once a year and evaluates the extent to which BioPorto complies with them. In the view of the Board, BioPorto complies with all, except for two of the Committee's 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 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. 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](http://company's website).

## Work of the Management and Board of Directors

The Board of Directors determines BioPorto's objectives, policies and areas of activity. In addition, the Board makes decisions in all cases of an

unusual nature or of great significance. The Board also approves, monitors, evaluates and revises the Management's business strategy and action plans.

Furthermore, the Board ensures that BioPorto is properly led and managed pursuant to the company's articles of association, general guidelines, policies and current laws and regulations. The Board lays down the guidelines for the division of duties between the Board and Management but does not take part in day-to-day management.

The Board's work is described in the rules of procedure of the Board of Directors and Management. thirteen board meetings were held in 2018, including a strategy meeting. six meetings are planned for 2019, in accordance with the Board's annual schedule, which naturally can be changed at any time to allow for additional meetings, if the need arises.

BioPorto's Board appoints the company's Management and determines the Management's working conditions and tasks. BioPorto's Management is responsible to the Board for ensuring that day-to-day operations are conducted in a proper businesslike and legal manner.

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

The Chairman of the Board is responsible for evaluating the Management and the Board of Directors every year by making a survey. In addition to examining cooperation with the Management, the survey, among other things, looks at the composition and qualifications of the Board, and assesses the results produced over the year. The evaluation is subsequently presented and discussed at a Board meeting each year. External assistance is obtained at least every third year to conduct the survey.

In 2018, the Chairman of the Board concluded that focus on U.S. experience and competencies among Board members will be required once a U.S. FDA clearance is obtained.

## Composition of the Board

The shareholder meeting, which is the executive authority of BioPorto, elects a Board of three to seven members. The Board elects its officers from its midst with a Chairman and one Vice Chairman, and currently comprises four members elected at the shareholder meeting.

The members of the Board elected at the shareholder meeting are elected for one year at a time. The members of the Board are selected and stand for election based on their specific qualifications and experience which are of relevance to BioPorto. Thus, the Board is composed with a view to ensuring an optimal combination of professional experience in the sector 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 Board members are assessed by the Board as being independent. Details of the unique expertise of each member can be viewed at the [company's website](http://company's website).

## Board committees

BioPorto's Board has appointed a remuneration committee, a nomination committee and an audit committee, as well as additional ad hoc committees. The Vice Chairman of the Board is the Chairman of the audit committee and possesses the expert knowledge and experience required. A review of the Board committees' remits and the composition of the committees is available on the [company's website](http://company's website).

## Amendments to the articles of association

The shareholder 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 2018.

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 2018 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 U.S. 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 2018, the Executive Management was made up of one person. In 2018, the Executive Management was paid DKK 3.8 million in salary, including pension (contribution-based) and bonus, excluding share-based compensation.



Remuneration Executive Management Covering BioPorto A/S and its subsidiaries  Peter Mørch Eriksen, CEO	2016	2017	2018
Base Salary	DKK 2,538,716	DKK 2,695,255	DKK 3,025,529
Other employee benefits	DKK 420,000	DKK 420,000	DKK 483,000
Bonus Agreement	DKK 0	DKK 255,000	DKK 314,000
- Explanation	KPI: Based on revenue growth, EBIT target and certain must win battles that supports the goals for 2016 set forth in the Annual Report 2015.	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.	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.  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. KPI: FDA clearance of NGAL (pediatric) 1/3 of bonus amount; and FDA approval of NGAL (adult) 2/3 of bonus amount.
Warrant Agreement	Cost occurred in year DKK 495,000 1,188,696 Warrants 278,696 warrants forfeited – non-achievement of KPI, 910,000 warrants remaining.	Cost occurred in year DKK 1,250,398 2,400,000 warrants 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 New warrants programs A) 1,700,000 warrants B) 1,800,000 warrants
-Explanation	910,000 warrants (No KPI), 278,696 warrants (KPI based on 2016 Revenue target).	KPI: FDA clearance of The NGAL Test before December 31, 2018.	A) KPI: FDA clearance of The NGAL Test, 50 new sites in 2019, and 100% revenue growth in NGAL in 2019. B) KPI: FDA clearance of NGAL (pediatric or adult) in 2019 and; 50 new hospital customer sites in the U.S. are achieved no longer than 12 months after the clearance and; the company achieve NGAL revenue growth of 100 % (in local currency in the U.S.) in the 12 months after the clearance compared to the 12 months before the clearance.
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	2016 Base fee	2016 Committee fee	2017 Base fee	2017 Committee fee	2018 Base fee	2018 Committee fee
Thomas Magnussen	500,000	-	500,000	-	500,000	-
Torben A. Nielsen	350,000	-	350,000	-	350,000	-
Britt Meelby Jensen	-	-	-	-	177,083	35,417
Kirsten Drejer	-	-	173,611	34,722	250,000	50,000
Niels Christian Nielsen	106,250	35,418	219,444	50,000	72,917	14,583
Roar Seeger	43,750	14,583	-	-	-	-
Jan Kuhlmann Andersen	100,000	33,333	-	-	-	-

## 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 four members, two of whom are men and two women, and thus BioPorto has a balanced gender representation on the Board of Directors.

The nominating committee has a clear policy for evaluating candidates of both genders for vacant Board positions, and for the election of a new Board member in 2018, a female candidate was deemed to have the best competency profile. 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).

## 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 2019, 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 U.S. 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 human rights. In 2017, BioPorto established a Code of Conduct covering respect for human rights. BioPorto's employees are obliged by BioPorto's Code of Conduct. In 2018 BioPorto initiated the process of implementing the Code of Conduct into supplier contracts to ensure that the company's suppliers respect human rights.

### 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 with respect to 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 in 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 labor rights. BioPorto's employees are obliged by BioPorto's Code of Conduct. In 2018, BioPorto initiated the process of implementing the Code of Conduct into supplier contracts to ensure that the company's suppliers respect Labor rights.

The BioPorto group has fair and equal employment terms and working conditions, including equality and non-discrimination. Both the physical and mental working environment are monitored and continually improved to avoid accidents, injury and illness.

In the composition of its staff, BioPorto endeavors 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 different perspectives for the benefit of staff and company efforts alike.

2018	Female	Male	Non-Danish
All Employees	52%	48%	22%
Head of Departments	37%	63%	0%
Executive Management (one person)	0%	100%	0%
Board of Directors	50%	50%	0%

BioPorto has adopted a policy on Diversity:

“BioPorto is committed to continue working towards ensuring and furthering equal opportunities for all employees with respect to 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 Company has reached its target and currently does not have an underrepresented gender, as the gender distribution is 50/50.”

BioPorto's Nomination Committee has a clear policy for evaluating candidates of both genders for vacant board positions, and for the election in 2018 a female candidate was found to honor the competency requirements. For future vacancies in the Board, the Nomination Committee will continue to evaluate candidates of both genders.

## 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. An ongoing effort will be made 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. In 2017, BioPorto established a Code of Conduct covering the above. BioPorto's employees are obliged by BioPorto's Code of Conduct. In 2018 BioPorto initiated the process of implementing the Code of Conduct into supplier contracts to ensure that the company's suppliers respect the environment.

## Anti-corruption

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

BioPorto takes sharp issue with corruption, bribery and similar methods. Suppliers and partners are chosen with care and are included in BioPorto's quality system. Corruption problems have not affected BioPorto's activities up to now. In 2017, BioPorto established a Code of Conduct covering the above. BioPorto's employees are obliged by BioPorto's Code of Conduct. In 2018 BioPorto initiated the process of implementing the Code of Conduct into supplier contracts to ensure that the company's suppliers follow anti-corruption policies.

# 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](http://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 dialog 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 the Management and the Board of Directors. For more relevant details relating to BioPorto, investors are referred to the company's website: [www.bioporto.com](http://www.bioporto.com).

## Shares

### ISIN, capital stock and price trends

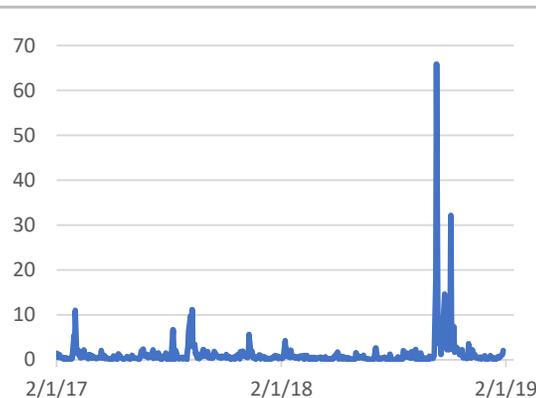
BioPorto's capital stock has a nominal value of DKK 165,687,798 divided into 165,687,798 shares with a nominal value of DKK 1 each, equivalent to 165,687,798 votes. BioPorto A/S's shares are listed on NASDAQ Copenhagen under the symbol "BIOPOR". The ISIN is DK0011048619. BioPorto had a market value of DKK 580 million at the end of 2018 (beginning of 2018: DKK 515 million).

BioPorto share, Closing price (DKK)



The closing price of the BioPorto share was DKK 3.50 on December 28, 2018, which equals an increase of 6% in the fiscal year.

BioPorto share, Volume (DKK million)



The value of traded shares was DKK 394 million in 2018 (2017: DKK 265 million), equivalent to average daily trading of DKK 1.6 million (2017: DKK 1.1 million) and a daily volume of 363,740 shares (2017: 367,986 shares).

## Capital increase

On November 11, 2018, 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 10,178,117, after which it nominally amounts to DKK 165,687,798. The subscription price of DKK 3.93 was the closing price of BioPorto shares traded on NASDAQ Copenhagen A/S on November 9, 2018.

The private placement generated gross proceeds of DKK 40 million for BioPorto. The new shares equated to 6.55% of BioPorto's registered capital stock before the implementation of the capital increase.

## Ownership

As of December 31, 2018, BioPorto had 8,544 registered shareholders, who in the aggregate owned 88.52% of the capital stock. On December 31, 2018, the following shareholders state that they own 10% or more of the company's shares/voting rights:

Ejendomsselskabet Jano ApS, Copenhagen	11,50 %
Media-Invest Danmark A/S, Copenhagen	10,38 %

## Warrant program

The Board established three warrant programs in 2018 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 9,932,500 warrants remained, which amounted to 6.0 % 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 2019. 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 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 have coverage of the BioPorto share:

Edison Group, US

Maxim Group, US

Nat Calloway

Jason McCarthy

## Annual Shareholder Meeting

BioPorto A/S will hold its annual shareholder meeting on March 18, 2019, 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](mailto:investor@bioporto.com)

## Financial calendar for 2019

Date	Description
January 25, 2019	Silent period before the annual report begins (4 weeks)
February 1, 2019	Deadline for shareholder proposals for the annual general meeting
February 22, 2019	Annual Report 2018 & Investor Meeting
March 18, 2019	Annual general meeting
April 25, 2019	Silent period before interim report begins (2 weeks)
May 9, 2019	Interim financial report – 3 months 2019 & Investor Meeting
August 1, 2019	Silent period before interim report begins (2 weeks)
August 15, 2019	Interim financial report – 6 months 2019 & Investor Meeting
October 24, 2019	Silent period before interim report begins (2 weeks)
November 7, 2019	Interim financial report – 9 months 2019 & Investor Meeting

## Company announcements

Date	No.	Description
JAN 8, 2019	1	Corrected Financial Calendar 2019
DEC 20, 2018	26	Grant of Warrants
DEC 5, 2018	25	Financial Calendar 2019
NOV 28, 2018	24	Share Capital and Votes
NOV 20, 2018	23	Announcement from major shareholder
NOV 20, 2018	22	Completion of share capital increase
NOV 12, 2018	21	Managers' transactions
NOV 12, 2018	20	Early close of fully subscribed private placement
NOV 11, 2018	19	BioPorto A/S increases the share capital through a cash issue, private placement.
NOV 8, 2018	18	Interim Report, Third Quarter 2018, BioPorto Group
OCT 3, 2018	17	BioPorto receives communication from FDA regarding The NGAL Test™
OCT 2, 2018	16	BioPorto initiates pivotal clinical study with The NGAL Test™ for children
AUG 20, 2018	15	Grant of Warrants
AUG 16, 2018	14	Interim Report, Second Quarter 2018, BioPorto Group
JUL 18, 2018	13	BioPorto submits FDA application for The NGAL Test™
JUN 27, 2018	12	BioPorto has finalized clinical studies enabling submission of the FDA application for The NGAL Test™ in July 2018
JUN 15, 2018	11	Grant of Warrants
MAY 3, 2018	10	Interim Report, First Quarter 2018, BioPorto Group
APR 18, 2018	9	BioPorto appoints Ole Larsen as CFO
APR 13, 2018	8	BioPorto A/S - Annual General Meeting
APR 3, 2018	7	BioPorto receives intention to grant for a divisional NGAL cutoff patent in Europe
MAR 21, 2018	6	Notice Convening the Annual General Meeting
MAR 8, 2018	5	Execution, Growth and Increased Awareness
MAR 6, 2018	4	BioPorto finalizes enrolment of patients for The NGAL Test™ clinical study in the U.S. and plans submission of FDA application in Q2 2018.
FEB 9, 2018	3	BioPorto and Roche Diagnostics sign a distribution agreement for NGAL
JAN 16, 2018	2	Changes in the Board of Directors
JAN 4, 2018	1	Changes in the Board of Directors

# 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

Board members	Data	Qualifications of relevance for BioPorto	Current directorships in other companies
<p>Thomas Magnussen (M) (1953)</p> 	<p><b>Chairman of the board</b></p> <p>Joined the Board in 2013, must be re-elected in 2019</p> <p>Independent board member</p> <p>Participation in 14 board meetings in 2018 &amp; participation in 4 committee meetings in 2018</p>	<p>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 Zylinx A/S. Thomas Magnussen holds an MBA from INSEAD as well as a Ph.D. and MSc from DTU.</p>	<p>Chairman of the Board for Therazone ApS, BioPorto Diagnostics A/S and Veterinary Diagnostics A/S. Director in Therazone ApS.</p>
<p>Torben A. Nielsen (M) (1960)</p> 	<p><b>Vice-chairman</b></p> <p>Joined the Board in 2013, must be re-elected in 2019</p> <p>Independent board member</p> <p>Participation in 14 board meetings in 2018 &amp; participation in 5 committee meetings in 2018</p>	<p>Torben Arnth Niels 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 is partner and co-owner of Linde &amp; Partners Kapitalrådgivning A/S and a board member for Wavepiston A/S as well as a director in Arnth Advice ApS. 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 in 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 an education within banking.</p>	<p>Partner in Linde &amp; Partners Kapitalrådgivning A/S and Board member for Wavepiston A/S, BioPorto Diagnostics A/S and Veterinary Diagnostics A/S. Director in Arnth Advice ApS.</p>
<p>Britt Meelby Jensen (F) (1973)</p> 	<p><b>Board member</b></p> <p>Joined the Board in 2018, must be re-elected in 2019</p> <p>Independent board member</p> <p>Participation in 11 board meetings in 2018 &amp; participation in 3 committee meetings in 2018</p>	<p>Britt Meelby Jensen has extensive global commercial and general management experiences from working in the life sciences area over the past 16 years at Novo Nordisk, Dako and Zealand Pharma. Since 2015, Britt Meelby Jensen has been the CEO of Zealand Pharma A/S, a medium sized biotech company listed on Nasdaq in Copenhagen and New York. Britt Meelby Jensen holds an MSc from Copenhagen Business School and an MBA from Solvay Business School in Brussels, Belgium.</p>	<p>Member of the Board of Directors of the Hempel Foundation and Hempel Holding.</p>
<p>Kirsten Drejer (F) (1956)</p> 	<p><b>Board member</b></p> <p>Joined the Board in 2017, must be re-elected in 2019</p> <p>Independent board member</p> <p>Participation in 13 board meetings in 2018 &amp; participation in 2 committee meetings in 2018</p>	<p>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.</p>	<p>Kirsten Aarup Drejer is chairman of Antag Therapeutics ApS, Resother Pharma and Bioneer A/S as well as a member of the board of directors of Zealand Pharma A/S and Lyhne &amp; Company A/S.</p>

# Executive Management

Executive Management	Data	Qualifications of relevance for BioPorto	Current directorships in other companies
<p>Peter Mørch Eriksen (M) (1960)</p> 	<p><b>Chief Executive Officer</b> Joined BioPorto as CEO in 2013</p>	<p>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.</p>	<p>Chairman of the Board for Medtech Innovation Center. Member of the Board for BioPorto Diagnostics A/S and Veterinary Diagnostics A/S. Member of the Board in Fluo Guide. Member of the Advisory Board at Lund University Diabetes Centre.</p> <p>Peter Mørch Eriksen also serves on the Medical Device and Diagnostics Advisory Committee of Cincinnati Children’s Hospital Center in Cincinnati, Ohio (US)</p> <p>Peter Mørch Eriksen is Director in PME Holding ApS.</p>

Shareholdings of the Board of Directors & Executive Management	December 31, 2017	Purchased	Sold	December 31, 2018
Thomas Magnussen, Chairman of the board (Thomas Magnussen & Therazone ApS)	612,500	254,453	-	866,953
Torben A. Nielsen, Vice-chairman	263,757	38,168	-	301,925
Britt Meelby Jensen, Board member	-	-	-	-
Kirsten Drejer, Board member	-	15,000	-	15,000
Peter M. Eriksen, CEO (PME Holding ApS)	69,239	-	-	69,239

# Financial review 2018

## Income Statement

The financial review is based on the Group's consolidated financial information for the year ended December 31, 2018, with comparative figures for 2017 in brackets. There is no significant difference in the development of the Group and the Parent Company.

In 2018, we generated revenues of DKK 26.0 million (DKK 25.2 million). Earnings before interest and taxes (EBIT) showed a loss of DKK 41.8 million (DKK 36.5 million). The cash position as of December 31, 2018 amounted to DKK 46.7 million (DKK 47.1 million).

## Revenue

Revenue for 2018 was DKK 26.0 million (DKK 25.2 million).

Revenue from The NGAL Test™ was DKK 9.2 million (DKK 6.4 million) and was composed by DKK 4.5 million (DKK 2.5 million) from RUO sales in the U.S. and DKK 4.7 million (DKK 4.0 million) from sales in the EU and the rest of the world. The increase in the U.S. is primarily related to an increase in the number of hospitals using The NGAL Test™.

Revenue from sale of antibodies amounted to DKK 9.4 million (DKK 12.2 million). The decrease is due to the lack or reduction of larger tenders.

Revenue from ELISA kits were DKK 4.8 million (DKK 5.7 million).

Revenues from other products and licenses amounted to DKK 2.6 million (DKK 0.8 million).

## Production costs

Production costs amounted to DKK 8.2 million (DKK 6.9 million). Costs related directly to revenue amounted to DKK 6.3 million (DKK 6.2 million). Other production costs totaled DKK 1.9 million (DKK 0.7 million). The increase in other production costs is primarily due to increased staff related cost (DKK 0.8 million).

## Sales and marketing costs

Sales and marketing costs totaled DKK 20.9 million (DKK 18.5 million). The increase is primarily following a growth in the U.S. organization, with additional staff related cost (DKK 1.7 million) and travel spend (DKK 0.5 million).

## Research and development costs

Research and development costs amounted to DKK 18.7 million (DKK 21.9 million). Clinical studies are down (DKK 5.5 million) as a larger part of the pivotal NGAL adult study happened in 2017 compared to 2018, partly offset by activities in Veterinary Diagnostics (DKK 0.6 million)

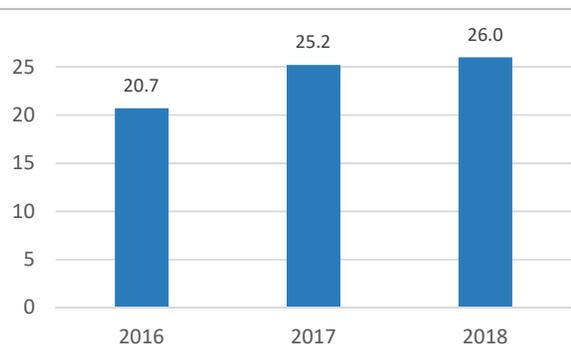
## Administrative costs

Administrative expenses were DKK 20.0 million (DKK 14.3 million). The increase is mainly due to an increase of consultancy cost (DKK 2.7 million), travel cost (DKK 1.0 million), fees to lawyers (DKK 0.7 million) and IT expenses (DKK 0.7 million).

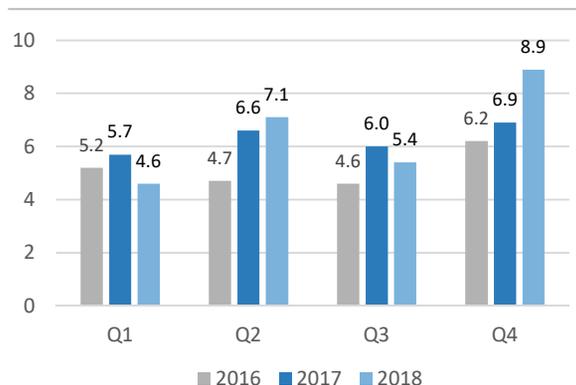
## Financial income and expenses

Financial income was DKK 0.3 million (DKK 0.0 million) and consisted of positive exchange rate adjustments of DKK 0.3 million. Financial expenses amounted to DKK 0.1 million (DKK 0.6 million) and consists of bank charges and interests. The decrease is due to reduced exchange rate losses.

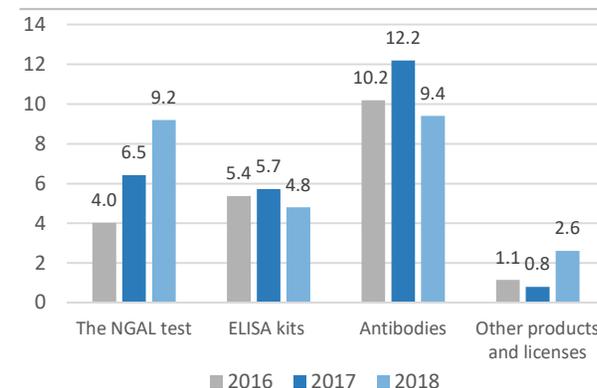
Revenue (DKK million)



Revenue by quarter (DKK million)



Revenue by product category (DKK million)



## Tax on income of the year

Tax on income of the year was an income of DKK 3.6 million (income of DKK 4.8 million) which is primarily related to refunded tax losses originating from research and development cost.

## Liquidity

As of December 31, 2018, BioPorto had a cash position of DKK 46.7 million (DKK 47.1 million). The liquidity position is required to meet our operating expenses and capital expenditures. The Company has funded our cash requirements for 2018 in a combination of revenue from product sales and a capital increase through a private placement.

## Cash flow

Net cash expenditure from operating activities amounted to DKK 38.0 million (DKK 29.2 million) mainly driven from an increase in working capital and the loss of the year partly off-set by a higher tax refund.

Net cash used in investing activities was DKK 1.5 million (DKK 0.1 million) of which the vast majority was investment in property, plant and equipment.

Net cash provided by financing activities totaled DKK 39.1 million (DKK 40.7 million) primarily from a capital increase through a private placement securing net proceeds of DKK 39.3 million (DKK 40.9 million).

The net cash flow for 2018 was negative by DKK 0.4 million (DKK 11.4 million positive).

## Balance Sheet

The balance sheet total was DKK 66.2 million as of December 31, 2018 (DKK 65.6 million).

## Assets

Fixtures and fittings, tools and equipment stood at DKK 1.4 million (DKK 0.3 million). The increase is primarily due to the investment in a lab and a lab instrument partly off-set by depreciations.

The intangible assets were DKK 1.4 million (DKK 1.6 million). The decrease is due to the amortization of the intangible assets. The Company has no capitalized research and development costs.

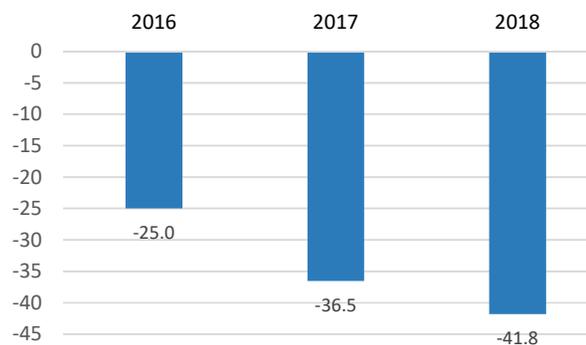
Financial assets stood at DKK 0.8 million (DKK 0.7 million) and consists of deposits.

The Company has no tax asset in the balance sheet. As of December 31, 2018, the total write-down of the tax asset amounted to DKK 44.4 million (DKK 39.4 million). The Company retains the right to use the tax loss carry forward of DKK 43.0 million (DKK 37.5 million) and the other tax assets of DKK 1.4 million (DKK 1.9 million) that were written down.

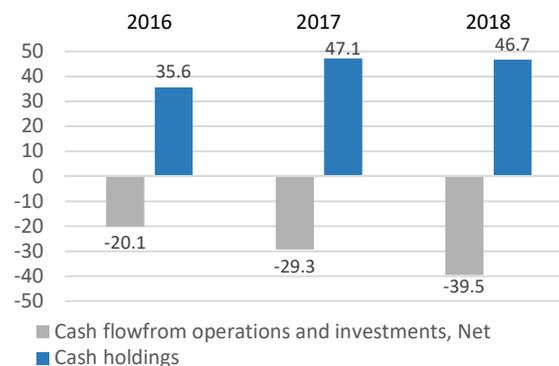
Inventories stood at DKK 3.6 million (DKK 3.4 million) of which finished goods consisted of DKK 3.6 million (DKK 3.2 million).

Receivables stood at DKK 12.3 million (DKK 12.5 million), of which trade receivables amounted to DKK 8.0 million (DKK 6.4 million). The increase is mainly due to strong sales in November and December not yet due as of December 31, 2018.

EBIT (DKK million)



Cash flows and Cash holdings (DKK million)



The income tax receivable totaled DKK 3.7 million (DKK 4.9 million) and other receivables DKK 0.6 million (DKK 1.2 million).

As of December 31, 2018, the cash position was DKK 46.7 million (DKK 47.1 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 56.2 million (DKK 56.1 million).

### Liabilities

The non-current liabilities stood at DKK 0.8 million (DKK 0.9 million). Current liabilities stood at DKK 9.2 million (DKK 8.7 million) of which trade payables amounted to DKK 4.5 million (DKK 3.4 million) and other payables amounted to DKK 4.6 million (DKK 5.1 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 our financial position.

## Statement of comprehensive income

Note		2018 DKK thousand	2017 DKK thousand
3	Revenue	26,016	25,155
4,6,12	Production costs	(8,181)	(6,907)
	<b>Gross profit/loss</b>	<b>17,835</b>	<b>18,248</b>
4,6	Sales and marketing costs	(20,935)	(18,545)
4,6	Research and development costs	(18,676)	(21,930)
4,6,7	Administrative costs	(20,005)	(14,267)
	<b>Profit/loss before financial items (EBIT)</b>	<b>(41,781)</b>	<b>(36,494)</b>
8	Financial income	277	25
8	Financial expenses	(113)	(595)
	<b>Profit/loss before tax</b>	<b>(41,617)</b>	<b>(37,064)</b>
9	Total income taxes	3,569	4,821
	<b>Profit/loss for the year</b>	<b>(38,048)</b>	<b>(32,243)</b>
		DKK	DKK
10	Profit/loss per share (EPS & DEPS)	(0.24)	(0.22)

## Total comprehensive income

Note		2018 DKK thousand	2017 DKK thousand
	<b>Profit/loss for the year</b>	<b>(38,048)</b>	<b>(32,243)</b>
	Amounts which will be re-classified to the income statement:		
	Adjustment of foreign currency fluctuations on subsidiaries	(277)	243
	<b>Total comprehensive income</b>	<b>(38,325)</b>	<b>(32,000)</b>

# Balance sheet

Note	ASSETS	2018	2017
		December 31 DKK thousand	December 31 DKK thousand
	<b>Non-current assets</b>		
	<b>Property, plant and equipment and intangible assets</b>		
11	Fixtures and fittings, tools and equipment	1,437	263
11	Rights and software	1,374	1,629
	<b>Total property, plant and equipment and intangible assets</b>	<b>2,811</b>	<b>1,892</b>
	<b>Financial assets</b>		
	Deposits	752	731
	<b>Total financial assets</b>	<b>752</b>	<b>731</b>
	<b>Total non-current assets</b>	<b>3,563</b>	<b>2,623</b>
	<b>Current assets</b>		
12,18	Inventories	3,631	3,434
13,16,18	Trade receivables	8,036	6,389
	Income tax receivable	3,656	4,864
13,16,18	Other receivables	606	1,223
	<b>Total inventories and receivables</b>	<b>15,929</b>	<b>15,901</b>
16	Cash	46,709	47,080
	<b>Total current assets</b>	<b>62,638</b>	<b>62,981</b>
	<b>Total assets</b>	<b>66,201</b>	<b>65,604</b>

Note	LIABILITIES	2018	2017
		December 31 DKK thousand	December 31 DKK thousand
	<b>Equity</b>		
14	Share capital	165,688	155,510
15	Treasury shares	-	-
	Exchange-rate adjustments	(347)	(70)
	Retained earnings	(109,144)	(99,372)
	<b>Total equity</b>	<b>56,197</b>	<b>56,068</b>
	<b>Liabilities</b>		
	<b>Non-current liabilities</b>		
16	Other non-current liabilities	787	883
	<b>Non-current liabilities</b>	<b>787</b>	<b>883</b>
	<b>Current liabilities</b>		
16	Current portion of non-current liabilities	141	182
16,18	Trade payables	4,451	3,412
16,18	Other payables	4,625	5,059
	<b>Current liabilities</b>	<b>9,217</b>	<b>8,653</b>
	<b>Total liabilities</b>	<b>10,004</b>	<b>9,536</b>
	<b>Total equity and liabilities</b>	<b>66,201</b>	<b>65,604</b>

## 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 January 1, 2018	155,510	-	(70)	(99,372)	<b>56,068</b>
Comprehensive income					
Profit/loss for the year/ comprehensive income	-	-	-	(38,048)	<b>(38,048)</b>
Adjustment of foreign currency fluctuations on subsidiaries	-	-	(277)	-	<b>(277)</b>
Transactions with owners:					
Issue	10,178	29,822	-	-	<b>40,000</b>
Issue costs	-	(681)	-	-	<b>(681)</b>
Share-based compensation	-	-	-	(865)	<b>(865)</b>
Transferred to retained earnings	-	(29,141)	-	29,141	-
<b>Equity at December 31, 2018</b>	<b>165,688</b>	<b>-</b>	<b>(347)</b>	<b>(109,144)</b>	<b>56,197</b>

	Share capital DKK thousand	Share premium DKK thousand	Exchange- rate adjustments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity January 1, 2017	142,494	-	(313)	(97,890)	<b>44,291</b>
Comprehensive income					
Profit/loss for the year/ comprehensive income	-	-	-	(32,243)	<b>(32,243)</b>
Adjustment of foreign currency fluctuations on subsidiaries	-	-	243	-	<b>243</b>
Transactions with owners:					
Issue	13,016	28,634	-	-	<b>41,650</b>
Issue costs	-	(729)	-	-	<b>(729)</b>
Share-based compensation	-	-	-	2,856	<b>2,856</b>
Transferred to retained earnings	-	(27,905)	-	27,905	-
<b>Equity at December 31, 2017</b>	<b>155,510</b>	<b>-</b>	<b>(70)</b>	<b>(99,372)</b>	<b>56,068</b>

	2018 DKK thousand	2017 DKK thousand	2016 DKK thousand	2015 DKK thousand	2014 DKK thousand
Share capital at January 1	155,510	142,494	129,599	117,874	117,874
Issue of new shares	10,178	13,016	12,895	11,725	-
<b>Share capital at December 31</b>	<b>165,688</b>	<b>155,510</b>	<b>142,494</b>	<b>129,599</b>	<b>117,874</b>

## Cash flow statement

Note	2018 DKK thousand	2017 DKK thousand
	(41,781)	(36,494)
<a href="#">6</a>	543	504
<a href="#">4</a>	(865)	2,856
	<b>(42,103)</b>	<b>(33,134)</b>
<a href="#">18</a>	(631)	2,325
	<b>(42,734)</b>	<b>(30,809)</b>
	1,692	977
	(1,766)	(1,410)
	4,799	2,005
	<b>(38,009)</b>	<b>(29,237)</b>
<a href="#">11</a>	(1,410)	(38)
<a href="#">11</a>	(52)	-
	(21)	(21)
	<b>(1,483)</b>	<b>(59)</b>
<a href="#">19</a>	40,000	41,650
<a href="#">19</a>	(681)	(729)
	(158)	(162)
	(40)	(24)
	<b>39,121</b>	<b>40,735</b>
	<b>(371)</b>	<b>11,439</b>
	47,080	35,641
	<b>46,709</b>	<b>47,080</b>

# Notes - Group

1. Accounting policies
2. Significant accounting estimates and judgments
3. Segment reporting
4. Staff costs
5. Incentive schemes
6. Depreciation and amortization
7. Fees to auditors appointed by the general meeting
8. Financial income and expenses
9. Deferred tax
10. Earnings per share
11. Fixtures and fittings, tools and equipment

12. Inventories
13. Receivables
14. Share capital
15. Treasury shares
16. Financial risks and financial instruments
17. Operating lease liabilities
18. Changes in working capital
19. Capital increase
20. Contingent liabilities and events after the end of the period
21. Cash preparedness and cash position during 2019
22. Related parties and ownership

# 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 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 1 January 2018 has been adopted by the group. This includes IFRS 9 Financial Instruments: Classification and Measurement of Financial Assets and Financial Liabilities and IFRS 15 Revenue from Contracts with Customers.

The implementation of IFRS 9 has had an insignificant impact on the consolidated financial statements. The basis for calculation of provision for bad debt has changed from incurred loss to expected loss, with an insignificant impact on the consolidated financial statements. Additional disclosures have been included in note 16 as a result of the implementation.

The implementation of IFRS 15 has not had an impact on the income statement or the related key ratios in the consolidated financial statements. All conditional receivables have been recognized as trade receivables.

Both IFRS 9 and IFRS 15 have been implemented using the modified retrospective method.

### Standards and interpretations not yet in force

At the time of publishing this Annual Report, there are several new or modified standards which have yet to come into effect and which are therefore not implemented into the consolidated financial statements. The following changes to standards and new interpretations issued by IASB but which have not yet been approved by the EU are considered the most relevant for BioPorto:

IFRS 16. "Leases" (approved by EU). Must be applied for accounting periods beginning on or after January 1, 2019.

BioPorto expects these standards and interpretations to be implemented once they come into effect. IFRS 16 "Leasing" changes the way in which undertakings must recognize lease agreements so that most lease arrangements must be recognized on the balance sheet going forward. Based on a preliminary assessment, the implementation of IFRS 16 is expected to increase BioPorto's balance sheet total by around DKK 4.7 million and is expected to impact EBIT by DKK 0.2 million. The impact of the remaining new and modified standards and interpretations is being examined at present, but the Board and Management do not expect them to significantly affect the consolidated financial statements in the years ahead.

## 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.

## 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.

## Note 1, continued

### Incentive programs

The company has issued warrants (share options) to the 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.

### Leasing

Leases in which the company retains all significant risks and rewards of ownership (finance leases) are recognized in the balance sheet at the lower of the asset's fair value and the present value of the lease payments, calculated using the interest implicit in the lease as the discount factor, or an approximate value. Assets held under finance leases are depreciated and written down for impairment according to the same accounting policy as the company's other long-term assets. The capitalized residual lease liability is recognized in the balance sheet as a liability, and the interest element of the lease payment is charged to the income statement over the term of the lease.

All other leases are considered operating leases. Payments in connection with operating leases are recognized in the income statement over the terms of the leases.

### 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 Human NGAL kits

ELISA Animal NGAL kits

ELISA MBL 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.

There are no noncurrent assets or investments outside Denmark.

## Income statement and statement of comprehensive income

### Revenue

Revenue from the sale of finished goods is recognized in 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 in the income statement if the general recognition criteria are met.

This is considered to be 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.

Typical payment terms are 30 days.

Revenue is measured at the transaction price excluding VAT and net of discounts related to sales.

### 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. during the year. This includes costs related to sales staff, advertising, exhibitions and depreciation and amortization.

### 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.

## Note 1, continued

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### 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 in 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 in 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 the company Management has declared its intention to manufacture and market or use the product.

Finally, it must be adequately demonstrated that the 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
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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 in the income statement under sales and marketing costs.

## Note 1, continued

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### 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.

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

### 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 overheads comprise 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 off 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.

### Prepayments

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

## 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.

# Note 1, continued

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## Warrants

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

## Financial liabilities

### Tax payable and deferred tax

Current tax liabilities and current tax receivables are recognized in 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.

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 the 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 a set-off against tax on future income or as a set off 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 in the income statement.

### 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 in the income statement under financial expenses over the term of the loan.

Other liabilities are measured at amortized cost.

## Deferred income

Deferred income comprises payments received relating to income in subsequent financial years. Prepayments are measured at 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.

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.

## Note 1, continued

### 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	$\frac{(\text{Revenue year 1} - \text{Revenue year 0}) \times 100}{\text{Revenue year 0}}$
Gross margin	$\frac{\text{Gross profit} \times 100}{\text{Net revenue}}$
Equity ratio	$\frac{\text{Equity, closing} \times 100}{\text{Total liabilities, closing}}$
Earnings per share (EPS)	$\frac{\text{Result for the year}}{\text{Average number of shares}}$
Net asset value per share at year end	$\frac{\text{Capital and reserves, closing}}{\text{No. of shares, closing}}$

## 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 in 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, 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 in the balance sheet.

## Note 3

### Segment reporting

GEOGRAPHIC DISTRIBUTION	2018	2017
	DKK thousand	DKK thousand
Denmark	1,350	1,481
Rest of Europe	9,655	8,818
North America	12,161	10,900
Asia	2,445	3,676
Other countries	405	280
<b>Revenue</b>	<b>26,016</b>	<b>25,155</b>

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

PRODUCT GROUPS	2018	2017
	DKK thousand	DKK thousand
The NGAL test	9,195	6,426
ELISA Human NGAL kits	1,071	1,448
ELISA Animal NGAL kits	1,083	1,672
ELISA MBL kits	2,671	2,608
Antibodies	9,369	12,199
Royalty	41	89
Other products and licenses	2,586	713
<b>Revenue</b>	<b>26,016</b>	<b>25,155</b>

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

One customer is responsible for more than 10% of BioPorto's revenue: The customer is based in Europe and made purchases amounting to DKK 3,116 thousand in 2018 (2017: DKK 2,880 thousand). The customer primarily purchases antibodies and ELISA kits. Out of net revenue, 45% was invoiced to customers based in the U.S. (2017: 44%) and 14% to customers based in the UK (2017: 14%).

## Note 4

### Staff costs

	2018	2017
	DKK thousand	DKK thousand
Wages and salaries	25,948	21,044
Defined contribution pension plans	1,874	1,688
Share-based compensation expenses	(865)	2,856
Other social security costs	842	909
Other staff costs	436	251
<b>Staff costs</b>	<b>28,235</b>	<b>26,748</b>
Average number of employees	28	25

SPECIFICATION OF STAFF COSTS	2018	2017
	DKK thousand	DKK thousand
Production costs	3,005	2,417
Sales and marketing costs	10,881	10,893
Research and development costs	4,549	3,767
Administrative expenses	9,800	9,671
<b>Staff costs</b>	<b>28,235</b>	<b>26,748</b>

## Note 4, continued

SPECIFICATION OF REMUNERATION FOR KEY MANAGEMENT PERSONNEL	2018 DKK thousand	2017 DKK thousand
<b>Executive Management:</b>		
<b>Peter Mørch Eriksen:</b>		
Salary	3,026	2,695
Paid bonus	314	255
Other employee benefits	483	420
<b>Remuneration, Total</b>	<b>3,823</b>	<b>3,370</b>
Share-based compensation expenses	(241)	1,250
<b>Executive Management, Total</b>	<b>3,582</b>	<b>4,620</b>
<b>Management:</b>		
<b>Ole Larsen (August to December 2018):</b>		
Salary	1,114	-
Paid bonus	292	-
Other employee benefits	195	-
<b>Remuneration, Total</b>	<b>1,601</b>	-
Share-based compensation expenses	171	-
<b>Jan Kuhlmann:</b>		
Salary	2,130	1,790
Paid bonus	131	267
Other employee benefits	201	167
<b>Remuneration, Total</b>	<b>2,462</b>	<b>2,224</b>
Share-based compensation expenses	(158)	239
<b>Board of Directors:</b>		
Remuneration	1,450	1,328
<b>TOTAL REMUNERATION FOR KEY MANAGEMENT PERSONNEL</b>	<b>9,108</b>	<b>8,411</b>

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 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 -0.9 million in 2018 (2017: DKK 2.9 million). Whilst the expenses for the issued programs were DKK 1.6 million this was more than off-set by warrants forfeited due to resigned employees and the cancellation of the warrant program from 2017 totalling 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](http://www.bioporto.com) under Investor Relations > Governance > Company Articles.

In 2018 the Board of Directors in BioPorto used its authorization and issued a total of 7,500,000 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.

### 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. The warrants can only be exercised in the period beginning on June 15, 2020 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. The warrants can only be exercised in the period beginning on August 20, 2020 until August 19, 2023. Conditions for exercising of all warrants apply in case the Company achieve 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 achieve FDA approval of The NGAL Test™ before December 31, 2019, if 50 new hospital customer sites in the USA are achieved no

longer than 12 months after the approval, and if the company achieve 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 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 two warrant programs were issued.

### 2017 program

In 2017 a total of 4,350,000 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 was set at DKK 2.41 per share. The warrants could only be exercised in the period beginning on January 1, 2019 until December 31, 2022. Within the exercise period, warrants could be exercised within ordinary trading windows. The program also included 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 2017 were restricted by terms concerning total or partial forfeiture. The theoretical market value of the warrants issued amounted to DKK 2,681,340 on the date of issue. The specification was based on the Black-Scholes equation, using a 2 years interest rate and the historical volatility of BioPorto A/S' shares over 24 months. The program was forfeited in Q4 2018.

### 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 years interest rate and the historical volatility of BioPorto A/S' shares over 24 months. By the end of 2018 the program has 2,432,500 outstanding warrants which all are exercisabl

## Note 5, continued

### Overview of outstanding warrants at December 31, 2018

Warrants overview	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	-
<b>Total</b>	<b>7,132,500</b>	<b>7,500,000</b>	-	-	<b>(4,700,000)</b>	<b>9,932,500</b>	<b>2,432,500</b>

	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
<b>Total</b>	<b>7,132,500</b>	<b>7,500,000</b>	-	-	<b>(4,700,000)</b>	<b>9,932,500</b>	<b>2,432,500</b>

## Note 5, continued

### Overview of outstanding warrants at December 31, 2017

Warrants overview	Outstanding at January 1	Granted	Exercised	Expired	Forfeited	Outstanding at December 31	Can be exercised at December 31
February 2011	139,500	-	-	(139,500)	-	-	-
April 2016	3,150,000	-	-	-	(367,500)	2,782,500	-
April 2017	-	4,350,000	-	-	-	4,350,000	-
<b>Total</b>	<b>3,289,500</b>	<b>4,350,000</b>	<b>-</b>	<b>(139,500)</b>	<b>(367,500)</b>	<b>7,132,500</b>	<b>-</b>

	Outstanding at January 1	Granted	Exercised	Expired	Forfeited	Outstanding at December 31	Can be exercised at December 31
Executive Management	910,000	2,400,000	-	-	-	3,310,000	-
Management	-	1,000,000	-	-	-	1,000,000	-
Other employees	2,379,500	950,000	-	(139,500)	(367,500)	2,822,500	-
<b>Total</b>	<b>3,289,500</b>	<b>4,350,000</b>	<b>-</b>	<b>(139,500)</b>	<b>(367,500)</b>	<b>7,132,500</b>	<b>-</b>

### Specification of parameters for Black-Scholes model

	Apr 2016	Apr 2017	Jun 2018	Aug 2018	Dec 2018
Exercise price at grant	4,58	2,41	3,11	3,44	3,75
Expected volatility rate	59,8%	71,5%	37,6%	37,3%	50,1%
Expected life (months)	24	21	24	24	24
Expected dividend per share	-	-	-	-	-
Risk-free interest rate p.a.	-0,429%	-0,577%	-0,556%	-0,578%	-0,514%
Fair value at grant (thousands)	7.509	2.681	575	2.868	2.561

## Note 5, continued

### Overview of exercise periods

April 2016	April 8, 2018 to April 7, 2021
April 2017	Program forfeited in 2018
June 2018	June 15, 2020 to June 14, 2023
August 2018	August 20, 2020 to August 19, 2023
December 2018	December 20, 2020 to December 19, 2023

## Note 6

### Depreciation and amortization

	2018	2017
	DKK thousand	DKK thousand
Property, plant and equipment	236	175
<b>Total depreciation</b>	<b>236</b>	<b>175</b>
<b>Specification of depreciation:</b>		
Production costs	84	80
Sales and marketing costs	1	2
Research and development costs	149	91
Administrative expenses	2	2
<b>Total depreciation</b>	<b>236</b>	<b>175</b>

	2018	2017
	DKK thousand	DKK thousand
Intangible assets	307	329
<b>Total amortization</b>	<b>307</b>	<b>329</b>
<b>Specification of amortization:</b>		
Sales and marketing costs	291	290
Research and development costs	-	23
Administrative expenses	16	16
<b>Total amortization</b>	<b>307</b>	<b>329</b>

## Note 7

### Fees to auditors appointed by the general meeting

	2018	2017
	DKK thousand	DKK thousand
<b>Fees to auditors appointed by the general meeting</b>	<b>849</b>	<b>513</b>
<b>Breakdown of fees:</b>		
Fees for statutory audit	230	314
Fees for tax consulting	395	122
Other services	224	77
<b>Total fees to auditors appointed by the general meeting</b>	<b>849</b>	<b>513</b>

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

	2018	2017
	DKK thousand	DKK thousand
<b>FINANCIAL INCOME</b>		
Interest income from bank	27	25
<b>Interest income from financial assets measured at amortized cost</b>	<b>27</b>	<b>25</b>
Exchange rate adjustments, net	250	-
<b>Total financial income</b>	<b>277</b>	<b>25</b>
<b>FINANCIAL EXPENSES</b>		
Interest expenses, other debt	(38)	(31)
<b>Interest expenses on financial liabilities measured at amortized cost</b>	<b>(38)</b>	<b>(31)</b>
Exchange rate adjustments, net	-	(489)
Other financial expenses	(75)	(75)
<b>Total financial expenses</b>	<b>(113)</b>	<b>(595)</b>

## 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 in the balance sheet, cf. note 2. The tax asset is of indefinite duration.

	2018	2017
	DKK thousand	DKK thousand
Calculated tax asset	44,382	39,354
Writedown to assessed value	(44,382)	(39,354)
<b>Carrying amount</b>	-	-

Deferred tax assets not recognised in the balance sheet	2018	2017
	DKK thousand	DKK thousand
Intangible assets	488	724
Property, plant and equipment	761	671
Current assets	182	500
Tax loss carryforwards	42,951	37,459
<b>Deferred tax at December 31, net</b>	<b>44,382</b>	<b>39,354</b>

Income taxes	2018	2017
	DKK thousand	DKK thousand
Net result before tax	(41,617)	(37,064)
<b>Computed, 22%</b>	<b>(9,156)</b>	<b>(8,154)</b>
Valuation allowance	9,156	8,154
Tax credit for research and development cost	3,632	4,824
Tax foreign subsidiaries	(38)	(45)
Adjustment of tax from previous years	(25)	42
<b>Total income taxes</b>	<b>3,569</b>	<b>4,821</b>

## Note 10

### Earnings per share

	2018	2017
	DKK thousand	DKK thousand
Profit/loss for the period	(38,048)	(32,243)
<b>BioPorto Group's share of profit/loss</b>	<b>(38,048)</b>	<b>(32,243)</b>
Average number of shares	156,653	144,562
Average number of treasury shares	(13)	(13)
Average number of shares in circulation	156,640	144,549
Diluted average number of shares in circulation	156,640	144,549
Earnings per share (EPS)	(0.24)	(0.22)

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

### Fixtures and fittings, tools and equipment

	2018	2017
	DKK thousand	DKK thousand
Cost at January 1	2,054	2,016
Additions during the year	1,410	38
<b>Cost at December 31</b>	<b>3,464</b>	<b>2,054</b>
Depreciation at January 1	(1,791)	(1,616)
Depreciation during the year	(236)	(175)
<b>Depreciation at December 31</b>	<b>(2,027)</b>	<b>(1,791)</b>
<b>Carrying amount at December 31</b>	<b>1,437</b>	<b>263</b>
Of which finance leases	-	20

### Rights and software

	2018	2017
	DKK thousand	DKK thousand
Cost at January 1	2,311	2,311
Additions during the year	52	-
<b>Cost at December 31</b>	<b>2,363</b>	<b>2,311</b>
Amortization at January 1	(682)	(352)
Amortization during the year	(307)	(330)
<b>Amortization at December 31</b>	<b>(989)</b>	<b>(682)</b>
<b>Carrying amount at December 31</b>	<b>1,374</b>	<b>1,629</b>

## Note 12

### Inventories

	2018	2017
	DKK thousand	DKK thousand
Finished goods	3,627	3,233
Raw materials and consumables	4	201
<b>Inventories</b>	<b>3,631</b>	<b>3,434</b>
Writedown of slow-moving items	248	560
Cost of sales included in production cost	3,151	3,774
Inventories expected to be sold after 12 months	1,205	1,035

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 13

### Receivables

	2018	2017
	DKK thousand	DKK thousand
Trade receivables	8,417	6,605
Other receivables	606	1,223
Provision for bad debts	(381)	(225)
<b>Total receivables</b>	<b>8,642</b>	<b>7,603</b>

For receivables, which 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. In 2017 the provision for bad debts on receivables was calculated based on an individual assessment of receivables. 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 set out in note 16.

## Note 14

### Share capital

NUMBER OF SHARES	2018	2017
	Number	Number
January 1	155,509,681	142,494,056
Issue	10,178,117	13,015,625
<b>December 31</b>	<b>165,687,798</b>	<b>155,509,681</b>

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

CAPITAL INCREASES IN 2017	Number of shares	Nominal value DKK	Share price DKK/share
Issue	13,015,625	1.00	3.20

The share capital consists of 165,687,798 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 April 10, 2019 to increase the company's capital stock on one or more occasions by a total of DKK 72,186,412. Further details are available in Article 16 of the Company Articles.

## Note 15

### Treasury shares

NOMINAL VALUE	2018	2017
	DKK thousand	DKK thousand
January 1	13	13
December 31	13	13

NUMBER	No.	No.
	January 1	13,000
December 31	13,000	13,000

% OF SHARE CAPITAL	%	%
	January 1	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 2018 or 2017.

## Note 16

### Financial risks and financial instruments

FINANCIAL INSTRUMENT CATEGORIES	2018	2017
	DKK thousand	DKK thousand
Trade receivables	8,036	6,380
Other receivables	606	1,223
Cash and cash equivalents	46,709	47,080
<b>Financial assets at amortized cost</b>	<b>55,351</b>	<b>54,683</b>

	2018	2017
	DKK thousand	DKK thousand
Loans, amortized cost	-	40
Other non-current liabilities	928	1,025
Trade payables	4,451	3,412
Other payables	4,625	5,059
<b>Financial liabilities at amortized cost</b>	<b>10,004</b>	<b>9,536</b>

CASH	Currency	Effective rate of interest	2018	2017
			DKK thousand	DKK thousand
Floating-rate deposits	DKK	-0.5% to 0.5%	46,709	47,080
Sensitivity to change in interest rates		1%1	135	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.

## Note 16, continued

### 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	2018	2017
			DKK thousand	DKK thousand
Revenue settled in	EUR	7.45	17,949	18,624
Sensitivity to change in exchange rates	1.00%	0.07	179	186
Revenue settled in	USD	6.32	6,837	4,847
Sensitivity to change in exchange rates	10.00%	0.63	684	485

#### Interest rate risk

The Group's cash are 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).

#### 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. Trade receivables' financial situation and ability to pay are continuously evaluated, and payment upon placement of order is required if ability-to-pay are evaluated to be low. To measure the 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 off when there is no reasonable expectation of recovery. The maximum credit risk of the group as of December 31, 2018 is estimated to be DKK 8,036 thousand (DKK 6,380 thousand).

	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
<b>December 31, 2018</b>		<b>8,417</b>	<b>381</b>	<b>8,036</b>

The majority of the 'More than 90 days overdue' are receivables from U.S. hospitals and U.S. Universities, where the credit risk is considered low.

BioPorto has recognized a bad debt provision of DKK 0.4 million 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, 2018, BioPorto's liquid assets amounted to DKK 46.7million. Provided that the presented guidance for 2019 is achieved and that the processing times usually seen with the U.S. registration-application process are followed, the liquid assets and capital resources are deemed sufficient for submitting the application for the two FDA clearances of The NGAL Test™ in 2019, and initiation of commercialization of The NGAL Test™ in the U.S. 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.

## Note 16, continued

### Financial risks and financial instruments

2018	Less than 1 year	Between 1 and 5 years	More than 5 years	Total
	DKK thousand	DKK thousand	DKK thousand	DKK thousand
Other non-current liabilities	141	488	299	928
Trade payables and other payables	9,076	-	-	9,076
<b>Financial liabilities</b>	<b>9,217</b>	<b>488</b>	<b>299</b>	<b>10,004</b>

2017	Less than 1 year	Between 1 and 5 years	More than 5 years	Total
	DKK thousand	DKK thousand	DKK thousand	DKK thousand
Lease obligations	40	-	-	40
Other non-current liabilities	142	493	390	1,025
Trade payables and other payables	8,471	-	-	8,471
<b>Financial liabilities</b>	<b>8,653</b>	<b>493</b>	<b>390</b>	<b>9,536</b>

## Note 17

### Operating lease liabilities

#### Lease agreements:

BioPorto has entered into lease agreements for offices, laboratories and production premises. The lease agreement for the Headquarters is non-terminable until April 1, 2021.

	2018	2017
	DKK thousand	DKK thousand
Less than 1 year	2,323	2,106
1-5 years	2,902	4,895
<b>Lease agreements</b>	<b>5,225</b>	<b>7,001</b>

#### Payments recognized in profit/loss for the year

	2018	2017
	DKK thousand	DKK thousand
Less than 1 year	2,186	2,114

#### In-licensing agreement with Statens Serum Institut

BioPorto Diagnostics A/S' agreement for using and depositing cell lines with Statens Serum Institut will remain in force until 2024, after which time the agreement may be terminated by giving 12 months' notice. The overview includes the agreed minimum royalty percentage until and including 2019. The agreement is non-terminable within this period, after which time the right to use the products will continue without a pre-determined minimum royalty percentage.

	2018	2017
	DKK thousand	DKK thousand
Less than 1 year	1,050	1,000
1-5 years	4,752	4,526
More than 5 years	1,340	2,616
<b>In-licensing agreement</b>	<b>7,142</b>	<b>8,142</b>

## Note 18

### Change in working capital

	2018	2017
	DKK thousand	DKK thousand
Change in inventories	(197)	507
Change in receivables	(1,039)	(1,749)
Change trade payables	1,039	2,243
Change in other payables	(434)	1,324
<b>Total change in working capital</b>	<b>(631)</b>	<b>2,325</b>

## Note 19

### Capital increase

	2018	2017
	DKK thousand	DKK thousand
Issue, gross proceeds	40,000	41,650
Issue costs	(681)	(729)
<b>Total net proceeds</b>	<b>39,319</b>	<b>40,921</b>

## Note 20

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

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, however.

#### 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 21

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### Cash preparedness and cash position during 2019

The guidance for 2019 and the expected cash position at 31 December 2019 are based on assumptions of FDA clearance of The NGAL Test™ for children and/or adults in 2019 and a significant increase in RUO sales of the NGAL Test(TM) mainly in the U.S. in 2019 and a slight decrease in revenue generated by antibodies compared to 2018.

The Board of Directors will together Management monitor the development in the cash position through out 2019 ensuring an at all time appropriate financial readiness.

If against our expectations, FDA delays the approval or do not provide approval of our U.S. regulatory application for The NGAL Test(TM) for AKI in children, the Board of Directors and Management will take corrective actions to secure sufficient cash until 31 December 2019 and beyond.

# Note 22

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## 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)

Britt Meelby Jensen (elected April 13, 2018)

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. There have not been transactions with other related parties.

## Income statement

Note		2018	2017
		DKK thousand	DKK thousand
2	Revenue	9,600	9,600
	<b>Gross profit</b>	<b>9,600</b>	<b>9,600</b>
3	Sales and marketing cost	(2,577)	(2,894)
3,4	Administrative expense	(17,450)	(13,664)
	<b>Profit/loss before financial items (EBIT)</b>	<b>(10,427)</b>	<b>(6,958)</b>
5	Income from investments in subsidiaries	(43,686)	(36,346)
6	Financial income	17,440	14,221
6	Financial expenses	(18)	(1,312)
	<b>Profit/loss before tax</b>	<b>(36,691)</b>	<b>(30,395)</b>
7	Total income taxes	(1,357)	(1,848)
	<b>Profit/loss for the year</b>	<b>(38,048)</b>	<b>(32,243)</b>

# Balance sheet

Note	ASSETS	2018	2017
		December 31 DKK thousand	December 31 DKK thousand
	<b>Financial assets</b>		
5	Investments in subsidiaries	3,183	3,414
	Receivables from subsidiaries	20,038	11,871
	Deposits	752	731
	<b>Total financial assets</b>	<b>23,973</b>	<b>16,016</b>
	<b>Total non-current assets</b>	<b>23,973</b>	<b>16,016</b>
	<b>Current assets</b>		
	Income tax receivables	3,632	4,824
	Other receivables	285	260
	<b>Total receivables</b>	<b>3,917</b>	<b>5,084</b>
	Cash	41,363	40,792
	<b>Total current assets</b>	<b>45,280</b>	<b>45,876</b>
	<b>Total assets</b>	<b>69,253</b>	<b>61,892</b>

EQUITY AND LIABILITIES	2018	2017
	December 31 DKK thousand	December 31 DKK thousand
<b>Equity</b>		
Share capital	165,688	155,510
Exchange rate adjustments	(347)	(70)
Retained profit/loss	(109,144)	(99,372)
<b>Total equity</b>	<b>56,197</b>	<b>56,068</b>
<b>Provisions</b>		
Investments in subsidiaries with negative equity	9,531	3,765
<b>Total provisions</b>	<b>9,531</b>	<b>3,765</b>
<b>Liabilities</b>		
<b>Current liabilities</b>		
Trade payables	635	456
Other payables	2,890	1,603
<b>Current liabilities</b>	<b>3,525</b>	<b>2,059</b>
<b>Total liabilities</b>	<b>3,525</b>	<b>2,059</b>
<b>Total equity and liabilities</b>	<b>69,253</b>	<b>61,892</b>

## 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, 2018	155,510	-	(70)	(99,372)	<b>56,068</b>
Comprehensive income					
Profit/loss for the year	-	-	-	(38,048)	<b>(38,048)</b>
Adjustment of foreign currency fluctuations on subsidiaries	-	-	(277)	-	<b>(277)</b>
Transactions with owners					
Issue	10,178	29,822	-	-	<b>40,000</b>
Issue costs	-	(681)	-	-	<b>(681)</b>
Share-based compensation	-	-	-	(865)	<b>(865)</b>
Transferred to Retained earnings	-	(29,141)	-	29,141	-
<b>Equity at December 31, 2018</b>	<b>165,688</b>	<b>-</b>	<b>(347)</b>	<b>(109,144)</b>	<b>56,197</b>

	Share capital DKK thousand	Share premium DKK thousand	Exchange rate adjustment DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity at January 1, 2017	142,494	-	(313)	(97,890)	<b>44,291</b>
Comprehensive income					
Profit/loss for the year	-	-	-	(32,243)	<b>(32,243)</b>
Adjustment of foreign currency fluctuations on subsidiaries	-	-	243	-	<b>243</b>
Transactions with owners					
Issue	13,016	28,634	-	-	<b>41,650</b>
Issue costs	-	(729)	-	-	<b>(729)</b>
Share-based compensation	-	-	-	2,856	<b>2,856</b>
Transferred to Retained earnings	-	(27,905)	-	27,905	-
<b>Equity at December 31, 2017</b>	<b>155,510</b>	<b>-</b>	<b>(70)</b>	<b>(99,372)</b>	<b>56,068</b>

# Notes - Parent

1. Accounting policies
2. Revenue
3. Staff costs
4. Fees to auditors appointed by the general meeting
5. Investments in subsidiaries
6. Financial income and expenses
7. Deferred tax
8. Operating lease liabilities
9. Contingent liabilities
10. Distribution of the year's result
11. Other notes

## 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.

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 "Tax payable and deferred tax" in the consolidated financial statements.

## Note 2

### Revenue

	2018	2017
	DKK thousand	DKK thousand
<b>GEOGRAPHIC DISTRIBUTION</b>		
Denmark	9,600	9,600
<b>Revenue</b>	<b>9,600</b>	<b>9,600</b>

The sale of services in BioPorto A/S exclusively concerns intra-group selling of services.

## Note 3

### Staff costs

	2018	2017
	DKK thousand	DKK thousand
Wages and salaries	11,133	8,732
Share-based compensation expenses	(865)	2,433
Defined contribution pension plans	991	853
Other social security costs	58	49
Other staff costs	85	-
<b>Staff costs</b>	<b>11,402</b>	<b>12,067</b>
Average number of employees	6	6

SPECIFICATION OF STAFF COSTS	2018	2017
	DKK thousand	DKK thousand
Sales and marketing costs	2,304	2,463
Administrative expenses	9,098	9,604
<b>Staff costs</b>	<b>11,402</b>	<b>12,067</b>

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

	2018	2017
	DKK thousand	DKK thousand
Fees for statutory audit	230	238
Fees for tax consulting	105	56
Other services	224	153
<b>Total fees to auditors appointed by the shareholders</b>	<b>559</b>	<b>447</b>

## Note 5

### Investments in subsidiaries

	2018 DKK thousand	2017 DKK thousand
Cost at January 1	51,364	49,364
Additions	-	2,000
<b>Cost at December 31</b>	<b>51,364</b>	<b>51,364</b>
Revaluation at January 1	(299,703)	(264,023)
Income from investments in subsidiaries	(43,686)	(36,346)
Exchange rate adjustments investments in subsidiaries	(277)	243
Equity changes in subsidiaries	-	423
<b>Revaluation at December 31</b>	<b>(343,666)</b>	<b>(299,703)</b>
<b>Value at December 31</b>	<b>(292,302)</b>	<b>(248,339)</b>
Negative value of investments set off against receivables from group	285,954	247,988
Negative value of investments recognized as a provision	9,531	3,765
<b>Value at December 31</b>	<b>3,183</b>	<b>3,414</b>

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	2018	2017
	DKK thousand	DKK thousand
Interest income from subsidiaries	16,618	14,196
Interest income from bank	27	25
Exchange rate adjustments, net	795	-
<b>Total financial income</b>	<b>17,440</b>	<b>14,221</b>

FINANCIAL EXPENSES	2018	2017
	DKK thousand	DKK thousand
Interest expenses, other debt	(16)	(15)
Exchange rate adjustments, net	(2)	(1,279)
Other financial expenses	-	(18)
<b>Total financial expenses</b>	<b>(18)</b>	<b>(1,312)</b>

## 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 in the balance sheet. Reference is made to note 2 in BioPorto's consolidated financial statements.

	2018	2017
	DKK thousand	DKK thousand
Calculated tax asset	52	52
Writedown to assessed value	(52)	(52)
<b>Carrying amount</b>	<b>-</b>	<b>-</b>

DEFERRED TAX ASSETS NOT RECOGNIZED IN THE BALANCE SHEET	2018	2017
	DKK thousand	DKK thousand
Property, plant and equipment	52	52
<b>Deferred tax at December 31, net</b>	<b>52</b>	<b>52</b>

TOTAL INCOME TAXES	2018	2017
	DKK thousand	DKK thousand
Net result before tax	(36,691)	(30,395)
<b>Computed 22%</b>	<b>(8,072)</b>	<b>(6,687)</b>
Valuation allowance	8,072	6,687
Taxation contribution, group companies	(1,357)	(1,847)
Adjustment of tax from previous years	-	(1)
<b>Total income taxes</b>	<b>(1,357)</b>	<b>(1,848)</b>

## Note 8

### Operating lease liabilities

#### Lease agreements:

BioPorto has entered lease agreements for offices, laboratories and production premises. The lease for the Headquarters is non-terminable until April 1, 2021.

	2018 DKK thousand	2017 DKK thousand
Less than 1 year	2,323	2,106
1-5 years	2,902	4,895
<b>Lease agreements</b>	<b>5,225</b>	<b>7,001</b>

#### Payments recognized in profit/loss for the year

	2018 DKK thousand	2017 DKK thousand
Minimum lease payments recognised in profit/loss for the year	2,186	2,114

## Note 9

### Contingent liabilities

BioPorto A/S has acknowledged towards the subsidiary BioPorto Diagnostics A/S, Veterinary Diagnostics A/S and BioPorto Inc. that it will finance its operations in 2019.

## Note 10

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### Distribution of the year's result

The Board of Directors proposes that BioPorto a/s's loss for the year 2018 of DKK 38,049 thousand (2017: loss of DKK 32,243 thousand) to be transferred to retained earnings.

## Note 11

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### Other notes

Reference is made to notes 14 and 15 in BioPorto's consolidated financial statements with respect to share capital and treasury shares.

Reference is made to note 22 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 the Management

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The Board of Directors and the Executive Management have today considered and adopted the Annual Report of BioPorto A/S for the financial year January 1 – December 31, 2018.

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, 2018 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, 2018.

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, February 22, 2019

Executive Management:

**Peter Mørch Eriksen**  
CEO

Board of Directors:

**Thomas Magnussen**  
Chairman

**Torben A. Nielsen**  
Vice Chairman

**Britt Meelby Jensen**

**Kirsten Drejer**

# 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, 2018 and of the results of the Group's operations and cash flows for the financial year January 1 to December 31, 2018 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, 2018 and of the results of the Parent Company's operations for the financial year January 1 to December 31, 2018 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, 2018 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 5 years including the financial year 2018.

## Key audit matters

We have determined that there are no 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, February 22, 2019  
PricewaterhouseCoopers  
Statsautoriseret Revisionspartnerselskab  
CVR No 3377 1231

Torben Jensen  
State Authorised Public Accountant  
mne18651

Allan Knudsen  
State Authorised Public Accountant  
mne29465

# Glossary

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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.
Central laboratory	Many hospitals have a central laboratory which handles a wide range of analyses and typically many at a time – by contrast with the relatively few analyses that can be carried out in the individual wards. A central laboratory usually has many large automated machines for handling the analyses.
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 approval	The "Food and Drug Administration", is the U.S. authority that authorizes the use of medicines, including diagnostic products.
GLP-1	"Glucagon-like peptide-1", is a peptide hormone secreted from the intestines during eating. GLP-1 stimulates the secretion of insulin and is relevant for the treatment of type-2 diabetes and other diseases.
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.
KDIGO	The global non-profit organization developing and implementing evidence-based clinical practice guidelines in kidney disease.

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 already at an early stage.
Prevalence	The proportion of a population who have a specific characteristic in a given time period.
RUO	Products that are for Research Use Only.
Routine diagnostics	Diagnostic analyses that are performed on a routine basis at the time of hospitalization.
Specificity	The degree to which an antibody molecule, for example, binds only to a unique structure on another molecule and not to other structures or molecules, or the degree to which a diagnostic procedure only diagnoses a given pathological condition and does not give a positive result in other conditions, including the normal state.
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 radiation of light.

BioPorto is an in-vitro diagnostic company that provides healthcare professionals in clinical and research settings a range of diagnostic tests and antibodies. Our pioneering product portfolio includes assays for underserved disease states such as NGAL for acute kidney injury.

[www.bioporto.com](http://www.bioporto.com)



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