"A good diagnosis is half the cure"

Annual Report 2016



BioPorto A/S Tuborg Havnevej 15, ground floor DK-2900 Hellerup www.bioporto.com Company reg. no. 17500317 Please note that this is a translated version. In case of discrepansies, the Danish version shal prevail.

About BioPorto

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

The portfolio revolves around antibodies that are used by pharmaceutical companies to develop new drugs and conduct research and BioPorto's own biomarker, developed in-house, for diagnosing acute kidney injury, The NGAL Test[™]. This test is unique as it can detect acute kidney injury far earlier and more reliably than other tests on the market. Acute kidney injury is a well-known risk factor relating to kidney transplants and heart by-pass surgery. The NGAL Test[™] enables doctors to plan a care pathway more quickly and effectively and thus reduce the risk of life-threatening injury and so reduce the mortality rate. Accordingly, the test helps optimize the use of resources to benefit patients, hospitals and health authorities.

Focus on the approval of The NGAL Test[™] and sales

BioPorto's product portfolio of antibodies and biomarkers is distributed world-wide through the company's own sales team, distributors and OEM agreements.

The company's strategy focuses on realizing the significant potential growth inherent in a global market penetration of The NGAL Test™. The test has been launched in Europe and Asia, where a targeted growth plan has been implemented to boost sales. In addition BioPorto will prepare an application for registration with the US Food and Drug Administration (FDA).

The intention behind the application is to pave the way for the launch of the test in 2018 in the US, which is the biggest and most important market in the world for biomarkers.

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Financial Highlights

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

	2016 DKK thousand	2015 DKK thousand	2014 DKK thousand	2013 DKK thousand	2012 DKK thousand
Revenue	20,720	20,383	18,705	16,625	17,858
Operating profit/loss (EBIT)	(25,047)	(12,759)	(15,256)	(19,802)	(13,870)
Netfinancials	148	(255)	159	(2,071)	(2,080)
Operating profit/loss before tax	(24,899)	(13,014)	(15,097)	(21,873)	(15,950)
Profit/loss for the year	(22,800)	(10,732)	(12,926)	(21,873)	(14,700)
Total comprehensive income	(23,113)	(10,732)	(12,926)	(21,873)	(14,700)
Non-current assets	3,069	1,676	1,456	528	470
Current assets	47,572	47,317	35,783	50,064	17,708
Total assets	50,641	48,993	37,239	50,592	18,178
Share capital	142,494	129,599	117,874	117,874	141,449
Equity	44,291	44,485	28,686	41,612	(1,150)
Non-current liabilities	1,204	64	87	105	0
Current liabilities	5,146	4,444	8,466	8,875	19,328
Total equity and liabilities	50,641	48,993	37,239	50,592	18,178

	2016 DKK thousand	2015 DKK thousand	2014 DKK thousand	2013 DKK thousand	2012 DKK thousand
Cash flows from operating ac- tivities	(19,660)	(16,574)	(16,138)	(16,640)	(15,280)
Cash flows from investing activi- ties, net	(401)	(517)	(1,199)	(33)	(87)
Of which investment in prop- erty, plant and equipment	(157)	(50)	(542)	(28)	(82)
Cash flows from financing activi- ties	20,836	26,511	(18)	51,126	9,611
Total cash flows	774	9,420	(17,355)	34,453	(5,756)
Revenue growth	2%	9%	13%	-7%	-4%
Gross margin	76%	76%	71%	54%	62%
EBIT margin	-121%	-63%	-82%	-119%	-78%
Equity ratio (solvency)	87%	91%	77%	82%	-6%
Return on equity	-51%	-29%	-37%	-108%	-1054%
Average number of employees	27	22	24	25	25
Average number of shares (1,000)	131,025	121,652	117,874	79,137	45,308
Earnings per share (EPS), DKK	(0.17)	(0.09)	(0.11)	(0.28)	(0.24)
Net asset value per share, year- end, DKK	0.31	0.34	0.24	0.35	(0.02)
Share price, year-end, DKK	2.10	4.82	1.69	1.40	4.82

To BioPorto's shareholders



Peter Mørch Eriksen

CFO

Rejection—but a strong comeback

2016 was a seminal year for BioPorto. From the beginning of the year, we worked intensively to optimize the prerequisites for launching The NGAL Test[™] in the US following an anticipated approval of our registration application submitted to the US Food and Drug Administration (FDA) in 2015. Unfortunately, and contrary to expectation, we were notified in late May 2016 that the FDA had rejected our application, primarily because the dataset for mild cases of acute kidney injury (AKI) did not support approval.

This meant we were compelled to put our original plans of launching The NGAL Test[™] in the US on hold and reorient our focus halfway through the year. Rather than launch the clinical assay in the US, we allocated our efforts to establishing the prerequisites for a new submission process and adapting our costs to the current level of activity to make us more efficient and agile.

New process of applying for registration in the US receives massive support

An AKI test that radically optimizes treatment procedures, reduces mortality rates and saves billions of dollars for the healthcare system has enormous potential and is hugely important. Seeing that we still aim to launch The NGAL Test[™] at a global level, we have initially decided to boost our regulatory and clinical teams. In addition, we entered into close, positive dialog with the FDA. The agency clarified the areas in which our data collection and application needed to be improved.

A significant in-house and external use of resources, which has included seeking the advice of a number of the best process specialists in the world in the field of FDA approvals, has meant that we have already laid down the protocol for a new clinical study to be carried out in 2017 involving twenty US hospitals. Therefore, we expect to be able to submit a new registration application so that the test can be approved for clinical use in the US in mid-2018.

Our targeted efforts to introduce the assay on the US market are receiving massive support from leading US clinicians and doctors who work daily at organ-transplant centers and intensive care units where AKI afflicts almost one-fourth of all patients and is often fatal.

Through previous testing processes and research use of The NGAL Test™, doctors have gained access to a dynamic tool that is the best on the market for meeting clinical needs to reduce AKI and sequelae associated with treatment that is either incorrect or too late. As this tool significantly improves diagnosis and prognosis in the event of AKI, it is frequently the difference between life and death.

Continuation of business optimization

In 2016, BioPorto expended substantial managerial resources on establishing the framework for a new process for US approval of The NGAL TestTM.

But we also found the time to develop our commercial business, which included entering into a global distribution agreement concerning NGAL with Siemens Healthcare, and strengthening our patent portfolio. In addition, we continued our development activities and expect to be able to launch new products in 2017.

Returning to growth in 2017

We will look back on 2016 as a year when we used our shared ambitions, will and focus to set out the framework and lay the groundwork for a new FDA registration application, based on enhanced new process knowledge. Despite tough odds, we strengthened the strategic position of The NGAL TestTM through scientific support, intensification of our IP rights and optimized marketing conditions through the agreement with Siemens Healthcare, initiatives which have prompted sales of The NGAL TestTM to rise.

This means we can look forward to increasing growth as early as 2017, and we will focus our efforts to realize the full potential of our portfolio when, in 2018, we expect to start selling The NGAL Test[™] for clinical use in the US after a successful FDA approval process.

Main events in 2016

Important strategic progress in a challenging year

2016 was a year of big advances and setbacks for BioPorto. The biggest setback was the company's failure to achieve FDA approval of its biomarker, The NGAL Test[™]. At the same, however, significant progress was made in the proliferation of NGAL awareness and of its use as a biomarker of AKI, a trend that was driven by substantial corporate efforts and by growing acceptance from scientists and medical experts alike. For this reason, BioPorto initiated a new application process for The NGAL Test[™] at the FDA in the summer of 2016, a process which profoundly affected the year's activities.

New application process for The NGAL Test ${\ensuremath{^{\rm M}}}$ and strengthening of the regulatory team

The landmark event for BioPorto in 2016 was the FDA's rejection of the company's application for registration of The NGAL Test[™] in May 2016. In the FDA's assessment, the clinical data provided did not sufficiently support an approval of the test, particularly in mild cases of AKI. This unexpected outcome meant that BioPorto had to set aside the commercialization of the test for clinical use and continue to pursue research-use-only sales of the product in the US.

Convinced of NGAL's potential in improving AKI diagnosis and support from leading US specialists, BioPorto promptly entered into a dialog with the FDA after the rejection to discuss the basis for submitting a revised application.

In this light, BioPorto announced its decision in July 2016 to reapply to the FDA for approval of The NGAL Test[™]. At the same time, BioPorto hired Elisabeth Erhardtsen to be Vice President for Clinical and Regulatory Affairs and lead the process. Elisabeth Erhardtsen came to BioPorto with 23 years of international experience from her clinical and regulatory work for Novo Nordisk, Baxter and Bayer, where she, among other things, dealt with gaining US FDA approval of Novo Nordisk's NovoSeven[®].

Pre-submission processed by the FDA – final approval expected in 2018

After having consulted and cooperated with a number of the world's leading consultants on the design of a new application process, BioPorto filed its pre-submission application concerning The NGAL Test[™] with the FDA in October 2016. The aim of the pre-submission application was to get feedback on the protocol that lays the basis for the final application for official approval of The NGAL Test[™] in the US market. Since then, BioPorto has been engaged in positive dialog with the FDA in this respect, consequently finalizing the protocols and application process in January 2017. BioPorto expects to be able to begin enrolling patients for clinical studies in Q2 2017 and receive FDA approval of the registration application in mid-2018.



The NGAL Test[™] is a game changer

Dr. Rajit K. Basu is Associate Professor of Pediatrics in the Division of Critical Care Medicine and the Co-Director of the Center for Acute Care Nephrology at the Cincinnati Children's Hospital Medical Center in the United States. Dr. Basu and his team have been using The NGAL TestTM for research purposes for two years, and their results demonstrate how real-time urine NGAL quantification is a value-add for the management of critically ill patients with acute kidney injury (AKI).

"From a medical perspective, the problem is substantial even though we think we do, we simply don't know enough about AKI. This syndrome affects roughly 25% of all patients (children and adults) requiring intensive care. The combination of a lack of visceral symptomatology (AKI patients experience no pain and exhibit no visible symptoms) and our reliance on creatinine-based and urine output based methods to assess renal health, metrics that are slow to change in response to injury and highly variable (particularly in children) have likely synergistically contributed to the poor outcomes associated with AKI. AKI associated mortality is high and in many situations, may be because we implement treatment when it is too late. Further, in some cases, we expose the patient to unnecessary risks and treatments because we have insufficient knowledge of what is actually happening in the kidney.," Dr. Basu explains.

"The NGAL Test™ can move the needle for us. It detects incipient signs of AKI much earlier than changes in creatinine and urine output. Unlike other biomarkers, we have data indicating the test is dynamic – meaning that following changes in NGAL level is associated with relevant physiologic changes in a patient. And, perhaps most importantly, we can use it in real time, enabling us to make clinical decisions at a pace more in line with how critically ill patients change and need us to make decisions. The assay increases the accuracy of AKI diagnosis and prediction compared to just using creatinine alone. Used thoughtfully, the information yielded by realtime NGAL testing can improve a doctor's ability to make informed choices for patients suffering AKI and associated problems like fluid overload. These kinds of decisions carry a ripple effect, potentially saving patients and the medical system time and money, while simultaneously improving healthcare outcomes," Dr. Basu states.

US organization disseminates knowledge of The NGAL Test[™] and prepares for commercialization

In the beginning of 2016, BioPorto manifested its targeted strategy in the US by establishing a US subsidiary in Chicago, Illinois. The US organization has been a key player in the dialog with the FDA for clarifying the upcoming application for registration of The NGAL Test[™]. It has also continued its targeted work aimed at hospitals and clinics already using the test for research. Interest has been enormous here, particularly in the field of pediatric medicine. As a result, eight US hospitals are now using the test for research and it is being evaluated by a number of major, influential US institutions. Their acceptance and use of the test will be essential for making prospective users more knowledgeable of NGAL in the run-up to the expected final approval in mid-2018.

Use of NGAL in clinical practice covered by scientific journal

In February 2016, the US *Journal of Thoracic and Cardiovascular Surgery* published an article about the proposed use of NGAL as part of cardiac surgery procedures during which AKI is frequently a complication. The authors of the article presented for the first time a decision tree for the practical use of NGAL in a cardiac surgery intensive care unit, which could help promote official clinical guidelines for the use of NGAL tests in such units. The publication represents vital recognition of NGAL as a biomarker of AKI and is deemed a significant milestone towards gaining worldwide acceptance of The NGAL Test[™].

Important distribution agreement with Siemens

In early 2016, BioPorto and Siemens Healthcare entered into an exclusive global distribution agreement of great strategic significance to BioPorto that will increase the knowledge of and accessibility to NGAL as a biomarker. According to the agreement, BioPorto must supply an NGAL assay adapted to Siemens Healthcare's BN II and BN ProSpec systems. Since entering into the agreement, Siemens Healthcare has worked to validate the NGAL assay for its systems. This work concluded in 2016 and BioPorto received its first NGAL order from Siemens in January 2017.



BioPorto expects sales of NGAL for Siemens' systems to have a positive financial effect on the company in 2017.

BioPorto strengthens and enlarges its patent portfolio

BioPorto's patent portfolio and patent position were strengthened in several areas in 2016. The European Patent Office (EPO) upheld the validity of BioPorto's NGAL forms patent and in addition approved its NGAL cut-off patent application for issuance in November 2016. By contrast, the EPO maintained, in an opposition case, that BioPorto's exclusion patent was invalid, a ruling subsequently appealed by BioPorto.

In December 2016, BioPorto enlarged its NGAL patent portfolio by entering into an exclusive licensing agreement with the trustees of Columbia University concerning a number of the university's NGAL patents that BioPorto has also acquired the right to sub-license.

The agreement is crucial because it boosts BioPorto's chances of entering into partnerships with diagnostics companies.

Reduction of cost base

Because of the year's unfulfilled expectations of growth and the disappointing trend in operating profit, BioPorto restructured its Danish organization in the last half of 2016, reducing the number of employees by 20%. Once the restructuring has been fully implemented in 2018, it will annually reduce costs by around DKK 4 million.

New COO intensifies sales focus

On September 12, 2016, Jan Kuhlmann Andersen, Ph.D., M.Sc. (Biology/Immunology) took up his duties as new Chief Operating Officer (COO) at BioPorto. At the same time, he withdrew from BioPorto's Board of Directors, having been elected to the Board in 2015. Jan Kuhlmann Andersen left a position as vice president at Chr. Hansen A/S, where he had global responsibility for sales and marketing in the area of animal health and nutrition. Jan Kuhlmann Andersen's primary task at BioPorto will be to optimize operations, including to streamline the supply chain and R&D and to ensure an efficient execution of the sales strategy with a view to increasing revenues from as early as 2017.

Consolidated capital base through private placement cash issue

To consolidate the company's capital base and, above all, to help fund the approval process for The NGAL Test™ at the FDA, BioPorto carried out a private placement cash issue in November 2016 where a total of 12,895,096 new shares at DKK 1.00 were offered. The offering was equivalent to approximately 9.95% of the registered capital stock prior to implementation of the issue. The shares were offered to a limited number of selected investors in return for payment of DKK 1.69 per share at DKK 1.00. Based on the great interest, the issue was fully subscribed with net proceeds of DKK 20.9 million.

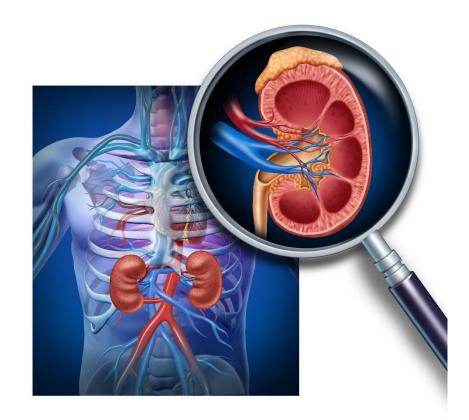
Financial development in 2016

BioPorto's revenue totaled DKK 20.7 million in 2016, which was 2% higher than in 2015. Revenue was substantially lower than originally anticipated, due to the FDA's rejection of the registration application concerning The NGAL Test[™] in the US in May 2016. In addition to a directly adverse effect on revenue forecasts, it meant that BioPorto earmarked a significant portion of its resources since then for the evaluation and preparation of a new application process. In spite of this, revenue generated by The NGAL Test[™] increased by 7% and revenue generated by antibodies also increased by 7% in 2016, whereas revenue generated by ELISA kits was 11% lower than in 2015.

The operating loss (EBIT) for 2016 was DKK 25.0 million compared to a loss of DKK 12.8 million the previous year. Overheads increased in 2016 as a result of establishing and operating the US subsidiary, just as costs for resuming the FDA application process and consolidating the BioPorto management caused costs to increase. The Danish organization was restructured in the last half of the year, but the effects of the restructuring will not be felt until 2017.

The financial result for the year 2016 after tax was a loss of DKK 22.8 million, compared to a loss of DKK 10.7 million in 2015.

At the end of 2016, BioPorto's capital resources were strong, with liquid assets totaling DKK 35.6 million.



Strategy and objectives

Approval of The NGAL Test[™] in the US and strengthened global commercialization of the biomarker top the agenda

The NGAL Test[™] enables doctors and clinical staff to make a much faster and significantly more precise assessment of the stage and severity of possible kidney injury than can be achieved with other tests

on the market, and thus to make a correct diagnosis and put together the right treatment. This reduces inappropriate treatment procedures, mortality rates and treatment costs. This explains why BioPorto assesses that the commercial potential of The NGAL Test™ is enormous globally, as 13 million people suffer from AKI each year.¹

BioPorto's strategy focuses on achieving registration approval of The NGAL Test^M in the US in 2018 and strengthening of the use of the test

in Europe and Asia, where it is already being sold to clinics, hospitals and research institutions.

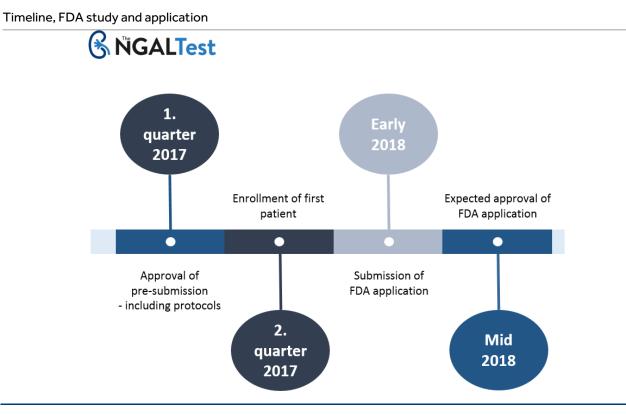
The sales strategy for the test initially focuses on increasing the number of routine users at cardiac and kidney transplant centers, where use of The NGAL Test™ and early diagnosis of AKI are critical in terms of the patient's prognosis, state of health and ongoing care. The scope of the business and lessons learned from routine users are intended to help increase the number of distribution agreements with diagnostic partners and prospective licensing agreements, which, in addition to BioPorto itself, will carry sales to hospitals and clinics.

BioPorto is working to enter into partnerships with small analyzer suppliers who can get their products into specialized market segments quickly. At the same time, BioPorto is continuing its dialog with major diagnostics players, which could eventually lead to more widespread use of The NGAL Test[™] in intensive care units where the potential is sizable. This is exemplified by the distribution agreement BioPorto entered into with Siemens Healthcare. From 2017, the agreement means that Siemens Healthcare will be distributing an NGAL test adapted to Siemens Healthcare's BN II and BN ProSpec systems, which is an important strategic step towards disseminating knowledge of and access to NGAL assays.

Global market breakthrough will originate in the US

For years, The NGAL Test[™] has been offered in Europe and, since 2015, it has gained large market shares in e.g. South Korea. Sales and the number of routine users are rising in both Europe and South Korea, but developments are slower than originally anticipated, as familiarity with NGAL as a biomarker is still low.

As a result, a decisive breakthrough for The NGAL Test™ will not occur until after the test has been launched in the US, which represents more than 50% of the total market for diagnostic tests. Increasing use in the



¹ Hoste, 2008, Critical Care Med.

US, where the will and financial incentive to try out new treatment methods are greater than in the rest of the world, will therefore precede the global acceptance of a new treatment or diagnostic method.

In 2016, BioPorto began a targeted cultivation of the US market by building up a local sales organization charged with optimizing the rollout of The NGAL TestTM.

The organization focuses on making experts and specialized hospitals more knowledgeable of the test. These efforts will intensify in the year ahead where it will be necessary to build up a wide range of customers who are currently using the test for research purposes and serving as ambassadors for The NGAL Test[™], and then convert them into customers when the clinical launch takes place after obtaining registration approval.

New registration application is expected to lead to the approval of The NGAL TestTM in the US in 2018

In the summer of 2016, BioPorto strengthened the part of the organization charged with planning and executing a new process, together with external consultants, aimed at ensuring an approved application for registration of The NGAL Test™ in the US in 2018. After thoroughly discussing the matter with the FDA, BioPorto filed a pre-submission document with the FDA in October 2016, containing a draft of the protocols that were to form the basis of the clinical study and the final De Novo classified application.

Since then, BioPorto has received the FDA's feedback and completed the protocols and also selected twenty US hospitals to take part in the clinical study.

The enrollment of a total of 530 patients for the studies will begin in Q2 2017 and will probably lead to the submission of the final registration application in 2018.

Contingent on normal processing times as part of the US registrationapplication process, BioPorto expects to receive FDA approval in mid-2018 and immediately afterwards to be able to launch the commercialization of The NGAL TestTM on the largest diagnostics market in the world.

The costs of implementing the application registration process in 2017 and 2018 are expected to be DKK 17–18 million, in addition to the roughly DKK 3 million that BioPorto spent on the process in 2016.

The antibody portfolio generates revenue and provides new biomarkers

BioPorto commands a highly specialized portfolio of antibodies, which are sold to customers through distributors and BioPorto's own sales channels. BioPorto endeavors to increase sales of research products by continuously optimizing sales channels and through ongoing in-house development, as well as by in-licensing antibodies with a view to strengthening the portfolio as a whole.

The antibody portfolio is a cornerstone of the company's development activities and the point of departure for developing new biomarkers for BioPorto. Development activities focus on two main areas: innate immune response and new NGAL products.

OBJECTIVES	2017	2018 ONWARDS
Primary	 ✓ Finalization of a protocol for an FDA study for The NGAL Test™ in the US in Q1 ✓ Begin enrolling patients in clinical studies for The NGAL Test™ in the US in Q2 ✓ Increase the number of routine NGAL users in Europe and Asia ✓ Disseminate knowledge and increase sales of NGAL for research use only in the US ✓ Launch new products in the areas of NGAL and innate immune response 	 ✓ Submit application to the FDA, early 2018 ✓ Obtain approval of the registration application for The NGAL Test™ in the US in mid-2018 ✓ Increase the number of NGAL distribution agreements
Secondary	 ✓ Increase sales of ELISA kits ✓ Enlarge the antibody portfolio ✓ Negotiate new licensing and OEM agreements 	 Continue to enlarge the antibody and ELISA portfolio Negotiate new licensing and OEM agreements
Growth in revenue	✓ 20-35%	✓ Maintain high rates of growth

Focus on strategic progress in the US in 2017

The initiation of clinical studies, data collection and analysis, as well as preparing the application for registration of The NGAL Test[™] for the FDA will be the primary areas of focus for the BioPorto Management and Board in 2017. It is crucial for achieving the future value-creating potential of BioPorto that the process runs smoothly and reliably, so that the US launch can take place in 2018 as expected.

In addition, sales activities must be strengthened and must produce better results. Sales of The NGAL Test[™] will be an important source of this, driven by research-use-only sales in the US, the initiation of distribution via Siemens Healthcare and other initiatives. Also, the antibody portfolio must continue to grow, and the decline in sales of ELISA kits must be turned around.

Expectations for 2017

In 2017, BioPorto expects to generate revenue of around DKK 25–28 million, equivalent to a growth rate of 20–35%. The growth will primarily be generated as higher revenue from The NGAL Test[™], but revenue generated by the antibody portfolio and ELISA kits also needs to be increased through targeted sales efforts.

Costs for new clinical studies and other procedures relating the application for registration of The NGAL Test[™] in the US are expected to amount to around DKK 10 million in 2017. On the other hand, the initiatives BioPorto implemented in the last half of 2016 to reduce overheads are expected to reduce costs by DKK 3 million in 2017. In 2017, BioPorto expects its combined financial operating loss (EBIT) to be around DKK 25–28 million.



Products and markets

BioPorto develops and markets in vitro diagnostic (IVD) tests. IVD diagnostics are done outside the body, such as by analyzing blood and urine samples in a laboratory. Such analyses are an essential, objective source of information that can help doctors detect disease, select appropriate treatments and monitor a patient's response to treatment. In addition, scientists can use new tests to better understand the causes of a specific disease and to discover and develop new treatment methods.

BioPorto's product portfolio comprises monoclonal antibodies and antibody-based diagnostic tests, all of which are characterized as highly specialized and unique. Depending on the format and scope of use, the products are intended for diagnostics, clinical research and basic research. The overarching objective of the portfolio is to support the treatment of critically ill patients.

Product portfolio The NGAL Test[™]

Each year, some 13 million people² suffer from acute kidney injury, and about one-fourth of them die.³ In spite of this, developments in kidneyinjury diagnostics have been dormant for the past fifty years. Current methods, such as the measuring of serum creatinine, do not identify renal dysfunction until 48 to 72 hours⁴ after the kidney has been injured. At the same time, serum creatinine is a non-specific marker of kidney function, as its concentration depends on several factors such as medication, age, gender, fluid and food intake.

Neutrophil Gelatinase Associated Lipocalin (NGAL) is a biomarker which diagnoses AKI much earlier than is the case today, where AKI is diagnosed by measuring serum creatinine. Unlike serum creatinine, an NGAL increase can be measured a few hours after the injury has occurred. Measuring an increase of NGAL makes it possible for the doctor to make crucial decisions before the kidney injury develops into potentially fatal kidney failure or before initiating a costly and invasive treatment such as dialysis.

Therefore, the use of The NGAL Test™ as an early biomarker for AKI has several important advantages, including the following:

- » It can save a patient's life because it enables the doctor to make medical decisions earlier that can help prevent the development of AKI in a patient.
- » It can reduce the length of hospitalization and reduce the risk of having to initiate dialysis treatment. It will reduce hospital costs relating to treating renal dysfunction.
- » It can increase patients' quality of life by reducing the risk of developing AKI and subsequent potentially fatal renal failure.

The NGAL Test[™] is a particle-enhanced turbidimetric test designed for use on most clinical chemical analyzers. The test can measure NGAL in plasma or urine and does not limit the user to a specific type of analyzer. The vast majority of hospitals in the Western world have one or more analyzers in their central laboratories capable of running the assay.

BioPorto's strategy for The NGAL Test[™] focuses on penetrating three medical segments: Coronary artery bypass surgery, kidney transplants and intensive care units. The segments represent a large unexploited market potential which BioPorto will address through its own sales

² Hoste, 2008, Critical Care Med.

⁴ Wagener, 2008 + Bennet, 2008

From 2 hours 48-72 hours Reduced Kidnev Damage kidnev Death failure function

NGAL

The development of kidney injury over time

INTERVENTION ³ Susantitaphong, 2013, Clin J Am Soc Nephrol

Serum Creatinine

channels and local distributors, as well as through distribution and licensing agreements.

As of 2016, there is a competing product which has been approved by the FDA and which is CE-marked: Nephrocheck from 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 markets its kidney-injury test on its own analyzer, Astute 140 Meter, and the analysis of one urine sample can determine whether the patient has a higher risk of developing moderate/severe kidney failure within the next 12 hours. Therefore, Nephrocheck is regarded as a biomarker capable of providing an earlier diagnosis of AKI than the standard tests used today.

The NGAL Test[™] differs from Nephrocheck in some significant ways, as The NGAL Test[™] can measure NGAL in either urine or plasma and can be used on the most prevalent analyzers on the market (thus requiring no additional investment in special equipment). In addition, NGAL can be measured several times for the same patient and can thus be used as a prognosis biomarker. This enhances the clinical value of NGAL.

NGAL ELISA kits

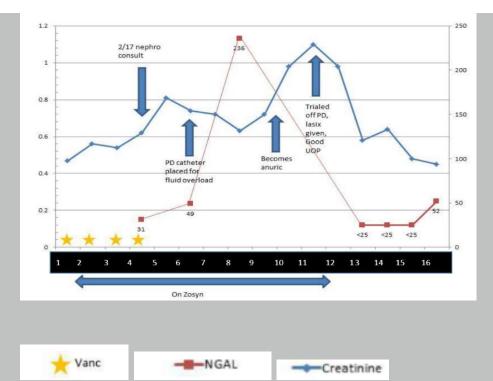
To supplement and, in some instances, serve as a precursor for The NGAL Test[™], BioPorto provides an NGAL ELISA kit for human use. It is widely used in research and to a lesser extent in clinical practice. Another important use of NGAL is in the pharmaceutical industry (clinical trials) where NGAL is used in the development of medicines for estimating a specific medicine's side-effects that are harmful to kidneys. BioPorto provides NGAL ELISA kits for five animal models used in research and NGAL ELISA kits for human use.

Care pathways which include NGAL-based diagnosis make a difference, both in terms of thousands of dollars and in terms of life or death.

The care pathway of a preteen girl at Cincinnati Children's Hospital in early 2017 exemplifies the difference that an NGALbased diagnosis can make for patients and doctors. The patient was admitted to Dr. Basu's intensive care unit with sepsis (massive infection), impaired cardiac function and respiratory failure. Because of her infection, she was administered antibiotic drug therapy that was potentially damaging to the kidney. With rising creatinine levels and anuria (a failure of the kidneys to produce urine), she was showing signs of kidney injury three days into her treatment process and given her unstable, critical state discussions were started about the need for emergency dialysis treatment.

In the subsequent 36-48 hours, her creatinine levels continued to rise but sequential NGAL levels actually decreased. These results suggested to Dr. Basu that her kidneys were actually recovering and that stable kidney function and return of urine output (including response to diuretic medication) was imminent. He decided against dialysis, including the need to insert a hemodialysis catheter, and on day six, the patient began to pass urine again and her hemodynamics improved. Over the ensuing days, her fluid balance was restored, at the same time that her levels of both creatinine and NGAL declined.

"In a conventional diagnosis process, we would probably have started dialysis around day 4 or 5. This would have been, as it turns out, a totally unnecessary intervention, because her kidney function was stabilized and recovering. The declining NGAL levels told us this as early as day three to four, sparing the patient a much longer and costlier treatment process, involving a higher treatment risk. This case is an apt example of how a real-time NGAL Test, with the speed of response and ability to yield information about changes in kidney function is superior to just using creatinine and urine output. In fact, the assay gives the doctor a far better basis for initiating the right treatment at the right time." Dr. Basu explains



MBL ELISA kits

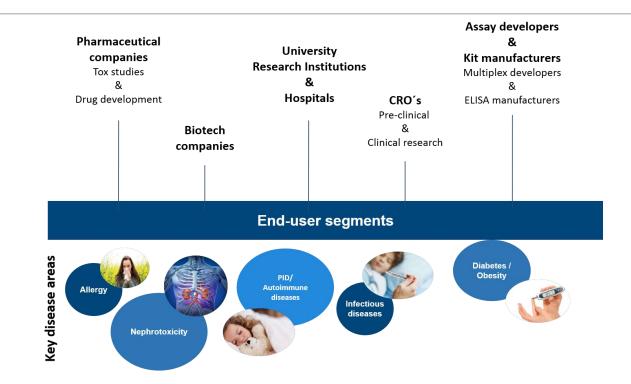
Mannose-binding lectin (MBL) is an important molecule in the innate immune response. MBL deficiency can affect a patient's ability to combat a foreign organism, such as a virus or bacterium.

Roughly 12% of the population in the West is completely or partly deficient in MBL. In some instances, children aged 0-2 can be affected by an MBL deficiency, the symptoms of which include the 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 in the immune response.

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

Antibodies

AntibodyShop is the trademark for BioPorto's product portfolio of antibodies. This unique portfolio primarily comprises monoclonal antibodies (roughly 300 all told), spanning a number of different research disciplines such as microbiology, biomarkers, peptide hormones and plasma proteins. The portfolio is continuously being enlarged to increase the



added sales potential on the existing sales platform and ensure the basis for the company's own development of new biomarkers.

One of the unique groups of antibodies provided by BioPorto is a portfolio of antibodies targeting peptide hormones, including GLP-1 (glucagon-like peptide-1), which is key for the development of a new generation of products aimed at treating Type II diabetes and obesity.

In 2015, BioPorto launched a number of in-licensed antibodies and also gRAD, which is a unique generic testing platform for use with antibodies.

The competitive situation of the various products in BioPorto's antibody portfolio varies significantly. The competition is quite limited for certain research reagents, because similar products are unavailable or there are no alternative methods for conducting the analyses without these specific reagents. Other antibodies are available in similar versions and are therefore subject to more competition. BioPorto has a competitive advantage in delivering well-characterized antibodies, however, as the specificity of antibodies varies greatly among the providers.

Distribution and OEM

With the establishment of a US subsidiary in 2016, BioPorto will use a two-pronged strategy to distribute The NGAL Test[™]. Sales for both research use only and efforts subsequent to obtaining FDA approval will be conducted directly by BioPorto's sales team in the US.

Sales in Europe and the rest of the world will be carried out by distributors and by BioPorto directly. The global distribution agreement entered into with Siemens Healthcare in early 2016 is a strategically important supplement to the proliferation of NGAL. BioPorto is engaged in ongoing dialog to enter into more agreements of this type, as well as more licensing agreements, thus ensuring that the roll-out of NGAL assays is as broad and as fast as possible. ELISA kits, antibodies and research reagents are typically sold through large, global, online-based vendors, and BioPorto has entered into distribution agreements with some of the most influential distributors. Together with BioPorto's own web-shop, this establishes a strong global distribution network with customers in Europe, the US and Asia.

Intellectual property rights

BioPorto's portfolio of intellectual property rights for NGAL is an important asset for optimizing future NGAL market share and comprises the following patents:

- » The NGAL cut-off patent, which describes the cut-off of 250 ng/mL or higher that can be used to diagnose acute kidney injury.
- » The NGAL exclusion patent, which is complementary to the cut-off patent and concerns lower NGAL levels and rules out an immediate risk of kidney injury.
- » The NGAL ratio patent, which involves the use of a ratio between NGAL concentrations in urine and plasma and increases diagnostic specificity and sensitivity to acute kidney injury. The method supplements the NGAL cut-off patent, but in certain clinical situations it can also work independently as a more accurate alternative to the NGAL cut-off patent.
- » The NGAL trauma patent, which deals with NGAL analysis of plasma or urine and assesses the severity of physical traumas. This patent constitutes a significant protection of the company's rights in the utilization of NGAL in Europe's expanding point-of-care market, including NGAL measurements at emergency rooms, trauma centers and, potentially, in ambulances.
- » The NGAL forms patent, which deals with an analysis of individual molecular forms of NGAL in urine and blood to increase the diagnostic specificity of illnesses characterized by different increases in the levels of these forms, including acute kidney injury.

Two of BioPorto's patents are currently being assessed in an opposition case by the European and South Korean patent offices, where the possible outcomes in the cases are that the patent will be upheld; that the patent will be upheld in part; or that the patent will cease to apply.

Irrespective of the outcome of these cases, BioPorto still takes the view that the freedom of other diagnostics companies to operate is obstructed by the remaining patents. The opinions cases do not impinge on BioPorto's freedom to operate.

Licensing access to BioPorto's IP rights

In 2014, BioPorto entered into an agreement with Abbott concerning a new cross license for both parties' respective IP rights within the NGAL area. All licenses are granted on a non-exclusive basis.

In 2016, BioPorto entered into an additional in-licensing agreement on an exclusive basis with the trustees of Columbia University concerning

a number of key world-wide NGAL patents and applications where BioPorto has the right to sublicense these patents.

These NGAL patents will boost BioPorto's existing portfolio of NGAL patents, thereby consolidating the position of BioPorto's NGAL products. Also, it improves scope for entering into partnerships with diagnostics companies.

BioPorto's NGAL patents including licensed NGAL patents	EU	USA	Rest of the world
NGAL Cutoff-patent	Approved to be issued	Application filed	Issued in Australia, Hong Kong, India, Japan, China and Singapore. South Korea (opposi- tion filed). Application also filed in Canada
NGAL Exclusion patent	lssued Opposition filed	Application filed	
NGAL Ratio patent	Issued	Issued	
NGAL Trauma patent	lssued	Application filed	
NGAL Forms patent	lssued	Application filed	
NGAL Serum/Plasma patent (In-licensed)	lssued (opposition filed)	Application filed	Issued in Australia, China and Japan. Appli- cation filed in Canada
NGAL Urine patent (In-licensed)	Issued		Issued in Australia, China, Japan, Mexico, New Zealand. Application filed in Hong Kong, India and and Brazil
NGAL Chronic patent (In-licensed)	lssued	Application filed	
NGAL Kidney dysfunction patent (In-licensed)			Issued in USA

Registration

In order for a diagnostic product to be marketed for clinical use, the product must undergo a registration process with the health authorities in each individual country. The NGAL Test[™] has qualified for registration in a number of countries, including the European countries, South Korea and Canada. In addition, the following countries were registered in 2016: India, Thailand, Chile, Colombia, Russia, Iran and several north African countries (Algeria, Morocco and Tunisia). The company's human NGAL and MBL ELISA kits are also registered in a number of countries, including east European countries, Canada and India. In addition, the following countries were registered in 2016: Iran, Chile and several north African countries (Algeria, Morocco and Tunisia).



Financial review

Income Statement

Revenue and costs rise

BioPorto's revenue amounted to DKK 6.3 million in Q4 2016, and was thus 9% higher than in the same period in 2015. The revenue rise in Q4 was primarily due to higher antibody sales, whereas sales of ELISA kits did not meet expectations. In Q4, The NGAL TestTM generated revenue of DKK 1.7 million, which is on a par with the expectations of the Management and Board.

Loss of DKK 5.5 til 7.5 mio.

BioPorto achieved revenue of DKK 20.7 million for the whole of 2016, compared to DKK 20.4 million in 2015. This is DKK 0.8 million lower than the most recently announced forecasts and is primarily attributable to lower sales of ELISA kits in Q4.

Revenue generated by The NGAL Test[™] grew by 7% in 2016 to DKK 4.0 million. The rise in sales of The NGAL Test[™] is primarily due to higher sales in Europe, which saw an increasing number of users in 2016. The demand for NGAL is still great in South Korea and the assay is routinely used at more than 20 hospitals.

Loss of DKK 22.8 mio.

	tinely used at more than 20 hos	spitais.	
Forecast 2016 Annual Report 2015	Updated forecast 2016, Interim financial report Q3 2016	Realized 2016	
DKK 27-30 mio.	DKK 21.5 mio.	DKK 20.7 mio.	
Loss of DKK 7 til 9 mio.	Loss of DKK 23.5 mio.	Loss of DKK 25.0 mio.	

Loss of DKK 21.5 mio.

Antibody sales ended up at DKK 10.2 million in 2016, compared to DKK 9.5 million in 2015. This equates to a 7% rise, primarily attributable to higher antibody sales within GLP-1 and NGAL. ELISA kits, on the other hand, saw an 11% decline, which should be seen in the light of a large one-off order in late 2015. Earnings for other products and licenses ended at DKK 1.1 million, on a par with 2015.

BioPorto's revenue generated in Europe in 2016 was 12% higher than the previous year. This increase is among other the result of a leaner distributor set-up where, in 2016, BioPorto focused on cooperating with a number of selected distributors, and terminated cooperation with distributors who have failed to meet expectations in recent years.

North American revenue amounted to DKK 7.8 million in 2016, which is 2% higher than in 2015. Revenue generated by The NGAL Test[™] in the US in 2016 was strikingly lower than that forecasted at the beginning of the year, due to the FDA's rejection of BioPorto's registration application in May 2016. Intense efforts are being made to heighten awareness of The NGAL Test[™] in the US in the lead up to the commercialization expected in 2018. This has prompted an increase in the number of hospitals and clinics utilizing NGAL for research.

Figure 1. Revenue (DKKm)

Profit/loss for the year

Revenue

EBIT

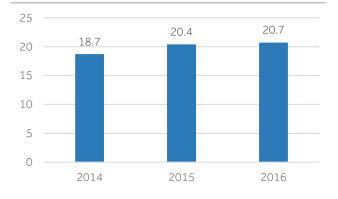


Figure 2. Revenue by quarter (DKKm)

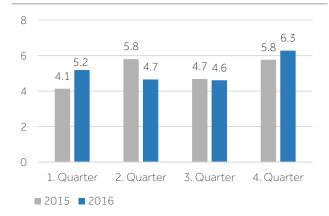
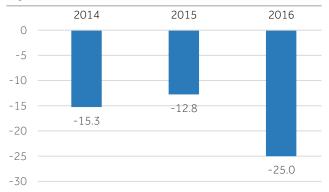


Figure 3. EBIT (DKKm)



The two main markets, Europe and the US, together generated 86% of BioPorto's revenue. Asia and other countries fell by DKK 0.9 million to DKK 2.7 million.

Gross operating result, operating costs and net operating result

Production costs totaled DKK 5.0 million in 2016, equivalent to a gross margin ratio of 76%. This is on a par with the gross margin ratio in 2015.

Overheads totaled DKK 40.7 million, which is DKK 12.5 million higher than in 2015. Sales and marketing costs rose from DKK 8.9 million to DKK 18.0 million in 2016, primarily due to the costs of setting up and running the US organization, as well as the hiring of a COO as from January 1, 2016. R&D costs ended up at DKK 9.7 million and largely went to the FDA registration application for The NGAL Test[™]. Administration costs were DKK 3.6 million higher in 2016 compared to 2015, which is primarily due to higher wage costs, resulting from the hiring of a CFO as well as costs for warrants for the Management and selected key employees. Costs not requiring liquid assets for warrants totaled DKK 2.1 million in 2016. After this, the operating loss (EBIT) amounted to DKK -25.0 million, which is DKK 12.2 million lower compared to last year.

Financial items

Net financial items amounted to an income of DKK 0.1 million in 2016 compared to a net expenditure of DKK 0.3 million in 2015. The income is primarily due to foreign currency translation adjustments.

Financial result

BioPorto's financial result before tax was a loss of DKK 24.9 million in 2016, which is DKK 11.9 million lower compared to 2015. The tax on the loss for the year amounts to a net income of DKK 2.1 million, after which the result for the year amounts to a loss of DKK 22.8 million, compared to a loss of DKK 10.7 million in 2015.

Balance Sheet

At the end of 2016, BioPorto's balance sheet totaled DKK 50.6 million, compared to DKK 49.0 million last year.

Assets

Property, plant and equipment and intangible assets totaled DKK 2.4 million at December 31, 2016, which is DKK 1.3 million higher than at the end of 2015. The increase is primarily due to the capitalization of the exclusive licensing agreement entered into by BioPorto with the trustees of Columbia University concerning a number of the university's NGAL patents.

Inventories amounted to DKK 3.9 million at the end of 2016, which is on a par with the previous year. Receivables from sales were DKK 4.7 million at December 31, 2016 compared to DKK 4.0 million at December 31, 2015. The increase in receivables from sales is due to a negative trend in the debtor days ratio.

Equity

At the end of 2016, equity amounted to DKK 44.3 million compared to DKK 44.5 million in 2015.

A private placement cash issue was carried out in 2016, where a total of 12,895,096 new shares at DKK 1.00 each were sold at a price of DKK 1.69 per share.

Figure 4. Revenue by product category (DKKm)

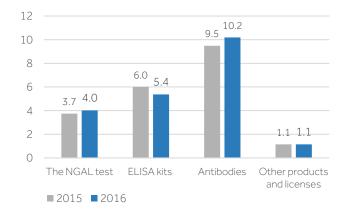


Figure 5. Revenue by Geography (DKKm), 2015

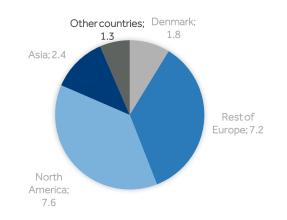
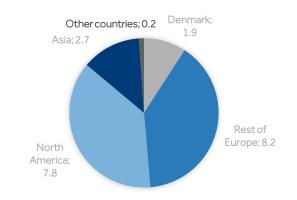


Figure 6. Revenue by Geography (DKKm), 2016



The Board of Directors established a new warrants program for BioPorto's Management and certain key employees in April 2016. The exercise price is set at DKK 4.58 per share and it will be possible to exercise warrants after April 8, 2018 up until April 7, 2021. The purpose of the warrants program was to support the company's long-term objectives and establish performance-based remuneration which reflects the interests of the company and the shareholders. At December 31, 2016, the number of outstanding warrants was 3,289,500.

Liabilities

As at December 31, 2016, BioPorto's liabilities totaled DKK 6.4 million compared to DKK 4.5 million at the end of 2015. Basically, the liabilities comprised short-term payables, provisions for salary and holiday-leave pay; and other accrued expenses. The change from the end of 2015 to the end of 2016 is primarily due to a liability assumed by BioPorto in the form of future minimum royalty payments as part of the licensing agreement with the trustees of Columbia University.

BioPorto had no bank debt on the balance sheet date.

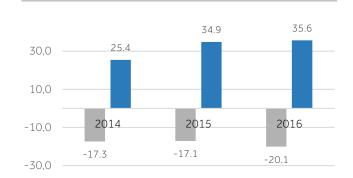
Cash flow statement

Cash flows generated by operating activity were DKK -19.7 million in 2016 (2015: DKK -16.6 million) and the net investments for the year amounted to DKK 0.4 million. Cash flows generated by financing activities were DKK 20.8 million, resulting from the implemented issue of shares. The cash flow for the year ended at DKK 0.8 million compared to DKK 9.4 million in 2015.

Liquid assets and capital resources

As at December 31, 2016, BioPorto's liquid assets amounted to DKK 35.6 million. Provided that the presented guidance for 2017 is achieved and that the processing times usually seen with the US registration-application process are followed, the liquid assets and capital resources are deemed sufficient for obtaining FDA approval of The NGAL Test[™] in mid-2018. Financing needs for commercialization of





Cash flowfrom operations and investments, NetCash holdings

The NGAL Test[™] in the US market will be assessed on an ongoing basis in light of market related possibilities. Notably, the approval and commercialization of The NGAL Test[™] are eventually expected to consolidate equity through rising operating income and positive cash flows.

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.



Risk situation and management

BioPorto carries out development and sales activities in the area of diagnostics. Through its activities, the group is exposed to a number of risks that could significantly affect the group's activity, in the event that these risks were not correctly assessed or controlled. BioPorto's objective is to identify and minimize the risks deriving from the group's operations and to establish sufficient scope of insurance coverage. BioPorto has established risk management as a formalized process for the purpose of generating a close correlation between the group's ongoing aims and activities and the individual risk elements of the group's sphere of activity.

Commercial and developmental risks

BioPorto is exposed to commercial risks, including market size, competing products, market penetration, the ability to establish alliances, and the possibility of obtaining patent protection.

BioPorto seeks to control these commercial risks by continuously monitoring and assessing the market situation and patent positions. The success of new diagnostic products and methods depends on the products being accepted in research environments and subsequently in the healthcare system. BioPorto expends significant resources on generating awareness of new biomarkers, supporting clinical experiments and establishing partnerships with a view to commercialization of the products. BioPorto's competitiveness is also ensured by continuously achieving, enlarging and upholding patent rights within the established areas of focus.

The most significant short-term risks include the following:

- » That the company does not manage to establish the required number of routine users in the principal markets of the US, Europe and South Korea and that the roll-out of The NGAL Test[™] does not take place at the speed wished for.
- » BioPorto does not obtain FDA approval of The NGAL Test[™] in mid-2018 as planned.

- » That competing technologies adversely affect the market roll-out of NGAL.
- » That BioPorto does not retain exclusivity for sales of a number of antibodies, but can sell them non-exclusively instead.
- » BioPorto cannot obtain financing in the event of future financing needs.

Staff-related risks

BioPorto is dependent on being able to attract and retain skilled employees in order to create new product opportunities, uphold the group's competitiveness and ensure growth and results. BioPorto offers its employees professional development opportunities, remuneration and incentive schemes at market levels, but also makes an active effort to create a positive working atmosphere where employees' efforts are respected.

Production risks and quality-related risks

BioPorto actively works to establish alternative manufacturing options for the group's ELISA kits for the purpose of enhancing reliable supply. BioPorto's quality assurance system is compliant with ISO13485:2012. This includes procedures for all product-related processes, supplier audits, optimization plans and periodic management reviews.

Currency risks and other financial risks

As the group exports its products to several different markets, it is vulnerable to fluctuating exchange rates, including in particular for EUR and USD. Revenues are still so relatively modest that no effort is being made to use financial instruments to hedge these risks. This could change in the years ahead in the event that BioPorto's focus on the US market results in higher exposure to the US dollar.

The group's credit risk is associated with bank deposits and the subsidiary's receivables. Liquid assets are deposited in the company's bank, as well as with other major Danish banks. The customers' financial situation and ability to pay are known by the company, and the credit risk entailed by each receivable is assessed as modest. Prepayment of deliveries may be necessary for new customers. Otherwise, the group does not hedge the credit risk in any other way.

Internal control and risk management relating to the presentation of the financial statements

The Board and Management have overarching responsibility for the group's risk management and internal control related to financial reporting. BioPorto's policy is to identify and minimize the risks deriving from the group's operations and to establish sufficient scope of insurance coverage. The group's control and risk management systems can create a reasonable, but not absolute, certainty that unlawful use of assets, loss and/or material misstatement and omissions relating to the presentation of the financial statements are avoided.

The Management and Board assess that all significant elements of risk have been identified and addressed. The Board has discussed the need for internal audit and deems that the company, with the current number of employees, does not have a need for this, nor is it possible in practice.

Details of the group's internal control and risk management relating to the presentation of the financial statements are found on the company's website, pursuant to Section 107b of the Danish Financial Statements Act: <u>http://www.bioporto.com/Admin/Public/DWSDownload.aspx?File=%2fFiles%2ffiles%2ffiles%2ffiles%2fforestor%2fCompany-Documents%2fRisk-situation-and-management.pdf</u>

Corporate governance in BioPorto

In its corporate governance, BioPorto focuses on investor relations, and the Board of Directors gives priority to exercising good corporate governance as defined on the basis of 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 good corporate governance

BioPorto is covered by the recommendations of the Committee for Good Corporate Governance, which are available on <u>www.corporategovernance.dk</u>.

BioPorto's Board of Directors continuously assesses how the 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 of the Committee's recommendations concerning good corporate governance. The mandatory review of corporate governance, pursuant to Section 107b of the Danish Financial Statements Act, is found on the company's website http://www.bioporto.com/Admin/Public/DWSDownload.aspx?File=%2fFiles%2fFiles%2fInvestor%2fCompany-Documents%2f2016-Comparte-Governance-English.pdf

Work of the Management and Board of Directors

The Board 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 the day-to-day management.

The Board's work is described in the rules of procedure of the Board and Management. Six board meetings were held in 2016, including one lengthy strategy meeting. Six meetings are planned for 2017, 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.

The Chairman of the Board is responsible for evaluating the Management and the Board of Directors every year. In addition to examining the cooperation with the Management, the evaluation also looks at the composition and qualifications of the Board, and assesses the results produced over the year; this evaluation is subsequently presented and discussed at a Board meeting.

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 chairperson and one vice chairperson, and currently comprises three members elected at the shareholder meeting.

The members of the Board elected at the shareholder meeting are elected for one year at a time. Persons aged 70 or over on the date of election are not eligible to become members of the company's Board.

The members of the Board are selected and stand for election on the basis of 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: <u>www.bi-</u>oporto.com/About-Us/Board-of-directors.aspx

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://www.bioporto.com/Admin/Public/DWSDownload.aspx?File=%2fFiles%2fFiles%2flowestor%2fCompany_Documents%2fBoard-committees-2016.pdf

Amendments to the articles of association

The shareholder meeting adopts amendments to the articles of association and takes all other decisions on the basis of 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

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. In the event that a committee is established, or in the event that 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 for this. The Board may submit a recommendation to the shareholder meeting approves the remuneration. Each year, the shareholder meeting approves the remuneration of Board members, and any remuneration for alternates, for the current fiscal year in connection with the discussion of the annual report.

The Board does not participate in the company's share-option programs. The annual director's fee amounted to DKK 150,000 in 2016, while the Vice-Chairman receives 2.33 times the standard fee (DKK 350,000), and the Chairman of the Board receives 3.33 times the standard fee (DKK 500,000). Participation on a committee can be remunerated with a supplementary fee of DKK 25,000 per committee, but a maximum total of DKK 50,000 per ordinary Board member. The Chairman and Vice- Chairman do not receive supplementary fees for committee participation.

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

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

The annual bonus may at most comprise 100% of the fixed yearly salary. This may also involve a retention bonus, loyalty bonus or similar. Whether a bonus is actually paid 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 2016, the Management was made up of one person. In 2016, the Management was paid DKK 3.0 million in salary, inclusive of pension (contributionbased) and bonus.

The company has not assumed any obligation to disburse severance pay to the Management upon termination of the employment relationship. The employment relationship can be terminated by giving 12 months' notice effective at the end of a month. No special severance terms have been entered into for the eventuality of a change of control. BioPorto's remuneration policy can be found on the company's website: <u>http://www.bi-</u> oporto.com/Admin/Public/DWSDownload.aspx?File=%2fFiles%2f Files%2fInvestor%2fCompany-Documents%2fRemuneration-policy.pdf

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. BioPorto has defined an objective stating that, no later than in 2018, at least two members of the Board must be women, provided that the Board is made up of at least four members. The objective is in accordance with Section 99b of the Danish Financial Statements Act. This target must not detract from the other competency requirements in the nomination of Board members.

The Board currently has three members, all of whom are men. 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 2016, a male 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

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 workplace and encourages good interplay for the benefit of staff and company efforts alike.

The company has a policy of providing equal opportunities to persons of either gender. For years, the company has had an equal number of men and women in managerial positions, which attests to compliance with this policy in practice.

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

For the year 2016, BioPorto had no policies for corporate social responsibility, including policies for the environment, social conditions and employee relationships, respect for human rights, anti-corruption and anti-bribery, which meet the stipulations of Section 99b of the Danish Financial Statements Act.

In 2016, BioPorto allocated all resources to building up a commercial foundation in the US and initiating a new application process for The NGAL TestTM at the FDA, both of which profoundly affected the year's activities.



Shareholder matters

Investor relations

BioPorto aims to give the market transparent, adequate information about the group's operations, strategy 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 laypersons. All stakeholders should have fast, equal access to important information about BioPorto's development and growth. This means, among other things, that relevant information is published in company announcements via NASDAQ Copenhagen A/S and is made available on the group's website: www.bioporto.com.

Other published information, including general company and investor presentations, is made available to everyone on the 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 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.

Shares

ISIN, capital stock and price trends

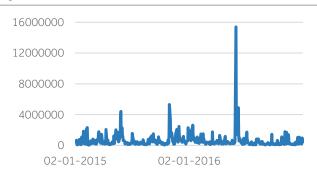
BioPorto's capital stock has a nominal value of DKK 142,494,056, divided into 142,494,056 shares with a nominal value of DKK 1 each, equivalent to 142,494,056 votes. BioPorto A/S's shares are listed on NASDAQ Copenhagen A/S under the symbol "BIOPOR". The ISIN is DK0011048619. BioPorto had a market value of DKK 299 million at the end of 2016 (beginning of 2016: DKK 625 million).

The closing price of the BioPorto share was DKK 2.10 on December 30, 2016, which equals a price drop of -56% in the fiscal year. The value of traded shares was DKK 435 million in 2016, equivalent to average daily trading of DKK 1.7 million and a daily volume of 551,779 shares.

Capital increase

On November 11, 2016, 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.

Figure 9. BioPorto share, Volume



As a result of the implementation of the issue, the capital stock of BioPorto A/S was increased in the nominal amount of DKK 12,895,096, after which it nominally amounts to DKK 142,494,056. The subscription price of DKK 1.69 was calculated as the average weighted share price at NASDAQ Copenhagen over the last five days of trading preceding November 11, 2016. The private placement generated gross proceeds of DKK 21.8 million for BioPorto. The new shares equated to 9.95% of BioPorto's registered capital stock before the implementation of the capital increase.

Ownership

As at December 31, 2016, BioPorto had 6,829 registered shareholders, who in the aggregate owned 82.34% of the capital stock. As at December 31, 2016, the following shareholders state that they own 5% or more of the company's shares/voting rights:

Ejendomsselskabet Jano ApS, Copenhagen	10.1%
Media-Invest Danmark A/S, Copenhagen	7.2%
Nordben Life and Pension Insurance Co. Limited, Guernsey	5.2%

Warrant program

The Board established a warrant program in 2016 for the purpose of creating an incentive for retaining current employees to actively work for the company and for attracting prospective new employees. At the end of the fiscal year, a total of 3,289,500 warrants remained, which amount to 2.3% 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. As a result 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 2017.

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, interim report and quarterly announcements.

Annual Shareholder Meeting

BioPorto A/S will hold its annual shareholder meeting on April 21, 2017, 3.00 pm at the company's address Tuborg Havnevej 15, ground fl., DK-2900 Hellerup.

IR contact



Gry Husby Larsen, General Counsel Tel.: +45 4529 0000 E-mail: <u>investor@bioporto.com</u>

Financial calendar for 2017

Date	Description
February 15, 2017	Silent period before the annual report begins
March 9, 2017	Deadline for shareholder proposals for the annual share- holder meeting
March 15, 2017	Annual Report for 2016
April 21, 2017	Annual shareholder meeting
April 22, 2017	Silent period before interim report begins
May 4, 2017	Interim financial report for Q1 2017
July 27, 2017	Silent period before interim report begins
August 10, 2017	Interim financial report for H1 2017
October 24, 2017	Silent period before interim report begins
November 7, 2017	Interim financial report for the first nine months of 2017

Company announcements

No.	Date	Description
3	February 9, 2017	Major shareholder announcement
2	February 2, 2017	Siemens cooperation transitions to next phase
1	January 30, 2017	BioPorto completes pre-submission dialog with the FDA
27	December 28, 2016	BioPorto enlarges its NGAL patent portfolio
26	December 12, 2016	Financial calendar 2017
25	November 24, 2016	Capital Stock and Voting Rights
24	November 18, 2016	Implementation of private placement cash issue and capital increase
23	November 14, 2016	Report on the transactions of managing employees
22	November 11, 2016	BioPorto carries out private placement case issue
21	November 11, 2016	BioPorto offers new shares in private placement
20	November 8, 2016	The EPO approves the issuance of BioPorto's NGAL cut-off patent
19	November 3, 2016	Quarterly report for the first nine months of 2016
18	October 10, 2016	BioPorto sends in pre-submission application concerning The NGAL Test™ to the FDA
17	August 8, 2016	Jan Kuhlmann Andersen to be new COO for BioPorto A/S – withdraws from the company's Board
16	August 4, 2016	Quarterly report for H1 2016
15	July 5, 2016	The EPO rules that BioPorto's NGAL exclusion patent is invalid; BioPorto appeals the ruling
14	July 4, 2016	BioPorto decides to re-apply to the FDA for approval of The NGAL Test™
13	May 28, 2016	The FDA rejects registration application for approval of The NGAL Test™
12	May 18, 2016	BioPorto prevails: the EPO rules that BioPorto's forms patent is valid
11	May 4, 2016	Quarterly report for Q1 2016
10	April 14, 2016	Notification of the proceedings at the annual shareholder meeting
9	April 8, 2016	Report concerning the transactions of managing employees and their associates involving BioPorto shares and affiliated securities
8	April 8, 2016	Issuance of warrants to employees and adjustment of forecasts of financial results for 2016
7	April 6, 2016	Report concerning the transactions of managing employees and their associates involving BioPorto shares and affiliated securities
6	April 6, 2016	Nomination of a candidate for the Board to the annual shareholder meeting
5	March 16, 2016	Notice convening the annual shareholder meeting
4	March 16, 2016	2015 Annual Report
3	February 13, 2016	Reputable journal's acceptance of article about NGAL use constitutes important strategic milestone for BioPorto
2	January 11, 2016	BioPorto enters into distribution agreement with Siemens Healthcare
1	January 4, 2016	Major-shareholder announcement

Company information

Bank

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

Lawyers

Gorrissen Federspiel H.C. Andersens Boulevard 12 DK-1553 Copenhagen V

Locations

BioPorto A/S and BioPorto Diagnostics A/S



Tuborg Havnevej 15, ground floor DK-2900 Hellerup Headquarters: Hellerup

Independent accountants

PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab

Strandvejen 44 DK-2900 Hellerup

BioPorto Inc. and BioPorto Diagnostics Inc.



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

Management and Board of Directors

Board m	nembers	Directorships in other companies
Thomas Magnussen (M) (1953)		Chairman of the Board for QuantumWise A/S and Zylinc. Director, Therazone ApS.
	Chairman of the board Joined the Board in 2013	
Torben	A. Nielsen (M) (1960) Vice-chairman Joined the Board in 2013	Partner in Linde & Partners Kapitalrådgivning A/S and Board member for Wavepiston A/S. Director, Arnth Advice ApS.
Niels Ch	Board member Joined the Board in 2016	Member of the Board for Tooling Invest A/S, Zylinc A/S, Unumed ApS and QuantumWise A/S.
Manage	ment	Directorships in other companies
Peter Mørch Eriksen (M) (1960) CEO of BioPorto A/S since 2013		Chairman of the Board for Innovision ApS and Medtech Innovation Center. Board member for Netpris A/S, Director in PME Holding ApS. Member of the Advisory Board at Lund University.

Shareholdings of the Management and Board of Directors						
December 31, 2015 Purchased Sold						
Board of directors						
100,000	100,000	-	200,000			
175,000	88,757	-	263,757			
-			-			
Management						
69,239	-	-	69,239			
	December 31,2015 100,000 175,000 -	December 31, 2015 Purchased 100,000 100,000 175,000 88,757 - -	December 31, 2015 Purchased Sold 100,000 100,000 - 175,000 88,757 - - - -			

* Peter M. Eriksen was granted 910,000 warrants on April 8, 2016, which are earned up until April 8, 2018. Further information is provided in note 5 of the consolidated financial statements.

Statement by the Management

The Board of Directors and the Management Board have today considered and adopted the Annual Report of BioPorto A/S for the financial year 1 January – 31 December 2016.

The Consolidated Financial Statements are prepared in accordance with International Financial Reporting Standards as adopted by the EU and additional requirements in the Danish Financial Statements Act. The Financial Statements are prepared in accordance with the Danish Financial Statements Act. Management's Review is also prepared in accordance with Danish disclosures requirements for listed companies.

In our opinion, the Consolidated Financial Statements and the Financial Statements give a true and fair view of the financial position at 31 December 2016 of the Group and the Company and of the results of the Group and Company operations and consolidated cash flows for the financial year 1 January - 31 December 2016.

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 Company, of the results for the year and of the financial position of the Group and the Company as well as a description of the most significant risks and elements of uncertainty facing the Group and the Company.

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

Hellerup, 15 March 2017

Management Board:

Peter Mørch Eriksen CEO

Board of directors:

Thomas Magnussen

Chairman

Torben A. Nielsen Vice Chairman

Niels Christian Nielsen

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 31 December 2016 and of the results of the Group's operations and cash flows for the financial year 1 January to 31 December 2016 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 31 December 2016 and of the results of the Parent Company's operations for the financial year 1 January to 31 December 2016 in accordance with the Danish Financial Statements Act.

What we have audited

BioPorto A/S' Consolidated Financial Statements for the financial year 1 January to 31 December 2016 comprise the consolidated income statement and statement of comprehensive income, the consolidated balance sheet, the consolidated statement of changes in equity, the consolidated cash flow statement and the notes to the financial statements, including summary of significant accounting policies.

BioPorto A/S' Parent Company Financial Statements for the financial year 1 January to 31 December 2016 comprise the income statement, the balance sheet, the statement of changes in equity and the notes to the financial statements, including summary of significant accounting policies.

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 International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants (IESBA Code) and the ethical requirements that are relevant

to our audit of the financial statements in Denmark. We have also fulfilled our other ethical responsibilities in accordance with the IESBA Code.

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 Responsibility 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 judgment and maintain professional skepticism 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, 15 March 2017 PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab CVR no 3377 1231

Torben Jensen State Authorised Public Accountant Allan Knudsen State Authorised Public Accountant

Statement of comprehensive income

Note		2016 DKK thousand	2015 DKK thousand
3	Revenue	20,720	20,383
4.6	Production costs	(5,027)	(4,902)
	Gross profit/loss	15,693	15,481
4.6	Sales and marketing costs	(18,041)	(8,876)
4.6	Research and development costs	(9,669)	(9,944)
4,6,7	Administrative expenses	(13,030)	(9,420)
	Profit/loss before financial items (EBIT)	(25,047)	(12,759)
8	Financial income	346	323
8	Financial expenses	(198)	(578)
	Profit/loss before tax	(24,899)	(13,014)
9	Total income taxes	2,099	2,282
	Profit/loss for the year	(22,800)	(10,732)
		DKK	DKK
10	Profit/loss per share (EPS & DEPS)	(0.17)	(0.09)

Total comprehensive income

Note	2016 DKK thousand	2015 DKK thousand
Profit/loss for the year	(22,800)	(10,732)
Amounts which will be re-classified to the income statement:		
Adjustment of foreign currency fluctuations on su	bsidiaries (313)	0
Total comprehensive income	(23,113)	(10,732)
	DKK	DKK
Total comprehensive income per share (EPS & DE	PS) (0.18)	(0.09)

Balance sheet

		2016	2015
Note	ASSETS	31 December DKK thousand	31 December DKK thousand
	Non-current assets		
	Property, plant and equipment and intangible assets		
11	Fixtures and fittings, tools and equipment	400	451
11	Rights and software	1,959	559
	Total property, plant and equipment and intangible as- sets	2,359	1,010
	Financial assets		
	Deposits	710	666
	Total financial assets	710	666
	Total non-current assets	3,069	1,676
	Current assets		
12.19	Inventories	3,941	4,034
13,17,19	Trade receivables	4,662	3,967
	Income tax receivable	2,138	2,299
13,17,19	Other receivables	1,190	2,150
	Total inventories and receivables	11,931	12,450
	Cash	35,641	34,867
	Total current assets	47,572	47,317
	TOTAL ASSETS	50,641	48,993

		2016	2015
Note	LIABILITIES	31 December DKK thousand	
	Equity		
14	Share capital	142,494	129,599
15	Treasury shares	0	0
	Exchange-rate adjustments	(313)	0
	Retained earnings	(97,890)	(85,114)
	Total equity	44,291	44,485
	Liabilities		
	Non-current liabilities		
17	Lease obligation	40	64
	Other non-current liabilities	1,164	0
	Non-current liabilities	1,204	64
	Current liabilities		
16.17	Current portion of non-current liabilities	242	22
17.19	Trade payables	1,169	1,227
17.19	Other payables	3,735	3,195
	Current liabilities	5,146	4,444
	Total liabilities	6,350	4,508
	TOTAL LIABILITIES	50,641	48,993

Statement of changes in equity

	Share capital DKK thousand	Share premium DKK thousand	Exchange- rate adjust- ments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity 1 January 2016	129,599	0	0	(85,114)	44,485
Profit/loss for the year/ comprehensive income	0	0	0	(22,800)	(22,800)
Issue	12,895	8,898	0	0	21,793
Issue costs	0	(935)	0	0	(935)
Other changes in equity	0	0	(313)	2,061	1,748
Transferred to Retained earnings	0	(7,963)	0	7,963	0
Equity at 31 December 2016	142,494	(0)	(313)	(97,890)	44,291

	Share capital DKK thousand	Share pre- mium DKK thousand	Exchange- rate adjust- ments DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity 1 January 2015	117,874	0	0	(89,188)	28,686
Profit/loss for the year/ comprehensive income	0	0	0	(10,732)	(10,732)
Issue	11,725	16,415	0	0	28,140
Issue costs	0	(1,609)	0	0	(1,609)
Transferred to Retained earnings	0	(14,806)	0	14,806	0
Equity at 31 December 2015	129,599	0	o	(85,114)	44,485

Cash flow statement

Note		2016 DKK thousand	2015 DKK thousand
	Profit/loss before financial items	(25,047)	(12,759)
	Amortization, depreciation and impairment losses	390	300
	Warrants	2,061	0
	Cash generated from operations before working capital	(22,596)	(12,459)
19	Changes in working capital	839	(6,012)
	Cash generated from operations	(21,757)	(18,471)
	Financial income, received	122	308
	Financial expenses, paid	(246)	(564)
	Establishment cost, subsidiaries	(115)	0
	Tax refund	2,336	2,153
	Cash flows from operating activities	(19,660)	(16,574)
	Purchase of operating equipment	(157)	(50)
	Purchase of rights and software	(200)	(464)
	Purchase of financial assets	(44)	(21)
	Sale of operating equipment	0	18
	Cash flows from investing activities	(401)	(517)
20	Capital increases	20,858	26,531
	Reduction of lease obligation	(22)	(20)
	Cash flows from financing activities	20,836	26,511
	Net cash flow from operating, investing and financing activities	774	9,420
	Cash and cash equivalents at 1 January	34,867	25,447
	Cash and cash equivalents at 31 December	35,641	34,867

List of notes to the financial statements

- **1.** Accounting policies
- 2. Significant accounting estimates and judgments
- **3.** Segment reporting
- 4. Staff costs
- 5. Incentive schemes
- 6. Amortization, depreciation and impairment
- 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.** Current portion of non-current liabilities
- **17.** Financial risks and financial instruments
- **18.** Operating lease liabilities
- **19.** Changes in working capital
- **20.** Capital increase
- **21.** Contingent liabilities and events after the end of the period
- 22. Related parties and ownership

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

The financial statements for 2016 are presented in accordance with the new and amended Standards (IFRS/IAS) and the new Interpretations (IFRIC) that apply to financial years beginning on or after 1 January 2016.

BioPorto has assessed the effect of the new IFRS standards and interpretations. BioPorto has concluded that all applicable standards and interpretations which came into effect for the financial year beginning on January 1, 2016 are either not relevant to the BioPorto Group or are not of material significance to the consolidated financial statements of the BioPorto Group.

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 incorporated into the consolidated financial statements. IASB has issued the following changes to standards and new interpretations that could be relevant to BioPorto, but which have not yet been approved by the EU:

IFRS 9. "Measurement and classification of financial assets and liabilities" (approved by EU) IFRS 15. "Revenue" (approved by EU) IFRS 16. "Leases" (not approved by EU)

BioPorto expects these standards and interpretations to be implemented once they come into effect. The implementation of IFRS 15 "Revenue" is not expected to affect the consolidated financial statements, as BioPorto's revenue primarily comprises the sale of products where revenue is recognized at the transition of control over the products that are being transferred to the customer. IFRS 16 "Leasing" changes the way in which undertakings must recognize lease agreements so that most type of leasing 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 15%. 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 intragroup 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.

Incentive programmes

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 on the basis of 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:

- a. The NGAL TestTM
- b. ELISA Human NGAL kits
- c. ELISA Animal NGAL kits
- d. ELISA MBL kits
- e. Antibodies
- f. Other products 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 risk 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.

In addition, public innovation assistance for the development and manufacturing of new products associated with the company's main activity is recognized in the financial statements. The amount is recognized in the income statement concurrent with the completion of the activity.

Revenue is recognized 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, royalties, rent and leasing and depreciation of production equipment.

Sales and marketing costs

Sales and marketing costs include 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, rent, leasing and other costs relating to the Group's research and development activities.

Administrative expenses

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

Financial income and expenses

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

Income tax

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

To the extent the Group benefits from a deduction in the determination of taxable income due to sharebased remuneration, the tax effect of such programmes is included in income tax. Any tax deduction exceeding the accounting cost is recognized directly in equity.

Balance sheet

Intangible 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 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

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.

Property, plant 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.

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 labour and production overheads. Production overheads comprise indirect material and labour 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

Receivables are measured at the lower of amortized cost and net realizable value, which typically corresponds to the nominal value less provisions for bad debts.

Impairment for losses are made to reduce the carrying amount of trade receivables, the value of which are impaired due to risk of loss. Impairment losses on receivables are calculated on the basis of an individual assessment of receivables.

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.

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 and income taxes paid.

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

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

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

Financial ratios

Earnings per share (EPS) and diluted earnings per share (DEPS) are calculated in accordance with IAS33.

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

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

Financial ratios are calculated according to Recommendations and Financial Ratios 2015 issued by the Danish Society of Financial Analysis.

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, convertible bonds, 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. 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.

The other notes to the financial statements comprise disclosures on assumptions of future events and other estimation uncertainties at the balance sheet date involving a considerable risk of changes that could lead to a material adjustment of the carrying number of assets or liabilities in the coming financial year.

Segment reporting

GEOGRAPHIC DISTRIBUTION:	2016	2015
	DKK thousand	DKK thousand
Denmark	1,898	1,783
Rest of Europe	8,182	7,195
North America	7,760	7,634
Asia	2,656	2,448
Other countries	224	1,323
Revenue	20,720	20,383

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

PRODUCT GROUPS	2016	2015
	DKK thousand	DKK thousand
The NGAL test	4,014	3,747
ELISA Human NGAL kits	1,720	2,554
ELISA Animal NGAL kits	1,302	920
ELISA MBL kits	2,347	2,530
Antibodies*	10,192	9,489
Other products and licenses	1,145	1,143
Revenue	20,720	20,383

*In 2016, public innovation assistance of DKK 1,334 thousand (2015: DKK 1,075 thousand) relating to the development and production of a new antibody is included as revenue.

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

Two customers are each responsible for more than 10% of BioPorto's revenue: One customer is based in Europe and made purchases amounting to DKK 2,246 thousand in 2016 (2015: DKK 2,316 thousand), and the other customer is based in the US and made purchases amounting to DKK 2,116 thousand in 2016 (2015: DKK 1,766 thousand). Both customers primarily purchase antibodies and ELISA kits. Out of net revenue, 36% was invoiced to customers based in the US (2015: 36%) and 15% to customers based in the UK (2015: 16%).

Note 4

Staff costs

	2016	2015
	DKK thousand	DKK thousand
Wages and salaries	21,322	15,518
Defined contribution pension plans	1,884	1,339
Share-based compensation expenses	2,061	0
Other social security costs	575	202
Other staff costs	270	273
Staff costs	26,112	17,332
Average number of employees	27	22
providentian of staff assta	2016	2015
Specification of staff costs:	DKK thousand	DKK thousand
Production costs	2,039	2,151
Sales and marketing costs	10,678	5,962
Administrative expenses	8,696	5,607
Research and development costs	4,699	3,612
Staff costs	26,112	17,332
Management Board		
Salaries	2,539	2,333
Pension	420	225
Share-based compensation expenses	495	0
Management Board, Total	3,454	2,558
Board of Directors		
Remuneration	1,183	1,188

Management Board was granted 910,000 warrants in 2016, which are earned up until April 8, 2018. See note 5.

Incentive schemes

For the purpose of motivating and retaining staff and Management, BioPorto A/S set up new warrants programs as an incentive and bonus scheme in 2011 and 2016. 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.

A total of 6,368,696 warrants were issued to BioPorto's Management and certain employees in 2016. 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 (on an assumption of expected fulfillment of 50% for the part of the program restricted by conditions of forfeiture). The specification is based on the Black-Scholes equation, using an interest rate of -0.429%, expiration of 2 years and the historical volatility of BioPorto A/S' shares of 59.8% over 24 months.

Out of the warrants issued in 2016, 2,868,696 have subsequently been forfeited, as they were restricted by conditions that were not met, and 350,000 have been cancelled in conjunction with termination of employment.

The share-based payment compensation expenses amounted to DKK 2.1 million in 2016 (2015: DKK 0).

Overview of outstanding warrants

	2016	2015
Outstanding at January 1	214 500	244,500
Outstanding at January 1	214,500	
Granted	6,368,696	0
Cancelled	3,293,696	30,000
Outstanding at December 31	3,289,500	214,500
The outstanding warrants can be specified as follows		
Warrants which are vested and can be exercised	139,500	0
Warrants which are vested (and can be exercised from April 8, 2018)	350,000	0
Warrants which have yet to be vested	2,800,000	214,500
Total	3,289,500	214,500
The vested warrants can be broken down as follows		
Management Board	0	0
Employees	489,500	214,500
Total	489,500	214,500

Out of the issued warrants, 139,500 can be exercised up to and including February 6, 2017 at an average exercise price of DKK 7.86 per warrant, and 3,150,000 can be exercised beginning on April 8, 2018 and ending on April 7, 2021 at an exercise price of DKK 4.58 per warrant. Within the exercise period, warrants can be exercised within ordinary trading windows.

Full or partial forfeiture conditions apply to 490,000 warrants, if BioPorto does not meet the specified revenue forecasts in 2017. 2,310,000 warrants are vested on an ongoing basis up until April 8, 2018.

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

Amortization, depreciation and impairment

	2016 DKK thousand	2015 DKK thousand
Property, plant and equipment	208	196
Total depreciation and impairment	208	196
Specification of depreciation and impairment:		
Production costs	88	82
Sales and marketing costs	8	8
Research and development costs	104	98
Administrative expenses	8	8
	208	196

	DKK thousand	DKK thousand
Intangible assets	182	104
Total amortization and impairment	182	104
Specification of amortization and impairment:		
Sales and marketing costs	166	104
Administrative expenses	16	0
	182	104

Fees to auditors appointed by the general meeting

	2016 DKK thousand	2015 DKK thousand
Fees to auditors appointed by the general meeting	629	506
Breakdown of fees:		
Fees for statutory audit	234	201
Fees for tax consulting	167	142
Other services	228	163
Total fees to auditors appointed by the general meeting	629	506

Note 8

Financial income and expenses

FINANCIAL INCOME

	2016 DKK thousand	2015 DKK thousand
Interest income from bank	64	93
Interest income from financial assets not measured at fair value	64	93
Exchange rate adjustments	282	230
Total financial income	346	323

FINANCIAL EXPENSES

	2016 DKK thousand	2015 DKK thousand
Interest expenses, other debt	(29)	(279)
Interest expenses on liabilities not measured at fair value	(29)	(279)
Exchange rate adjustments	(121)	(267)
Other financial expenses	(48)	(32)
Total financial expenses	(198)	(578)

Deferred tax

A significant deferred tax asset has been calculated. 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.

	2016 DKK thousand	2015 DKK thousand
Calculated tax asset	37,425	34,110
Write down to assessed value	(37,425)	(34,110)
Carrying amount	0	0

Deferred tax assets not recognized in the balance sheet:

	2016	2015
	DKK thousand	DKK thousand
Intangible assets	652	612
Property, plant and equipment	690	693
Current assets	388	356
Tax loss carryforwards	35,695	32,449
Deferred tax at 31 December, net	37,425	34,110
Income taxes	2016 DKK thousand	2015 DKK thousand
Tax refund, research and development costs	2,138	2,299
Tax foreign subsidiaries	(77)	0
Adjustment of tax from previous years	38	(17)
Total income taxes	2,099	2,282

Earnings per share

	2016 DKK thousand	2015 DKK thousand
Profit/loss for the period	(22,800)	(10,732)
BioPorto Group's share of profit/loss	(22,800)	(10,732)
Average number of shares	131,025	121,652
Average number of treasury shares	(13)	(13)
Average number of shares in circulation	131,012	121,639
Diluted average number of shares in circulation	131,012	121,639
Earnings per share (EPS)	(0.17)	(0.09)

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).

Fixtures and fittings, tools and equipment

	2016	2015
	DKK thousand	DKK thousand
Cost at 1 January	2,052	2,035
Additions during the year	157	50
Disposals during the year	(193)	(33)
Cost at 31 December	2,016	2,052
Depreciation at 1 January	(1,601)	(1,423)
Depreciation during the year	(208)	(196)
Reversed depreciation on disposals	193	18
Depreciation at 31 December	(1,616)	(1,601)
Carrying amount at 31 December	400	451
Of which finance leases	46	73

Rights and software

Carrying amount at 31 December	1,959	559
Depreciation at 31 December	(352)	(170)
Depreciation during the year	(182)	(104)
Depreciation at 1 January	(170)	(66)
Cost at 31 December	2,311	729
Additions during the year	1,582	464
Cost at 1 January	729	265
	DKK thousand	DKK thousand
	2016	2015

Note 12

Inventories

	2016	2015
	DKK thousand	DKK thousand
Finished goods	3.534	3.593
Raw materials and consumables	407	441
Inventories	3.941	4.034
Write down of slow-moving items	(76)	(140)
Cost of sales included in Production cost	2.613	2.577
Inventories expected to be sold after 12 months	1.680	1.497

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.

Receivables

	2016 DKK thousand	2015 DKK thousand
Trade receivables	4,837	4,017
Other receivables	1,190	2,150
Provision for bad debts	(175)	(50)
	5,852	6,117

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.

Impairment for losses are made to reduce the carrying amount of trade receivables, the value of which are impaired due to risk of loss. Impairment losses on receivables are calculated based on an individual assessment of receivables.

An overview of trade receivables is set out in note 17.

Note 14

Share capital

The share capital consists of 142,494,056 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.

NUMBER OF SHARES	2016 Number	2015 Number	
1 January	129,598,960	117,874,210	
Issue	12,895,096	11,724,750	
31. December	142,494,056	129,598,960	
CAPITAL INCREASES IN 2016	Number of shares	Nominal value DKK	Share price DKK/share
Issue	12,895,096	1.00	1.69
CAPITAL INCREASES IN 2015	No.	DKK	DKK/share
Issue	11,724,750	1.00	2.40
CAPITAL INCREASES IN 2013	No.	DKK	DKK/share
Issue	70,724,526	1.00	1.00
CAPITAL INCREASES IN 2012	No.	DKK	DKK/share
Cash private placement	2,000,000	3.00	5.10

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 95,380,154. Further details are available in Article 16 of the Company Articles.

Treasury shares

NOMINAL VALUE	2016 DKK thousand	2015 DKK thousand
1 January	13	13
31 December	13	13
NUMBER	No.	No.
1 January	13,000	13,000
31 December	13,000	13,000
% OF SHARE CAPITAL	%	%
1 January	0.01%	0.01%
31 December	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 2016 or 2015.

Note 16

Current portion of non-current liabilities

	2016 DKK thousand	2015 DKK thousand
Finance leases	24	22
Other non-current debt	218	0
Current portion of non-current liabilities	242	22

Total financial liabilities

Financial risks and financial instruments

FINANCIAL INSTRUMENT CATEGORIES	2016 DKK thousand	2015 DKK thousand
Trade receivables	4,662	3,967
Other receivables	1,190	2,150
Cash and cash equivalents	35,641	34,867
Total receivables and cash	41,493	40,984
	2016 DKK thousand	2015 DKK thousand
Loans, amortized cost	64	86
Other non-current liabilities	1,382	0
Trade payables	1,169	1,227
Other payables	3,735	3,195

6,350

4,508

Trade receivables

	2016	2015
	DKK thousand	DKK thousand
Not due	2,579	2,546
Overdue by 0-90 days	1,096	1,334
More than 90 days overdue	1,162	137
Total trade receivables before writedowns	4,837	4,017
Movements in receivables more than 90 days overdue	2016 DKK thousand	2015 DKK thousand
1 January	137	169
Disposals	(17)	(215)
Additions	1,042	183
31 December	1,162	137

In 2016, BioPorto has not recognized loss on bad debts. For receivables, which fall due within one year after the end of the financial year, the nominal value is considered to correspond to the fair value.

Note 17, continued

CASH	Currency	Effective rate of interest	2016 DKK thousand	2015 DKK thousand
Floating-rate loans	DKK	0%-0.5%	35,641	34,867
Sensitivity to change in interest rates		1%	250	0

Financial liabilities

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

Financial risks

Currency risk

As the Group exports its products to several different markets, it is exposed to exchange rate fluctuations. International sales are invoiced in EUR and USD, which reduces the direct exposure. Exchange rate fluctuations may affect BioPorto's competitive strength indirectly, which has not been assessed in the sensitivity calculation. Otherwise, the Group does not hedge its currency exposure. BioPorto has limited debt denominated in foreign currency.

	Currency	Exchange rate	2016 DKK thousand	2015 DKK thousand
Revenue settled in	EUR	7.45	16,449	14,616
Sensitivity to change in exchange rates	0.50%	0.04	82	73
Revenue settled in	USD	6.75	2,365	3,505
Sensitivity to change in exchange rates	5.00%	0.34	118	175

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). The effective rate of interest on the financial lease obligation is 10.5% per annum.

Credit risk

The Group's credit risk is associated with bank deposits and the subsidiary's receivables. Cash is deposited with the company's bank and with other major Danish banks. The customers' financial situation and ability to pay are known by the company, and the credit risk for each receivable is modest. Prepayment of deliveries may be necessary for new customers. Otherwise, the Group does not use any form of hedges against credit risk.

Liquidity risk

Capital resources and capital management are described in the management's review. 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.

Cash and capital resources

As at December 31, 2016, BioPorto's liquid assets amounted to DKK 35.6 million. Provided that the presented guidance for 2017 is achieved and that the processing times usually seen with the US registration application process are followed, the liquid assets and capital resources are deemed sufficient for obtaining FDA approval of The NGAL Test[™] in mid-2018. Financing needs for commercialization of The NGAL Test[™] in the US market will be assessed on an ongoing basis in the light of market-related possibilities. Notably, the approval and commercialization of The NGAL Test[™] are eventually expected to consolidate equity through rising operating income and positive cash flows.

Capital structure

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

Financial risks and financial instruments

2016	Less than 1 year DKK thousand	Between 1 and 5 years DKK thousand	More than 5 years DKK thousand	Total DKK thousand	
Lease obligations	24	40	0	64	
Other non-current liabilities	218	593	571	1,382	
Trade payables and other payables	4,904	0	0	4,904	
Financial liabilities	5,146	633	571	6,350	

2015	Less than Between 1 year 1 and 5 years DKK thousand DKK thousand		More than 5 years DKK thousand	Total DKK thousand	
Lease obligations	22	64	0	86	
Other non-current liabilities	0	0	0	4,422	
Trade payables and other payables	4,422	0	0	4,422	
Financial liabilities	4,444	64	0	4,508	

Note 18

Operating lease liabilities

Lease agreements:

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

	2016 DKK thousand	2015 DKK thousand
Less than 1 year	2,286	2,221
1-5 years	6,759	8,157
More than 5 years	0	529

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 2017. The agreement is non-terminable within this period, after which time the right to use the products will continue without a predetermined minimum royalty percentage.

	2016 DKK thousand	2015 DKK thousand
Less than 1 year	503	479
1-5 years	0	503
More than 5 years	0	0

Payments recognized in profit/loss for the year

	2016 DKK thousand	
Less than 1 year	2,428	2,271

Changes in working capital

	2016 DKK thousand	2015 DKK thousand
Change in inventories	93	(30)
Change in receivables	265	(1,956)
Change trade payables	(59)	28
Change in other payables	540	(4,054)
	839	(6,012)

Note 20

Capital increase

	2016	2015
	DKK thousand	DKK thousand
Issue, gross proceeds	21,793	28,140
Issue costs	(935)	(1,609)
	20,858	26,531

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.

Related parties and ownership

BioPorto - The Group's related parties are:

Board of Directors and Management Board

Thomas Magnussen, Chairman (elected 26.02.2013) Torben A. Nielsen, Vice Chairman (elected 02.04.2013) Niels Christian Nielsen (elected 14.04.2016) Roar Seeger, Board member (resigned 14.04.2016) Jan Kuhlmann Andersen, Board member (resigned 12.09.2016)

Peter Mørch Eriksen, CEO (appointed 18.07.2013)

Group-owned companies

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

BioPorto Diagnostics Inc, Chicago, Illinois, USA (established January 2016). Ownership: 100%

BioPorto Inc, Chicago, Illinois, USA (established January 2016). Ownership: 100%

Related party transactions

There have not been transactions with related parties, besides salary and remuneration.

Income statement

Note		2016 DKK thousand	2015 DKK thousand
3	Revenue	9,600	9,600
	Gross profit	9,600	9,600
	Sales and marketing cost	(2,633)	0
4,5,6	Administrative expense	(12,347)	(9,506)
	Profit/loss before financial items (EBIT)	(5,380)	94
	Income from investments in subsidiaries	(28,530)	(17,453)
7	Financial income	12,703	11,225
7	Financial expenses	(21)	(28)
	Profit/loss before tax	(21,229)	(6,162)
9	Total income taxes	(1,571)	(4,570)
	Profit/loss for the year	(22,800)	(10,732)
	Proposed appropriation of loss		
	To be transferred to retained earnings	(22,800)	(10,732)

Balance sheet

Note	ASSETS	2016 31 December DKK thousand	
	Non-current assets		
	Property, plant and equipment	0	0
	Financial assets		
8	Investments in subsidiaries	1,461	0
8	Receivables from subsidiaries	8,972	10,973
	Deposits	710	666
	Total financial assets	11,143	11,639
	Total non-current assets	11,143	11,639
	Current assets		
	Income tax receivables	2,138	2,299
	Other receivables	295	622
	Total receivables	2,433	2,921
	Cash	33,002	31,375
	Total current assets	35,435	34,296
	TOTAL ASSETS	46,578	45,935

EQUITY AND LIABILITIES	2016 31 December DKK thousand	2015 31 December DKK thousand
Equity		
Share capital	142,494	129,599
Exchange rate adjustments	(313)	0
Retained profit/loss	(97,890)	(85,114)
Total equity	44,291	44,485
Liabilities		
Current liabilities		
Trade payables	575	494
Other payables	1,712	956
Current liabilities	2,287	1,450
Total liabilities	2,287	1,450
TOTAL EQUITY AND LIABILITIES	46,578	45,935

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 1 January 2016	129,599	0	0	(85,114)	44,485
Profit/loss for the year	0	0	0	(22,800)	(22,800)
lssue	12,895	8,898	0	0	21,793
Issue costs	0	(935)	0	0	(935)
Other changes in equity	0	0	(313)	2,061	1,748
Transferred to Retained earnings	0	(7,963)	0	7,963	0
Equity at 31 December 2016	142,494	(0)	(313)	(97,890)	44,291

	Share capital DKK thousand	Share premium DKK thousand	Exchange rate adjustment DKK thousand	Retained earnings DKK thousand	Total DKK thousand
Equity at 1 January 2015	117,874	0	0	(89,188)	28,686
Profit/loss for the year	0	0	0	(10,732)	(10,732)
Issue	11,725	16,415	0	0	28,140
lssue costs	0	(1,609)	0	0	(1,609)
Transferred to Retained earnings	0	(14,806)	0	14,806	0
Equity at 31 December 2015	129,599	0	0	(85,114)	44,485

List of notes to the financial statements

- **1.** Accounting policies
- 2. Significant accounting estimates and judgments
- 3. Revenue
- 4. Staff costs
- 5. Amortization, depreciation and impairment
- 6. Fees to auditors appointed by the general meeting
- 7. Financial income and expenses
- 8. Investments in subsidiaries
- 9. Deferred tax
- **10.** Operating lease liabilities
- **11.** Contingent liabilities
- **12.** Other notes

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.

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.

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.

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, valuation of investments in the subsidiary, receivables from the subsidiary 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.

Note 2 to the consolidated financial statements contains a description of accounting estimates and judgments, which are common for the Group.

Note 3

Revenue

GEOGRAPHIC DISTRIBUTION	2016 DKK thousand	2015 DKK thousand
Denmark	9,600	9,600
Revenue	9,600	9,600

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

Staff costs

	2016 DKK thousand	2015 DKK thousand
Wages and salaries	7,857	5,357
Share-based compensation expenses	1,349	0
Defined contribution pension plans	858	423
Other social security costs	60	46
Other staff costs	0	0
Staff costs	10,124	5,826
Average number of employees	7	5

Specification of staff costs:

	2016 DKK thousand	
Sales and marketing costs	1,763	0
Administrative expenses	8,361	5,826

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

Note 5

Amortization, depreciation and impairment

There were no amortization, depreciation or impairment charges in 2016 or 2015.

Fees to auditors appointed by the general meeting

		2015 DKK thousand
Fees for statutory audit	234	201
Fees for tax consulting	66	142
Other services	192	163
Total fees to auditors appointed by the shareholders	492	506

Note 7

Financial income and expenses

FINANCIAL INCOME

	2016 DKK thousand	2015 DKK thousand
Interest income from subsidiaries	12,423	11,130
Interest income from bank	64	93
Other financial income	216	2
Total financial income	12,703	11,225

FINANCIAL EXPENSES

	2016 DKK thousand	
Interest expenses, other debt	(8)	0
Other financial expenses	(13)	(28)
Total financial expenses	(21)	(28)

Investments in subsidiaries

	2016	2015
	DKK thousand	DKK thousand
Cost at 1 January	48,000	48,000
Additions	1,364	0
Cost at 31 December	49,364	48,000
Net impairment at 1 January	(187,892)	(170,439)
Income from investments in subsidiaries	(28,530)	(17,453)
Exchange rate adjustments investments in subsidiaries	(313)	0
Equity changes in subsidiaries	712	0
Net impairment at 31 December	(216,120)	(187,892)
Negative value written down on receivable	216,120	187,892
Value at 31 December	1,461	0
Receivables from subsidiaries		
Cost at 1 January	198,894	179,280
Additions	26,228	19,614
Disposals	0	0
Cost at 31 December	225,122	198,894
Net impairment at 1 January	(187,921)	(170,468)
Negative equity transferred to be set off against receivables from group enterprises	(28,228)	(17,453)
Net impairment at 31 December	(216,149)	(187,921)
Value at 31 December	8,972	10,973

List of subsidiaries

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

BioPorto Inc, Chicago, Illinois, USA (established January 2016). Ownership: 100%

BioPorto Diagnostics Inc, Chicago, Illinois, USA (established January 2016). Ownership: 100%

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 31 December. 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 writedown has been made to reflect this.

Note 10

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, cf. note 2.

	2016 DKK thousand	2015 DKK thousand
Calculated tax asset	52	52
Write down to assessed value	(52)	(52)
Carrying amount	0	0

$\ensuremath{\mathsf{DEFERRED}}$ TAX ASSETS NOT RECOGNISED IN THE BALANCE SHEET:

	2016	2015
	DKK thousand	DKK thousand
Property, plant and equipment	52	52
Deferred tax at 31 December, net	52	52
TOTAL INCOME TAXES		
	2016	2015
	DKK thousand	DKK thousand
Income tax 2016	(1,608)	(2,656)
Adjustment of tax from previous years	37	(1,914)
Total income taxes	(1,571)	(4,570)

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 1 April 2021.

	2016 DKK thousand	2015 DKK thousand
Less than 1 year	2,286	2,221
1-5 years	6,759	8,157
More than 5 years	0	529

Payments recognized in profit/loss for the year

	2016 DKK thousand	
Minimum lease payments recognized in profit/loss for the year	1,949	1,753

Contingent liabilities

BioPorto A/S has acknowledged towards the subsidiary BioPorto Diagnostics A/S and BioPorto Inc. that it will finance its operations in 2017.

Note 12

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.

Biomarker	Theoretically, any analyzable phenomenon that can be used for indicating a biological condi- tion (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 a number of large automated machines for handling the analyses.
Diagnostics	Diagnostics is the process whereby a disease and possibly its cause are identified. Fast, accu- rate 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 chang- ing 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 US 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.
Homogene/ heterogene tests	Homogeneous analysis is performed in a single phase (liquid), whereas heterogeneous assays use both a liquid and a solid phase. Homogeneous analysis is simpler and can be performed or automated equipment from different manufacturers. Heterogenous analysis typically requires a wash step and have different designs in the various automated equipment supplied by vari- ous manufacturers why a heterogeneous analysis typically cannot be transferred to another manufacturer's equipment.

IVD	"In vitro diagnostic(s)", a diagnostic procedure that takes place outside the body, e.g. b analyzing blood and urine samples in a laboratory, as opposed to "in vivo diagnostics", whic are performed on the patient, such as a prick test in the skin or an X-ray.
MBL	"Mannan-binding lectin", a blood protein that binds to foreign organisms and contributes t congenital (innate) immune response.
Monoclonal	Derived from a single "clone", in this case a single cell line. A monoclonal antibody thus consist of antibody molecules which are all identical, whereas a polyclonal antibody consists of man different antibody molecules produced by many different cell lines in the body.
NGAL	"Neutrophil gelatinase-associated lipocalin", a biomarker that can indicate renal injury alread at an early stage.
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 o another molecule and not to other structures or molecules, or the degree to which a diagnos tic procedure only diagnoses a given pathological condition and does not give a positive resu in other conditions, including the normal state.
Therapy/therapeutic pr ucts	od-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 reager fluid containing substances, often antibodies, that react with the biomarker in the sample t 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.

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