



Annual Report 2015



BioPorto A/S
Tuborg Havnevej 15, st.
DK-2900 Hellerup
www.bioporto.com
CVR 17500317

About BioPorto A/S

BioPorto develops and markets monoclonal antibodies and antibody-based in-vitro diagnostic assays used in the treatment of critically ill patients, in clinical research and in basic research.

The company's technology is built up around a unique, specialized niche portfolio comprising antibodies developed in-house and in-licensed. These antibodies are marketed commercially and used as the point of departure for the company's in-house development of diagnostic biomarkers such as MBL (mannose-binding lectin) and NGAL (neutrophil gelatinase-associated lipocalin). The products are distributed through BioPorto's own sales organization, external distributors and OEM partners.

Ambitious strategy for growth revolving around The NGAL Test™

BioPorto's diagnostic portfolio forms the basis for implementing an ambitious strategy for growth. The strategy centers on an accelerated

global roll-out of The NGAL Test™, which was developed in-house and which is capable of diagnosing acute kidney injury only a few hours after the injury has occurred. As a result, life-saving treatment of the roughly 13 million cases of acute kidney injury a year can be initiated much faster than is currently the case using traditional markers and assays.

Contingent on the approval of a registration application with the US Food and Drug Administration (FDA), BioPorto will introduce The NGAL Test™ in the US, where the company has just set up its own sales subsidiary. Along with substantial sales of the test in Asia, persistent revenue growth of ELISA kits and antibodies, commercialization of new products and the upholding of a cost-effective organization, the introduction in the US is expected to lay the groundwork for a sharp rise in revenue and earnings in the years ahead.

BioPorto Diagnostics Product overview



The NGAL Test™

Acute kidney injury

Diagnostic test for clinics, hospitals, GPs and laboratories

**DIRECT SALES,
DISTRIBUTORS,
LICENSE AND OEM**



NGAL ELISA kits

Toxic effect on kidneys (nephrotoxicity)

Basic research test for the biotech and pharmaceutical industries

**DIRECT SALES AND
DISTRIBUTORS**



MBL ELISA kits

Immunodeficiency (MBL deficiency)

Diagnostic tests for hospitals and immunodeficiency centres

**DIRECT SALES AND
DISTRIBUTORS**



Antibodies

Basic research within allergy, diabetes and infectious diseases amongst others

Basic research test for research institutions, the pharmaceutical industry and assay manufacturers

**DIRECT SALES, OEM
AND DISTRIBUTORS**



Contents

Management review

About BioPorto	2
Contents	3
Financial highlights	4
To BioPorto's shareholders	5
Key events	6
Strategy and objectives	8
Our products and markets	10
Financial review	16
Risk factors and risk management	19
Corporate governance	20
Investor relations	22
Company details	25
Board of Directors and Management Board	26

Statements

Statement by the management	27
Independent auditors' report	28

The BioPorto Group

Statement of comprehensive income	29
Balance sheet	30
Statement of changes in equity	32
Cash flow statement	33
List of notes to the financial statements	34

BioPorto A/S

Income statement	65
Balance sheet	66
Statement of changes in equity	68
List of notes to the financial statements	69

Glossary	85
----------	----

Financial highlights

A definition of financial ratios is set out in note 1 to the consolidated financial statements.

	2015	2014	2013	2012	2011
	DKK thousand	DKK thousand	DKK thousand	DKK thousand	DKK thousand
Revenue	20,383	18,705	16,625	17,858	18,584
Operating profit/loss before interest and tax (EBIT)	(12,759)	(15,256)	(19,802)	(13,870)	(12,858)
Net financials	(255)	159	(2,071)	(2,080)	(1,980)
Operating profit/loss before tax	(13,014)	(15,097)	(21,873)	(15,950)	(14,838)
Profit/loss for the year	(10,732)	(12,926)	(21,873)	(14,700)	(14,838)
Non-current assets	1,676	1,456	528	470	572
Current assets	47,317	35,783	50,064	17,708	20,680
Total assets	48,993	37,239	50,592	18,178	21,252
Share capital	129,599	117,874	117,874	141,449	135,449
Equity	44,485	28,686	41,612	(1,150)	3,940
Non-current liabilities	64	87	105	0	12,186
Current liabilities	4,444	8,466	8,875	19,328	5,126
Total equity and liabilities	48,993	37,239	50,592	18,178	21,252
Cash flows from operating activities	(16,574)	(16,138)	(16,640)	(15,280)	(13,606)
Cash flows from investing activities, net	(517)	(1,199)	(33)	(87)	(30)
Of which investment in property, plant and equipment	(50)	(542)	(28)	(82)	(23)
Cash flows from financing activities	26,511	(18)	51,126	9,611	13,815
Total cash flows	9,420	(17,355)	34,453	(5,756)	179
Revenue growth	9%	13%	-7%	-4%	35%
Gross margin	76%	71%	54%	62%	57%
EBIT margin	-63%	-82%	-119%	-78%	-69%
Equity ratio (solvency)	91%	77%	82%	-6%	19%
Return on equity	-29%	-37%	-108%	-1054%	-410%
Average number of employees	22	24	25	25	25
Average number of shares (1,000)	121,652	117,874	79,137	45,308	43,084
Earnings per share (EPS), DKK	(0.09)	(0.11)	(0.28)	(0.24)	(0.26)
Net asset value per share, year-end, DKK	0.34	0.24	0.35	(0.02)	0.07
Share price, year-end, DKK	4.82	1.69	1.40	4.82	7.05

Please note that this is a translated version. In case of discrepancies, the Danish annual report should be referred to.

To BioPorto's shareholders

BioPorto ready for massive growth

2015 was a busy, outstanding and crucial year for BioPorto. 2016 will continue along these same lines and features a number of important milestones.

From the beginning of the year, we had set a number of clear strategic goals whose achievement is essential for optimizing BioPorto's long-term potential. Our primary—and essential—aim was to submit FDA application and prepare the roll-out of The NGAL Test™ in the US. Next, we had to increase the number of routine-diagnostics users and increase revenue generated by the test in markets where we are already present. Finally, we had to keenly focus on developing and further strengthening the portfolio of ELISA kits and antibodies and, thus, their future revenue potential for our core business.

Today, we can look back on 2015 and ascertain that we have been successful on every point, and then some, if we include in our accomplishments the successful implementation of a share issue and the powerful entry of The NGAL Test™ in South Korea. Early in 2016, we entered into an important distribution agreement with Siemens Healthcare, we officially set up a US subsidiary and we consolidated our organization by engaging a COO and a CFO.

The NGAL Test™ being readied for US roll-out in 2016

In the spring of 2015, we finalized the clinical studies of The NGAL Test™ in the US and subsequently submitted our registration application to the FDA in September. This was a crucial milestone which means that, in 2016, after receiving authorization from the FDA, we can commence the commercialization of the unique The NGAL Test™ on the largest market in the world for diagnostic assays.

The assay has enormous potential in the US, which is why we drew up and invested in an aggressive US strategy in 2015 aimed at speeding up the growth and accelerating our exploitation of NGAL's potential. We have hired the first key employees in the US. Their initial focus is implementing a niche strategy which, in 2016, ambitiously targets selected hospitals and transplant clinics. Based on these efforts, we will double the number of clinics using the test from 2017 and widen the use at hospitals to include intensive care units, thus laying the groundwork for rapid replenishment.

Positive trends in our existing business to be intensified

Although our sales activities aimed at existing products and markets have generally grown at a reasonable rate, they have been affected by our intensified use of resources to establish the US organization.

Things will normalize in 2016, and at the same time we will see a positive effect on revenue generated by the new products gradually being introduced into the portfolio after we have sharpened our focus on developing products based on our antibody portfolio and antibody know-how. This should contribute to stabilizing the growth of our antibody and ELISA business areas in the years ahead and potentially help to launch new automated assays in the long run.

Focus on implementing a growth case from 2016

As a result of our targeted efforts in 2015, BioPorto's prospects are more attractive and attainable than ever. We are fielding a strong team who are dedicated and persevering in their efforts to achieve our goals, and I would like to express my gratitude to our employees for their efforts.

The implementation of a substantially more aggressive strategy for growth in the US and the allocation of resources to continue the development of new products also mean that we have increased our investments in boosting our long-term potential for growth at the expense of a short-term goal of becoming profitable in 2016. We are convinced that our priorities of a significant and quick uptake in the US and the enlargement of our portfolio of tests and antibodies—as well as the impact of the distribution agreement with Siemens—will enable us to strikingly accelerate our rate of growth from the last half of 2016, thereby ensuring a far greater value creation going forward, for the benefit of our shareholders, customers, employees and business partners.

Peter Mørch Eriksen

CEO



Key events

Significant strengthening of our growth platform by preparing for the US introduction of The NGAL Test™ and the enlargement of our product portfolio

In 2015, BioPorto achieved a number of key strategic milestones relating to the company's growth platform. Our activities were focused on submitting a registration application to the FDA for The NGAL Test™, laying the groundwork for a strong US presence, consolidating our capital base and intensifying our marketing efforts in Europe and Asia.

Completion of clinical studies and submission of an FDA application for The NGAL™ Test

In March 2015, BioPorto completed an accelerated enrollment of 250 patients in clinical studies of The NGAL Test™ at a number of leading US hospitals. Data from the studies were included in the test's registration application, which BioPorto submitted to the US Food and Drug Administration (FDA) in September 2015.

In BioPorto's view, data from the clinical studies adequately substantiate the use of The NGAL Test™ for diagnosing acute kidney injury. Against this background, the FDA is expected to approve the application, after which BioPorto can initiate a decisive commercial roll-out of The NGAL Test™ for clinical use in the US market, no later than second quarter of 2016.

US entry and the implementation of an aggressive strategy for growth

In the summer of 2015, BioPorto adopted an aggressive market-entry strategy aimed at laying the groundwork for the launch of The NGAL Test™ in the US once the test is approved by the FDA. The groundwork entails the setting up of a US subsidiary, which is charged with handling both sales and support for customers of The NGAL Test™ and over time assisting in the marketing of the rest of the products in the portfolio.

The first key staff members for BioPorto's US subsidiary were appointed in early 2016. In the first year, the organization will comprise 5 to 7 employees who will pursue a market strategy aimed at selected clinics and hospitals, including a number of the entities which already today are using The NGAL Test™ for research use only (RUO).

Sharp rise in the number of routine-diagnostics users of The NGAL Test™, but a hesitant European market

In 2015, BioPorto increased the number of routine-diagnostics users of The NGAL Test™ from 13 to 33. The increase primarily occurred outside Europe, particularly in South Korea, where BioPorto has used distributors to quickly set up 10 new routine-diagnostics users of the test. The increase occurred during the last half of 2015, when the test was set up for use on the new clinics' analyzers and will give rise to strong growth in sales from 2016.

On the other hand, purchases by and the influx of European routine-diagnostics users of The NGAL Test™ in 2015 did not meet our original expectations. This is due to long decision-making processes and the incentive structures within European healthcare systems, which slow the adoption of new diagnostics technology. The European roll-out of The NGAL Test™ is not expected to accelerate until the use of the test has been recognized and is widespread in the US.

Growth of ELISA-kits revenue and strengthening of the antibody portfolio

As expected, revenue generated by ELISA kits—both NGAL based and MBL based—sharply increased in 2015. The growth in sales of the NGAL ELISA kits (human) is particularly satisfying, because it indicates the generally increasing interest in and recognition of NGAL as a biomarker.

Revenues generated by antibodies grew slightly in 2015. Over the year, BioPorto enlarged its portfolio to include the inlicensed generic strip test gRAD (Generic Rapid Assay Device)—a unique testing system that enables the rapid development and use of qualitative and quantitative assays for detecting viruses, bacteria, etc., in the fields of research and veterinary medicine. At the end of 2015, BioPorto also prepared the launch of a number of new antibodies, which are expected to help grow sales of the AntibodyShop portfolio in 2016.

Distribution agreement entered into with Siemens Healthcare at the beginning of 2016

In January 2016, BioPorto and Siemens Healthcare entered into an exclusive, global distribution agreement whereby BioPorto will deliver an NGAL test adapted to selected Siemens Healthcare systems (BN II and BN ProSpec). As part of the agreement, Siemens Healthcare and BioPorto will collaborate on commercializing the adapted NGAL test as soon as it is ready for the systems. The agreement is deemed to be strategically important for the accessibility of NGAL tests and the awareness of NGAL as a diagnostic marker and it is expected to help generate revenue in the last half of 2016.

Reputable journal's acceptance of article about NGAL use constitutes important strategic milestone for BioPorto

An article written by BioPorto's European Advisory Board—under the leadership of Professor Jean-Louis Vincent, MD—about the proposed use of NGAL in clinical practice, specifically in relation to cardiovascular surgery procedures, was accepted by a distinguished US publication, The Journal of Thoracic and Cardiovascular Surgery, in February 2016. For the first time, the article equips clinical staff at intensive cardiovascular surgery units with a decision algorithm outlining the practical use of NGAL. BioPorto expects the article to be given high priority in decision-making processes, which lead to the inclusion of NGAL tests in official clinical guidelines laid down at national level in a number of countries.



Fully subscribed share issue

The financial framework for the initialization of the aggressive US strategy and for accelerating the development and marketing of new products was optimized in the last half of 2015 when BioPorto successfully implemented a fully subscribed share issue, generating total net proceeds of DKK 26.5 million.

BioPorto issued a total of 11,724,750 new shares, at DKK 1.00 each, or around 9.9% of the registered sharecapital before implementing the capital increase at a price of DKK 2.40 per share. The process, aimed at selected institutional and financial investors, was oversubscribed and closed within a short period of time.

Strengthening of and change to the organization: geared for US focus

BioPorto's Danish organization was restructured and new staff were appointed in early 2016. BioPorto's management was enlarged to include Michael Pålsson, COO, and Jakob Brix Christensen, CFO, the latter replacing the interim CFO who covered this position in 2015.

The organizational buildup of the US subsidiary commenced with the engagement of Jim Casey as Vice President of Sales and Lisa Anselmino as Senior Director of Business Development. Both executives have gained substantial sector experience at Abbott. BioPorto's CEO, Peter Mørch Eriksen, will also serve as CEO for the US company and frequently be present in the US.

Revenue growth of 9% and consolidation of the capital base

BioPorto's revenues increased by 9% to DKK 20.4 million in 2015, thereby continuing the rising revenue trend which began in 2014. Revenue is on a par with recently announced forecasts, but is lower than the management's original target. This is primarily because the revenue generated by the antibody portfolio was less than budgeted and because sales of The NGAL Test™ failed to grow as planned in Europe. On the other hand, revenue generated by NGAL Human ELISA and MBL kits grew substantially, by 50% and 22% respectively.

The operational loss (EBIT) was reduced by DKK 2.5 million in 2015 to a loss of DKK 12.8 million, despite sizable costs for clinical studies and the initial set-up of the US subsidiary in 2015. The financial result for the year was a loss of DKK 10.7 million compared to a loss of DKK 12.9 million the previous year. The loss corresponds to recently announced forecasts and is satisfactory in light of the strategic goals achieved for the year.

BioPorto's cash holdings totaled DKK 34.9 million at the end of 2015.

Strategy and objectives

Strategy

Since 2013, BioPorto's strategy has focused on commercializing the company's diagnostic portfolio. With this strategy, we have laid the groundwork for accelerating the global roll-out of The NGAL Test™ which is expected to contribute significantly to our growth from 2016. BioPorto has been working on NGAL as a biomarker for years, during the course of which NGAL has transitioned from being a single antibody for research use only and in manually demanding ELISA kits, to its current use for automated testing in hospitals' central laboratory systems where the response time has been reduced to 15 minutes. BioPorto's other biomarker—MBL for analyzing immunodeficiencies—also started out as an antibody and, in its present ELISA format, is also turning out to have prospects of steadily increasing sales over a number of years. Concurrent with this commercial focus, we are using the cornerstone of our core business—our portfolio of antibodies and our ability to develop new antibodies—to select new markers assessed as having attractive potential.

Exploiting the potential of The NGAL Test™

An essential part of the future growth of The NGAL Test™ will depend on the expected FDA approval. This is primarily because the US constitutes the largest segment of the global diagnostic-test market. The US market is followed by the European market, which has turned out to be sluggish for the implementation of NGAL tests, where an upturn is expected once the use of NGAL tests, in all probability, becomes widespread in the US. Near the end of 2015, BioPorto's targeted efforts in the South Korean market prompted a rapid increase in the number of routine-diagnostics users and sale (see the case on The NGAL Test™ in South Korea, p. 11).

BioPorto's strategy for The NGAL Test™ is based on penetrating the market for cardiovascular surgery and kidney transplants, where the use of The NGAL Test™ and an early diagnosis of acute kidney injury can make a significant difference in terms of patients' state of health and care pathways going forward. A key element of the strategy is to increase the number of routine-diagnostics users at cardiovascular and transplant centers. The scope of the business and the lessons learned from routine-diagnostics users will contribute to increasing the number of agreements with distributors and with prospective licensing and OEM partners. BioPorto is working on entering into partnerships with small analyzer suppliers who can get their products into specialized market segments relatively quickly. At the same time, BioPorto is continuing its dialog with major diagnostics players, which could eventually lead to a more widespread use of The NGAL Test™ in intensive care units where the potential is significant. In January 2016, BioPorto entered into a distribution agreement with Siemens Healthcare concerning the adaptation of the NGAL test to selected systems (BN II and BN ProSpec), constituting an important strategic step towards heightening an awareness of and increasing the accessibility of NGAL tests.

US establishment and strategy for the US market

In January 2016, BioPorto set up a US subsidiary, headquartered in Chicago, and engaged its first staff members. The new team works closely with the Danish organization to implement the strategy through action plans aimed at the US market. The points of focus for the current efforts include obtaining reimbursement for the test, pricing the test in the new market and setting up a scientific Advisory Board comprising American specialists and NGAL users.

In the near future, the US subsidiary will be enlarged to include sales reps and technical support totalling the planned 5 to 7 employees. In 2016, the team will cultivate existing customers and new prospects at 20–30 hospitals in selected geographical areas. A number of these hospitals are already using The NGAL Test™ for research use, which is why the rapid implementation of clinical use is expected once approval has been issued. BioPorto sees a number of differences in the European and US markets, including a keener interest and desire in the US to try out new diagnostic and treatment methods and a greater incentive, financially as well, to use new methods to identify risks. In addition, the US market is covered by a uniform reimbursement system as opposed to the vast array of different national reimbursement systems in Europe.

Immunodeficiency and MBL

For a number of years, BioPorto has noted a steadily increased demand for the MBL ELISA kit, which is used to diagnose immunodeficiency. For this reason, the company has chosen to exploit its position in this niche market to add more antibodies and ELISA kits, the first of which are expected to be launched in 2016. The new products are intended to give scientists and clinicians better diagnostic tools for identifying immunodeficiencies and ensure that BioPorto can consolidate its market position.

The portfolio of specialized antibodies prepares the ground for tomorrow's new biomarkers

Compared to the competition, BioPorto has fewer products in this part of its portfolio, but BioPorto's products are, on the other hand, highly specialized and unique. To increase sales of BioPorto's research products, existing sales channels are continuously being optimized, a web-shop has been set up, and unique new in-licensed and in-house-developed antibodies are being added to boost the overall portfolio and be a catalyst for higher sales. More importantly, however, the antibody portfolio is the cornerstone of the company's development activities and can serve as the basis for future biomarkers, just as it has for NGAL and MBL.

Development activities currently concentrate on two main areas: the innate immune system and Therapeutic Drug Monitoring (TDM), i.e. analyzing medicine in patient samples. In the area of the innate immune system, BioPorto is developing new ELISA kits intended to complement the company's unique MBL assay and ensuring that doctors involved in the treatment have the best possible information about the patients to optimize the treatment they provide. TDM development activities focus on antibodies of different active ingredients in drugs, as no practical methods are currently available for this purpose. Studies have shown that there is substantial optimization potential in enhancing the effectiveness of the treatments of many patients, that there are fewer side effects and that medicine costs can even be reduced.

Strategic milestones

Approval and subsequent roll-out in the US from 2016 will be a significant driver of growth for The NGAL Test™, together with the new South Korean market. On the other hand, the ongoing addressing and optimization of European markets is expected to generate some increases in sales of The NGAL Test™ in the years ahead.

The already launched ELISA-kit and antibody-portfolio initiatives are expected to increase growth and most of all foster new development opportunities. The achievement of the goals below depends on whether the FDA approves The NGAL Test™ as expected and whether the test can be launched in the US in Q2 2016. This will require the successful roll-out of The NGAL Test™ at the desired speed, which will in turn require the technology to be adopted by the healthcare system and will require BioPorto to be able to attract and retain commercially-minded employees.

Forecasts for 2016

In 2016, BioPorto expects to generate revenue of around DKK 27–30 million, equivalent to 30–50% growth. This growth must primarily be generated by significantly accelerating sales of The NGAL Test™, while the new focus of sales—aimed at the US and South Korea—creates new routine-diagnostics customers at the same time. A significant driver will therefore be the US launch which, together with the distribution agreement with Siemens and the launch of new products, is expected to prompt a sharp increase in the last half of 2016. Sales of ELISA kits and antibodies are generally expected to increase slightly.

The implementation of a significantly more aggressive strategy for growth in the US and the allocation of resources to continue the development of new products mean higher investments in our long-term growth potential at the expense of the short-term goal of becoming profitable in 2016. Accordingly, in 2016 a negative EBIT of around DKK 7–9 million, equivalent to a loss after tax of DKK 5.5–7.5 million, is expected.

Objectives	2016	2017 onwards
Primary	<ul style="list-style-type: none"> » FDA approval of NGAL » US roll-out of The NGAL Test™ in Q2 2016 and implementation at 20 hospitals. » Establishment of advisory board in the US » Continued growth of NGAL in South Korea and moderate growth on the European market » White paper on clinical use of NGAL ✓ 	<ul style="list-style-type: none"> » Double the number of hospitals in the US that have implemented NGAL by 2017 » Continuously enlarge NGAL's sphere of use » NGAL sales through major analyzer suppliers (licensing/OEM)
Secondary	<ul style="list-style-type: none"> » Launch of new immunodeficiency ELISA kits » Enlarge the antibody portfolio » Negotiation of new licensing and OEM agreements 	<ul style="list-style-type: none"> » Continue to enlarge the antibody and ELISA portfolio » Add new products/technologies » Negotiation of new licensing and OEM agreements
Growth	<ul style="list-style-type: none"> » 30–50% revenue growth 	<ul style="list-style-type: none"> » Maintain high rates of growth

Our products and markets

BioPorto develops and markets in vitro diagnostic (IVD) assays. IVD procedures take place outside the body, e.g. by analyzing blood and urine samples in a laboratory, as opposed to *in vivo* diagnostics which are performed on the patient, such as a prick test in the skin or an x-ray. IVD are important sources of information for doctors in diagnosing disorders, prescribing treatment and monitoring a patient's response to treatment.

The products are also used to provide scientists with a better understanding of the causes of a specific disease and to develop new treatment regimes and medicine.

RUO products

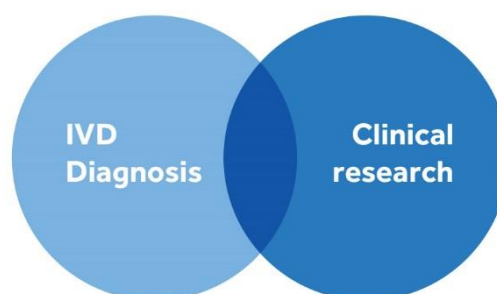
 **ANTIBODYSHOP®** Monoclonal antibodies & Animal NGAL ELISA kits



Customers: Pharmaceutical and biotech, universities and CRO's

IVD products

 **The NGAL Test** MBL ELISA kit & Human NGAL ELISA kit



Customers: Hospitals, clinical institutions and research centers

BioPorto's product pipeline consists of highly specialised and unique monoclonal antibodies and antibody-based diagnostic tests. Depending on the format and scope of use, the products are intended for diagnostics, clinical research and basic research. The overall objective of the portfolio is to help in the treatment of the critically ill patient.

Product portfolio

The NGAL Test™

Every year, over 13 million people¹ are affected by acute kidney injury, of whom about a fourth die². In spite of this statistic, developments in kidney-injury diagnostics have been dormant for the past fifty years. Currently available methods such as serum creatinine determination only signal kidney failure 48-72 hours³ after the injury has occurred. By contrast, NGAL rises to diagnostic levels within two hours of kidney injury, thus allowing the physician to make vital clinical decisions before the damage progresses to potentially fatal renal failure. The test makes it possible to

remedy kidney injury, and cost-benefit analyses have also shown that implementing NGAL testing will contribute to reducing hospital costs involved in treating kidney injury patients.

The use of The NGAL Test™ as an early biomarker of acute kidney injury offers several benefits for patients, healthcare professionals and the healthcare system as such worldwide⁴. These benefits include:

- » Usage may save patient lives because healthcare professionals can more quickly make medical decisions that may help prevent the development of acute kidney injury in a patient.
- » Usage may reduce the length of hospitalization and reduce the risk of patients requiring dialysis. This would reduce hospital costs for treating renal dysfunction.
- » Usage may improve patient quality of life by reducing the risk of developing acute kidney injury and subsequently potential fatal renal failure.

¹ Hoste, 2008, Critical Care Med.

² Susantitaphong, 2013, Clin J Am Soc Nephrol

³ Wagener, 2008 + Bennet, 2008

⁴ Shaw, 2011, Clinical Therapeutics

The NGAL Test™ in South Korea

Case

In recent years, BioPorto has focused on building up the European market for The NGAL Test™ and, at the same time, has prepared for the official approval and launch in the US. In South Korea, however, there turns out to be significant interest in NGAL tests, an interest that is initially being stimulated by market cultivation by competing NGAL tests. In the light of this interest, BioPorto has allocated resources aimed at intensifying efforts in the South Korean market in collaboration with local distributors. Initially, these efforts led to the registration of the test in the spring of 2015, followed by rapid results, as The NGAL Test™ had been implemented by 10 hospitals by the end of the year. A number of hospitals have received the test for trials, and the test has been implemented at several of these hospitals on an ongoing basis in the first months of 2016. Naturally, implementation has been aided by the fact that most hospitals are familiar with NGAL and are already using the test for early diagnosis of acute kidney injury. At the same time, it turns out that the health administration system is much more interested in trying out new diagnostic tests than we have seen in the European market, for instance. Finally, this underscores that, with the right distributors, BioPorto can respond quickly and deploy additional resources when favorable trends appear in a market. In the time ahead, BioPorto will continue its efforts to have The NGAL Test™ implemented at more South Korean hospitals and at the same time attempt to get information on the way in which and how frequently the test is being used. This will provide useful input for sales efforts going forward and also provide a basis for trying to widen the use at the hospitals concerned.



The NGAL Test™ is a particle-enhanced turbidimetric immunoassay designed for use on most clinical chemical analysers. The test can measure NGAL in plasma or urine and does not limit the user to a particular kind of instrument. The vast majority of hospitals in the western world have one or several analysers in their central laboratories, that The NGAL Test™ can be implemented on. The NGAL Test™ is relevant for several specialist areas in any hospital—including kidney, cardiology, anaesthesiology, urology, neurology and intensive care units.

The NGAL Test™ is able to measure NGAL in both urine and in plasma, while competing assays from Abbott Diagnostics and Alere, which was recently acquired by Abbott, measure NGAL in either urine or plasma, but not in both. Abbott Diagnostics markets its NGAL test on their Abbott Architect analyser, while Alere markets its NGAL test on Alere Triage Point of Care analysers. In this area, The NGAL Test™ differs notably from the competing tests in that The NGAL Test™ is approved for use on the major analysers from the principal players in the diagnostics industry. In 2014, BioPorto entered an agreement with Abbott on cross-license to both parties' respective IP rights within the NGAL area. Neither Abbott nor Alere have FDA approved NGAL tests.

BioPorto's strategy for The NGAL Test™ builds on penetrating three medical segments: Cardiac bypass surgery, kidney transplantation and intensive care units. The segments represent a large unexploited market potential that BioPorto intends to address through own sales channels, local distributors and through license- and distribution agreements.

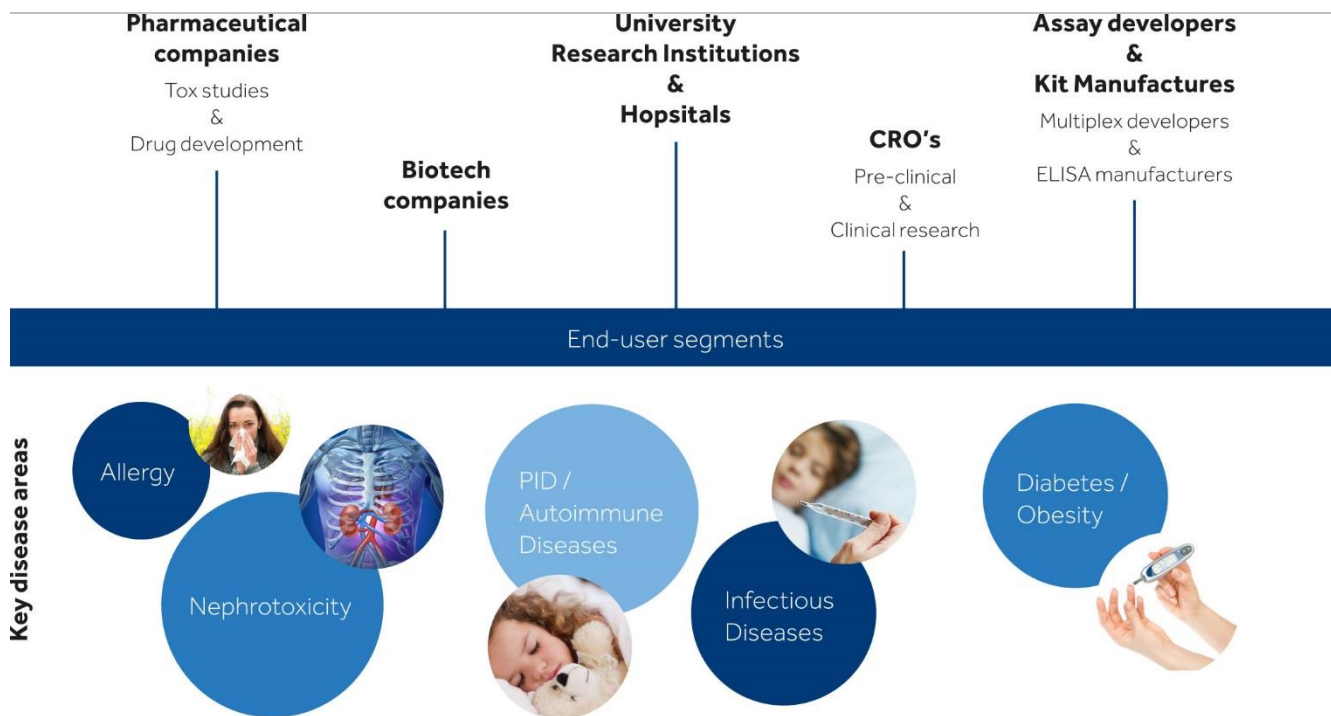
NGAL ELISA kits

As a complement to and in some cases the forerunner of The NGAL Test™, BioPorto markets an NGAL ELISA kit for human use. There is a widespread use in research and, to some extent for clinical use. Another important use of NGAL is in the pharmaceutical industry (clinical trials), where NGAL is used in drug development for estimating a specific compound's adverse renal effects (nephrotoxicity). BioPorto provides NGAL ELISA kits for all five animal models used for drug discovery purposes and NGAL ELISA kits for human use.

MBL ELISA kits

Mannose-binding lectin (MBL) is an important molecule in the innate immune system. MBL deficiency can effect the patients ability to combat a foreign organism such as virus or bacteria. As much as 12% of the population in the western world suffer from full or partial MBL deficiency. In some cases, children from the age of 0 to 2 years can be affected by MBL deficiency, presenting as recurrent serious or unusual infections. MBL deficiency may cause problems for organ transplant patients, patients with cystic fibrosis and persons suffering from other genetic immunodeficiencies. BioPorto's MBL ELISA kit is based on the most widely used monoclonal MBL antibodies, which have been described in a wide range of scientific articles. BioPorto is the only vendor of this specific assay, and the MBL ELISA kit has been the "gold standard" for quantitative measurement of MBL levels since 2002.

Key end user segments for ELISA kits and antibodies



Antibodies

AntibodyShop is the trademark for BioPorto's pipeline of antibodies. This unique and highly specific pipeline primarily comprises monoclonal antibodies (about 300 all told), spanning a number of different research disciplines such as microbiology, biomarkers, peptide hormones and plasma proteins. The pipeline is continuously expanded in order to grow the added sales potential from the existing sales platform and provide the basis for the company's own development of new biomarkers.

One of the unique group of antibodies BioPorto offers is a pipeline of antibodies targeting peptide hormones, including GLP-1 (glucagon-like peptide-1), which is crucial to the development of a new generation of products for treating Type II diabetes and obesity. In 2015, BioPorto launched a number of antibodies and also licensed gRAD, which is a unique generic test platform for use with antibodies.

The competitive environment for the different products in BioPorto's antibody pipeline varies significantly. There is only limited competition for certain research reagents, because similar products are unavailable or there are no alternative methods for conducting the analyses. Other antibodies are available from other vendors, and are therefore exposed to more competition. BioPorto however, has a competitive advantage in providing high quality, as the quality of antibodies varies considerably among providers.

Distribution and OEM

With the establishment of a subsidiary in the US, BioPorto will be pursuing a two-tiered distribution strategy for The NGAL Test™ going forward. After obtaining FDA approval, sales efforts in the US will be conducted directly by BioPorto's sales team. In Europe and the rest of the world, sales will be carried out by distributors, as previously. The distribution agreement entered into with Siemens in early 2016 is a strategically important supplement in the proliferation of NGAL. BioPorto is engaged in ongoing dialog to enter into more agreements of this type, as well as more licensing agreements, to ensure that the roll-out of NGAL tests is as broad and as fast as possible.

ELISA kits, antibodies and research reagents are typically sold through online-based vendors, and BioPorto has entered into long-term distribution agreements with some of the most influential distributors. Together with BioPorto's own web-shop, this provides a strong global distribution network with customers in Europe, the US and Asia. In conjunction with the set-up of the US subsidiary, BioPorto is launching a US web-shop to supplement the existing international web-shop. This will make it easier for American customers to buy the company's products. Whether a purchase is made through a US or foreign web-shop could make a difference, especially for research institutions. Together with BioPorto's own web-shop, this establishes a strong global distribution network with customers in Europe, the US and Asia.

CSA-NGAL score

A potential tool to monitor acute tubular damage

The Cardiac Surgery-Associated NGAL score - as presented in a new article by an expert group. Chaired by Dr. Jean-Louis Vincent¹.

CSA-AKI incidence and interventions

Cardiac surgery-associated acute kidney injury (CSA-AKI) is a serious postoperative complication and is the second most common cause of AKI in the ICU. The success of interventions aimed to reduce CSA-AKI

incidence and its related outcome depends on the best time to apply them, which is the very early stage of AKI.

The authors introduce the use of NGAL as the biomarker to use in a new definition for acute tubular damage (the Cardiac Surgery Associated NGAL Score (CSA-NGAL score)) in order to further complement the functional diagnosis of AKI².

Cardiac Surgery-associated (CSA) acute kidney tubular damage - Plasma samples

Concentration Sample (ng/mL)	Delta (Δ) NGAL At following measurements	CSA-NGAL SCORE
pNGAL <100		0 Tubular damage unlikely
pNGAL 100 - <200		1 Tubular damage possible
pNGAL 200 - <1000 or Δ >100 + second value ≥150		2 Tubular damage
pNGAL >1000		3 Severe tubular damage

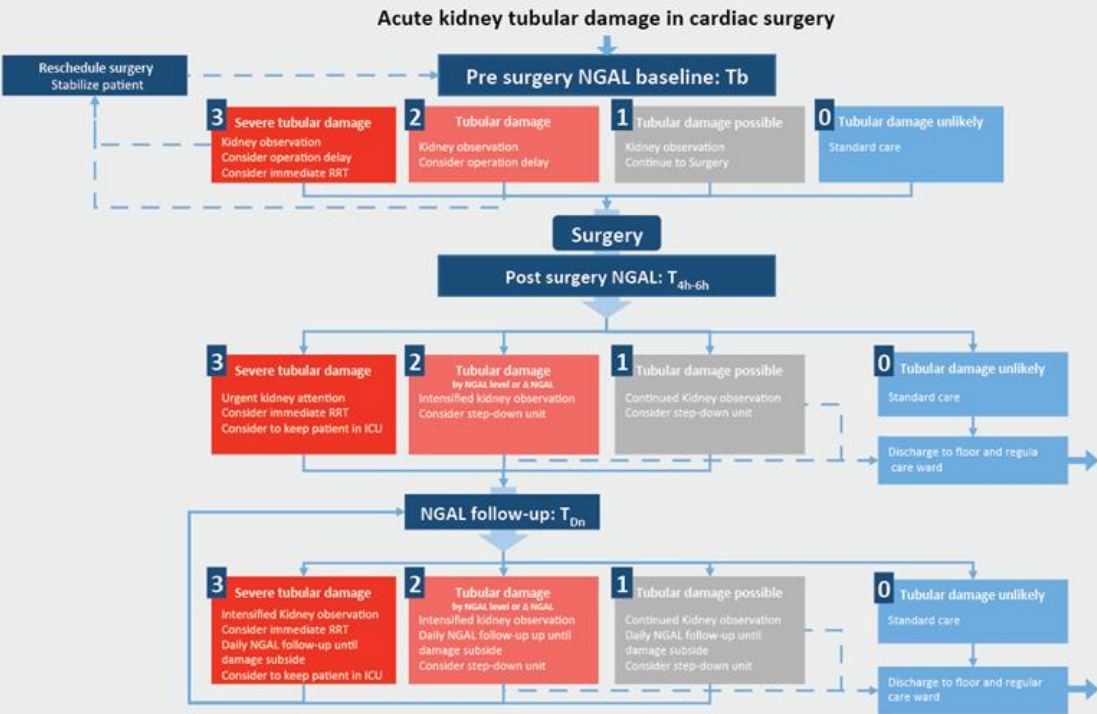
Sample timing

- T_b Pre surgery baseline, <24 hours prior to surgery
- T_{4h-6h} Post surgery 4-6 hours post surgery or at admission to ICU
- T_{Dn} NGAL Follow-up T_{D1} Day 1 post surgery, every 24 hours until damage has subsided Day post surgery

NGAL samples

- urine NGAL (uNGAL), spot urine sample
- or
- plasma NGAL (pNGAL) Heparin or EDTA plasma

CSA-NGAL Score based decision algorithm



1. de Geus HR, Ronco C, Haase M, Jacob L, Lewington A, Vincent J-L, The cardiac surgery-associated NGAL score: a potential tool to monitor acute tubular damage, The Journal of Thoracic and Cardiovascular Surgery (2016), doi: 10.1016/j.jtcvs.2016.01.037

2. Uchino S, Kellum JA, Bellomo R, et al. Acute renal failure in critically ill patients: a 269 multinational, multicenter study. JAMA. 2005;294:813-818

Intellectual property rights

BioPorto's NGAL IP rights portfolio is an important asset for optimization of the future market share of the NGAL market, and consists of the following patents:

- » The NGAL cut-off patent, which describes the cut-off of 250 ng/mL or higher that can be used for diagnosing acute kidney injury.
- » The NGAL exclusion patent, which is complementary to the cut-off patent and concerns lower NGAL levels which rule out an immediate risk of kidney injury.
- » 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 diseases characterised by different increases in the levels of these forms, including acute kidney injury.
- » The NGAL ratio patent, which involves the use of a ratio between NGAL concentrations in urine and plasma for increasing the diagnostic specificity and sensitivity to acute kidney injury. The method complements 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 to assess the severity of physical traumas. The patent represents a significant protection of the company's rights within the use of NGAL in the expanding European POC market, including NGAL measurements in emergency rooms, trauma centers and potentially in ambulances.

BioPorto patents	EU	USA	ROW
NGAL Cutoff-patent	Application filed	Application filed	Issued in Australia, Hongkong, India, Japan, China, and Singapore. South Korea (opposition filed). Application filed in Canada
NGAL Eksklusions-patent	Issued – opposition filed	Application filed	
NGAL Ratio-patent	Issued	Issued	
NGAL Traume-patent	Issued	Application filed	
NGAL Former-patent	Issued – opposition filed	Application filed	

Licensing access to BioPorto's IP rights

In 2014, BioPorto signed a licensing agreement with Abbott concerning a cross license for both parties' respective IP rights within the NGAL area. All licenses are granted on a non-exclusive basis and cover all NGAL-related IP rights controlled directly or indirectly by the parties—including sub-licenses granted by Phadia and Cincinnati Children's Hospital. In 2011, BioPorto entered into a non-exclusive licensing agreement with Instrumentation Laboratory concerning access to BioPorto's NGAL IP rights.

Registration

In order for a diagnostic product to be marketed, it 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. The company's humane NGAL and MBL ELISA kits are also registered in a number of countries including the European countries, Canada, and India

FDA approval expected in 2016

BioPorto submitted a 510(k) application to the FDA in September and, based on dialog and recommendations from the FDA, a new application was submitted a few weeks later under the De Novo classification. In the

first application, BioPorto had anticipated that The NGAL Test™ was sufficiently similar to another kidney injury marker that the approval of The NGAL Test™ could be based on a comparison with it. However, The NGAL Test™ distinguishes itself from other products in the market, which the company considers to be a commercial advantage, and The NGAL Test™ must therefore be approved as a new class of test. As anticipated, BioPorto received a number of questions from the FDA and will be submitting the answers to them in March 2016. The efforts to reply to these questions have primarily involved additional trials and the processing of the comprehensive statistical material from the clinical study. The company will be awaiting a response from the FDA concerning the ensuing process, and we will be ready for launch once the expected approval is received.

The NGAL Test™ registrations around the world



Reimbursement

Diagnostic assays are often eligible for financial reimbursement via public healthcare systems or private health insurance. The NGAL Test™ can be marketed and sold without qualifying for such reimbursement, but reimbursement is an incentive for the implementation if an immunoassay is to become a widely-used routine marker. However, a significant hurdle in respect of qualifying for reimbursement is that the use of NGAL remains limited, and the economic benefits of implementing the test are therefore currently undocumented. As part of ongoing and future trials, BioPorto will also work to ensure that financial data are collected for conducting cost-benefit analyses. Similarly, the preparation of clinical guidelines for the use of NGAL is a contributory factor in terms of qualifying for reimbursement.

Financial review

Revenue and the financial result for the year on a par with expectations

In 2015 BioPorto generated revenue of DKK 20.4 million, equivalent to 9% growth compared to 2014. This is on a par with recently announced forecasts, but lower than the management's original target. Revenue generated by The NGAL Test™ grew by 56% in 2015, and revenue generated by NGAL ELISA (humand and animal) and MBL kits also grew substantially, by 18% and 22% respectively. Antibodies saw moderate growth of 4%, whereas earnings from other products and licenses fell by 48% in 2015.

The operating loss before interest and tax (EBIT) ended up being DKK 12.8 million, which is DKK 2.5 million better than in 2014, in spite of higher R&D investments and costs relating to setting up a subsidiary in the US market.

The loss for the year after tax was DKK 10.7 million. This is on a par with the anticipated loss of DKK 11 million, and DKK 2.2 million better than in 2014.

	Expectations in the Annual Report 2014	Updated expectations, Interim financial report Q3 2015	Realised 2015
Revenue	DKK 22-25 million	DKK 21-22 million	DKK 20.4 million
EBIT	Loss of DKK 10 to 12 million	Loss of DKK 13 million	Loss of DKK 12.8 million
Profit/loss for the year	Loss of DKK 8 to 10 million	Loss of DKK 11 million	Loss of DKK 10,7 million

Figure 1. Revenue (DKKkm)

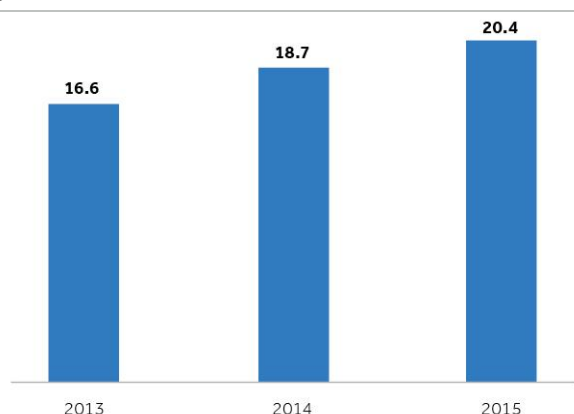
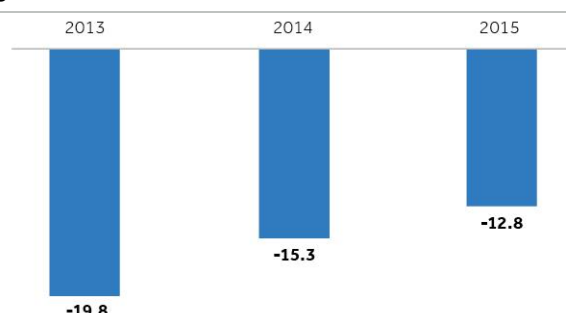


Figure 2. EBIT (DKKkm)



Profit and loss statement

Revenues

BioPorto's revenue in Q4 2015 amounted to DKK 5.8 million compared to DKK 4.9 million last year (+18%). In spite of favorable revenue from ELISA kits and The NGAL Test™, the quarterly revenues were less than originally forecast. This is because antibody sales did not meet expectations.

For the 2015 financial year, revenue totaled DKK 20.4 million, equivalent to 9% growth compared to 2014. The NGAL product portfolio generated revenue of DKK 7.2 million in 2015 compared to DKK 5.3 million in 2014. Of this amount, revenue generated by The NGAL Test™ amounted to DKK 3.7 million compared to DKK 2.4 million the previous year. ELISA MBL kits generated revenue of DKK 2.5 million, equivalent to a 22% increase. Revenue generated by antibodies increased by 4% to DKK 9.5 million, whereas earnings from other products and licenses fell by 48% to DKK 1.1 million in 2015

Figure 3. Revenue by quarter (DKKkm)

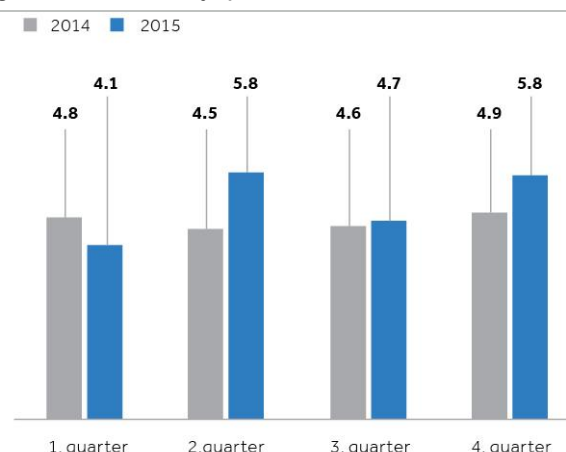
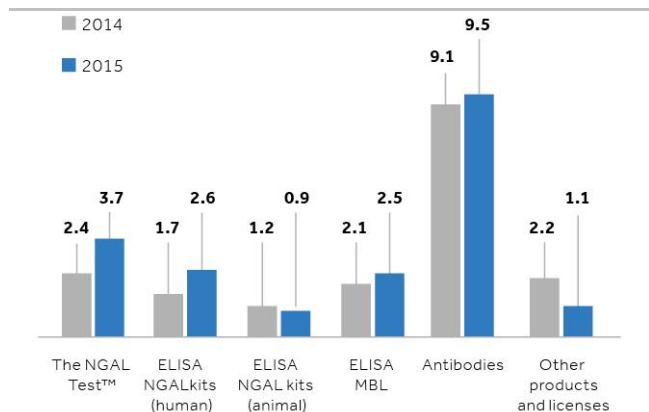


Figure 4. Revenue broken down by product category (DKKm)

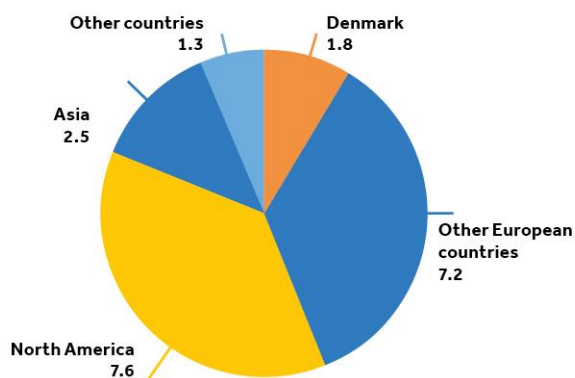


BioPorto's revenue generated in Europe increased by 15% in 2015. By contrast, revenue generated in North America fell 11% due to lower antibody sales and reduced licensing income. These two main markets together generated 81% of the revenue. Asia and other countries increased by 60% to DKK 3.8 million, primarily due to higher NGAL sales in Asia.

Gross profit/loss

Production costs totaled DKK 4.9 million in 2015, equivalent to a gross margin of 76% compared to last year's 71%. The gross-margin increase is due to higher efficiency in the production process which lowered wage costs.

Figure 5. Geographic break down, 2015 (DKKm)



Operating costs and operating results

Capacity costs totaled DKK 28.2 million, which is DKK 0.3 million lower than in 2014. As planned, R&D costs increased from DKK 8.6 million to DKK 9.9 million in 2015. The increase is due to costs relating to the completion of clinical studies and the submission of an FDA registration application for The NGAL Test™ totaling DKK 4.0 million, offset by lower patent and consultancy costs. Sales and marketing costs amounted to DKK 8.9 million compared to DKK 9.4 million in 2014. The decline in sales and marketing costs is attributable to lower licensing and traveling expenditure. Compared to 2014, administration expenditure was reduced by DKK 1.0 million to DKK 9.4 million, primarily as a result of lower wage costs.

After this, the operating profit/loss before interest and tax (EBIT) amounted to DKK -12.8 million, which is an improvement of DKK 2.5 million compared to last year.

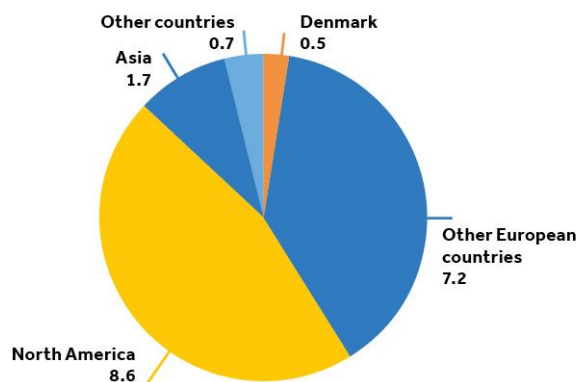
Financial items

Net financial items amounted to an expenditure of DKK 0.3 million in 2015 compared to a net income of DKK 0.2 million in 2014. The expenditure is primarily attributable to interest and fees concerning repayment of a tax credit for 2012.

Profit/loss for the year

BioPorto's financial result before tax was a loss of DKK 13.0 million in 2015, an improvement of DKK 2.1 million compared to 2014. The loss after tax was DKK 10.7 million compared to a loss of DKK 12.9 in 2014.

Figure 6. Geographic break down, 2014 (DKKm)



Balance sheet

At the end of 2015, BioPorto's balance sheet totaled DKK 49.0 million, compared to DKK 37.2 million last year.

Assets

After limited investment, non-current assets amounted to DKK 1.7 million as at December 31, 2015. The investments comprised inlicensed rights for new antibody cell lines from Statens Serum Institut and the development of a new US web-shop to supplement the existing international web-shop.

Inventories amounted to DKK 4.0 million at the end of 2015, which is identical to the amount at the end of 2014.

Receivables from sales were DKK 4.0 million as at December 31, 2015 compared to DKK 3.3 million as at December 31, 2014. The increase in receivables is primarily the result of higher sales in 4th quarter in 2015 compared to the previous year.

The cash position were DKK 34.9 million at the end of 2015, which is DKK 9.4 higher than at the end of 2014. The increase in cash is primarily attributable to the issue of new shares in August 2015, which generated net proceeds totaling DKK 26.5 million.

Equity

At the end of 2015, equity amounted to DKK 44.5 million compared to DKK 28.7 million in 2014. A direct share issue was carried out in 2015, where a total of 11,724,750 new shares at DKK 1.00 each were offered at a price of DKK 2.40 per share.

Liabilities

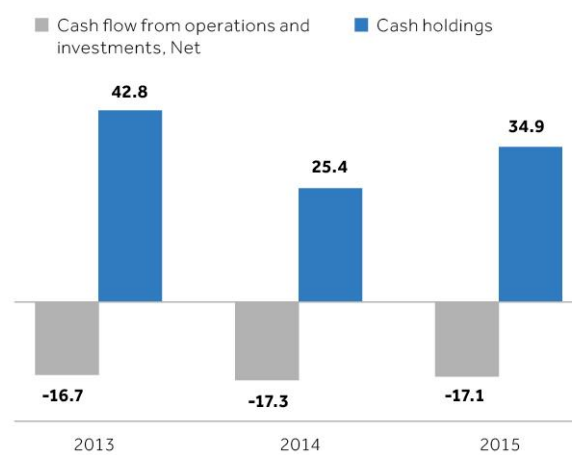
As at December 31, 2015, BioPorto's liabilities totaled DKK 4.5 million compared to DKK 8.6 million at the end of 2014. Basically, the liabilities comprised short-term payables, provisions for salary and holiday-leave pay; and other accrued expenses. The difference between the end of 2014 and the end of 2015 is primarily due to a reduction of other payables.

BioPorto had no bank debt on the balance sheet date.

Cash flow statement

Cash flows generated by operating activity were DKK -16.6 million in 2015 (2014: DKK -16.1 million) and the net investments for the year amounted to DKK 0.5 million. Cash flows generated by financing activities were DKK 26.5 million resulting from the share issue. The cash flow for the year ended up at DKK 9.4 million compared to DKK -17.4 million in 2014.

Figure 7. Cash flows and Cash holdings (DKKm)



Liquid assets and capital resources

As at December 31, 2015, BioPorto's cash holdings amounted to DKK 34.9 million. Thus, the cash resources are sufficient for supporting BioPorto's organic-growth strategy which, in the long term, is expected to strengthen the equity through increasing 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 debt/equity ratio.

Events after the end of the period

The board and management are not aware of any 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.

Risk factors and risk 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 its operations in the event these risks are not correctly assessed and managed. BioPorto's policy is to identify and mitigate risks deriving from the Group's operations and to establish adequate insurance coverage. BioPorto has established risk management as a formalised process for the purpose of generating a close correlation between the Group's ongoing objectives and activities and the individual risk elements of the Group's sphere of activity. In connection with the new corporate strategy, Management has specifically addressed risks relating to new objectives.

Commercial and developmental risks

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

BioPorto seeks to manage these commercial risks by continuously monitoring and assessing market conditions and patent positions. The success of new diagnostic products and methods relies on acceptance of our products in research environments and subsequently by the healthcare system. BioPorto expends significant resources on generating awareness of new biomarkers, supporting clinical trials and establishing partnerships with a view to commercialising the products. BioPorto's competitive strength is also ensured by continuously obtaining, enlarging and upholding patent rights within the established areas of focus.

Key short-term risks include:

- » Any revised requirements from the FDA during the application process could mean that FDA approval may not be obtained in time for launch in the second quarter of 2016 as otherwise planned. This would significantly delay the US product launch.
- » That the company fails to establish the required number of routine-diagnostic users in the main markets USA, Europe and Asia and that the roll-out of The NGAL Test™ is not taking place at the required speed.
- » That competing technologies and/or IP uncertainties adversely affect the market launch of NGAL.

HR risks

BioPorto relies on its ability to attract and retain skilled employees in order to create new product opportunities, maintain the Group's competitive strength and ensure growth and results. BioPorto offers its employees opportunities for professional development, remuneration and incentive schemes at market levels, but also makes an active effort to create a positive working environment where everyone is respected for their contribution.

Production risks and quality risks

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

Currency risks and other financial risks

As the group exports its products to a number of different markets, it is exposed to fluctuating exchange rates, especially for EUR and USD. Revenue is still so modest that financial instruments are not used to hedge these risks. That may change in the coming years as BioPorto's focus on the US market translates into an increased exposure to the US dollar. 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 considered to be modest. Prepayment of deliveries may be required of new customers. Otherwise, the Group does not use any form of hedges against credit risk.

Internal controls and risk management in relation to the financial reporting process

The primary responsibility for the Group's risk management and internal controls in relation to the financial reporting process rests with the Board of Directors and the Management Board. BioPorto's policy is to identify and mitigate risks deriving from the Group's operations and to establish sufficient insurance coverage. The Group's control and risk management systems may provide reasonable, but not absolute, assurance that misappropriation of assets, losses and/or significant errors and omissions in the financial reporting are avoided.

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

The Group's internal controls and risk management in relation to the financial reporting process is available on the company's website in accordance with the Danish Financial Statement Act § 107b <http://www.bioporto.com/Admin/Public/DWSDownload.aspx?File=%2fFiles%2fFiles%2finvestor%2fCompany-Documents%2fRisk-Management-2015.pdf>

Corporate governance

In its management process, BioPorto is focused on investor relations, and the Board of Directors gives priority to exercising sound corporate governance, which is defined on the basis of the company's articles of association, values and policies as well as relevant legislation and Nasdaq Copenhagen A/S' "Rules for Issuers of Shares".

Corporate governance recommendations

BioPorto is subject to the recommendations prepared by the Committee on Corporate Governance, which are available at www.corporategovernance.dk.

The Board of Directors regularly assesses how the recommendations may contribute to strengthening the management of BioPorto and ensure maximum value creation for the company's shareholders. Once a year, the Board of Directors reviews the recommendations, evaluating BioPorto's degree of compliance. The Board of Directors believes that BioPorto complies with all of the recommendations of the Committee.

A report on the company's compliance with the corporate governance recommendations is available at the company's website in accordance with the Danish Financial Statement Act §107b: <http://www.bioporto.com/Admin/Public/DWSDownload.aspx?File=%2fFiles%2fFiles%2finvestor%2fCompany-Documents%2f2015-Corporate-Governance-English.pdf>.

Work of the Board of Directors and the Management Board

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

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

The duties of the Board of Directors are described in the rules of procedure for the Board of Directors and the Management Board. The Board held seven board meetings in 2015, including one lengthy strategy meeting and two conference calls. Six meetings are planned for 2016 in accordance with the Board's annual schedule, which obviously can be changed at any time to allow for additional meetings, if the need arises.

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

The chairman of the Board is responsible for evaluating the Board of Directors and the Management Board every year. The evaluation also includes the collaboration with the Management Board and the composition

and special qualifications of the Board of Directors, and it must produce an assessment of the results achieved during the year, which are subsequently presented and discussed at a board meeting.

Composition of the Board of Directors

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

The members elected by the shareholders hold office for terms of one year at a time. Only persons who have not attained the age of 70 at the time of election are eligible for election to the Board of Directors.

The members of the Board are nominated and stand for election on the basis of their specific qualifications and experience of relevance to BioPorto. Thus, the Board is composed with a view to ensuring an optimum combination of professional industry experience in general, in research and development, in IP rights and conclusion of contracts, in sales and marketing, as well as in finance and economics. All current board members are considered independent. Each board member's special qualifications can be seen on the company's website: <http://www.bioporto.com/About-Us/Board-of-directors.aspx>

Board committees

BioPorto's Board of Directors has set up a remuneration committee, a nomination committee and an audit committee as well as other ad hoc committees. The vice chairman of the Board of Directors is chairman of the audit committee and possesses the necessary professional qualifications and experience. A review of the terms of reference of the board committees and their composition is available on the company's website <http://www.bioporto.com/Admin/Public/DWSDownload.aspx?File=%2fFiles%2fFiles%2finvestor%2fCompany-Documents%2fBoard-committees-2015.pdf>

Amendments to the articles of association

The shareholders adopt any amendments to the articles of association and make any other decisions based on a simple majority of votes unless a special majority or representation is stipulated by the Danish Companies Act or the company's articles of association.

Remuneration policy

The basic fee paid to board members is fixed at a level assessed as being competitive and reasonable compared to the industry in general and the company's current situation. Members of the Board receive a fixed annual fee, with the chairman and vice chairman being eligible for a higher fee as directed by the shareholders. If committees are set up or if board members are asked to perform special tasks for the Board, the Board may recommend to the general meeting that an additional fee be paid for such duties. The Board may recommend to the general meeting that alternates also receive a fee. Each year, the general meeting approves the remuneration to the board members and any remuneration to alternates for the current financial year in connection with the approval of the annual report. The members of the Board of Directors do not participate in the company's share option programmes.

The annual directors' fees amounted to DKK 150,000 in 2015, with the vice chairman receiving 2.33 times the basic fee (DKK 350,000) and the chairman receiving 3.33 times the basic fee (DKK 500,000). Participation in committees may be remunerated with an additional fee of DKK 25,000.

per committee, with a maximum of DKK 50,000 per. Non-executive boards-member. The Chairman and Deputy Chairman do not receive additional fees for participation in committees.

The remuneration of the Management Board is fixed at a level assessed as being competitive and reasonable compared to the industry in general and the company's current situation. Members of the Management Board do not receive any remuneration for directorships held in BioPorto A/S' subsidiary.

The remuneration consists of a fixed salary, pension scheme, annual bonus and participation in share option programmes. The Board of Directors believes that a combination of fixed and performance-based pay to the Management Board helps ensure that the Management Board is given an incentive to create shareholder value through remuneration that is partly incentive-based.

The annual bonus may not exceed an amount corresponding to 100% of the fixed salary. In extraordinary circumstances, the annual bonus may amount to 200% of the fixed salary if the Board of Directors finds that to be appropriate. Retention bonuses, loyalty bonuses or the like may also be applied. Any payment of bonus depends on whether the conditions and targets defined in the bonus agreement have been fully or partly met. These may be personal targets related to the performance of the individual member of the Management Board, the performance of BioPorto A/S or the occurrence of a specific event.

In the beginning of 2015, the Management Board consisted of two persons. Since February 1, 2015, the Management Board consisted of just one person, the company's CEO. In 2015, the Management Board received salaries of DKK 2,6 million, inclusive of pension (defined contribution scheme) and bonus. The company has not assumed any obligation to disburse severance pay to members of the Management Board at the time of severance of service. The employment relationship can be terminated by the company giving 12 months' notice to the end of a month. No special severance terms have been agreed in case of a change of control.

BioPorto's remuneration policy is available on the company's website <http://www.bioporto.com/Admin/Public/DWSDownload.aspx?File=%2fFiles%2fFiles%2finvestor%2fCompany-Documents%2fRemuneration-policy.pdf>

Diversity in the Board of Directors

BioPorto seeks diversity in the composition of the Board with a reasonable age composition, in terms of nationalities and an equal gender distribution. BioPorto has defined a target that, by 2018, at least two out of four members of the Board of Directors must belong to the under-represented gender. The target is in accordance with the Danish Financial Statement Act § 99b. However, this target must not rank prior to the other competency requirements in the nomination of board candidates.

The Board of Directors currently consists of four male members, as an additional member was elected at the AGM in 2015. The nomination committee has a clear policy for evaluating candidates of both genders for vacant board positions, and for the election in 2015 a male candidate was found to honor the competency requirements. For future vacancies in the Board, the nomination committee will continue to evaluate candidates of both genders

Diversity in other management levels

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

The company pursues a policy of providing equal opportunities for both genders. For a number of years, the company has had and still has an equal number of men and women in managerial positions, demonstrating compliance with this policy in practice

Social responsibility

BioPorto is aware of its corporate social responsibility and endeavours to improve social and environmental conditions. BioPorto has signed up to the UN Global Compact, and the latest *Communication on Progress*, which also constitutes the Group's report on corporate social responsibility, is available on the company's website in accordance with the Danish Financial Statement Act § 99a <http://www.bioporto.com/Admin/Public/DWSDownload.aspx?File=%2fFiles%2fFiles%2finvestor%2fCompany-Documents%2fCOP-for-2015-English.pdf>

Investor relations

Investor relations

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

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

To ensure efficient and expedient communication with our shareholders, BioPorto encourages its shareholders to have their shares registered in the company's register of shareholders and to participate in general meetings. The IR Department is also responsible for ensuring that information from the Group's IR stakeholders is passed on to the Management.

For more investor information about BioPorto please see the company's website www.bioporto.com.

The BioPorto share

ISIN code, share capital and share price performance

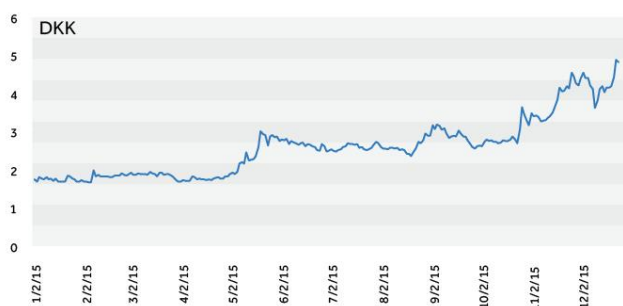
The share capital of BioPorto amounts to DKK 129,598,960 nominal value, divided into 129,598,960 shares with a nominal value of DKK 1 each, equivalent to 129,598,960 votes.

BioPorto A/S' shares are listed on Nasdaq Copenhagen A/S under the symbol "BIOPOR". The ISIN code is DK0011048619. BioPorto's market capitalisation at the end of 2015 was DKK 625 million (1 January 2015: DKK 199 million). The price of the BioPorto share closed at DKK 4.82 on 30 December 2015 and increased by 285% during the financial year. Total turnover in the share in 2015 was DKK 424 million, corresponding to an average daily turnover of DKK 1,7 million and a daily volume of 610,570 shares.

Capital increase

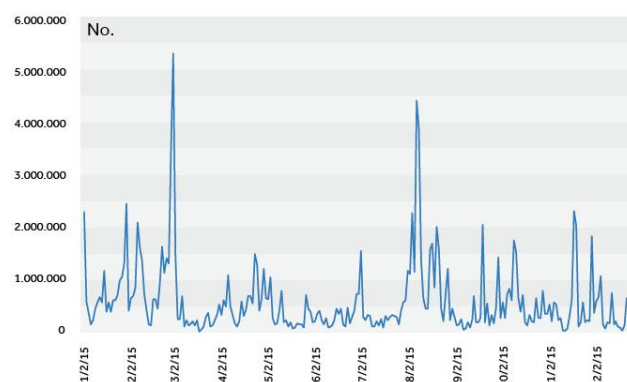
On August 31, 2015, The Board of Directors for BioPorto A/S decided to partially exercise the authorization in the Articles of Association § 16b to make a direct share issue to a limited number of institutional and financial investors. Following completion of the offering, BioPorto A/S' share capital was increased by nominally DKK 11,724,750 and amounts to nominally DKK 129,598,960. The subscription price of DKK 2.40 was calculated as the share-weighted average price on the Nasdaq Copenhagen over the past 10 trading days prior to August 31, 2015. The issue resulted in gross proceeds of DKK 28.1 million. The new shares corresponded to 9.9% of BioPorto's registered share capital before the capital increase.

Figure 8. Closing price



The chart does not reflect the capital increase

Figure 9. Volume



Ownership

As of 31 December 2015 BioPorto had 5,611 registered shareholders, who held a total of 80.67 % of the share capital.

As of 31 December 2015 the following shareholders had announced that they hold 5% or more of the company's shares/voting rights:

Jan Leth Christensen	10.1%
Through companies in which he has control:	
EG Kapital ApS, Vedbæk	
Jano Div ApS, København	
Ejendomsselskabet Jano ApS, København	
Media-Invest Danmark A/S, København	9.9%
Nordben Life and Pension Insurance Co. Limited, Guernsey	5.5%

Warrant programme

In order to create an incentive for the current employees to remain with and actively work for the company and also to be able to attract new employees, the Board of Directors established a warrant programme in 2011. At the end of the financial year, a total of 214,500 warrants remained outstanding, which amounted to 0.2% of the current nominal share capital.

Dividend policy

BioPorto pursues the policy that shareholders should receive a return on their investment in the form of share appreciation driven by the Group's progress. 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 2016. In the long term and as the company becomes profitable, the company wishes to be able to provide shareholders with direct returns in the form of dividends and/or share buybacks in addition to share price appreciation.

Financial calendar for 2016

Dato	Beskrivelse
16. feb, 2016	Quiet period prior to the annual report begins
2. mar, 2016	Deadline for shareholder proposals for the AGM
16. mar, 2016	Annual report for 2015
14. apr, 2016	Annual General Meeting
20. apr, 2016	Quiet period prior to the Interim report begins
4. may, 2016	Interim report - 3 months 2016
21. jul, 2016	Quiet period prior to the Interim report begins
4. aug, 2016	Interim report - 6 months 2016
20. oct, 2016	Quiet period prior to the Interim report begins
3. nov, 2016	Interim report - 9 months 2016

Equity analysts and investor meetings

BioPorto maintains ongoing contact with investors and equity analysts and organise regular presentations and meetings to discuss its strategy and risks.

BioPorto generally organises investor meetings after the release of its annual report, half-year report and quarterly announcements.

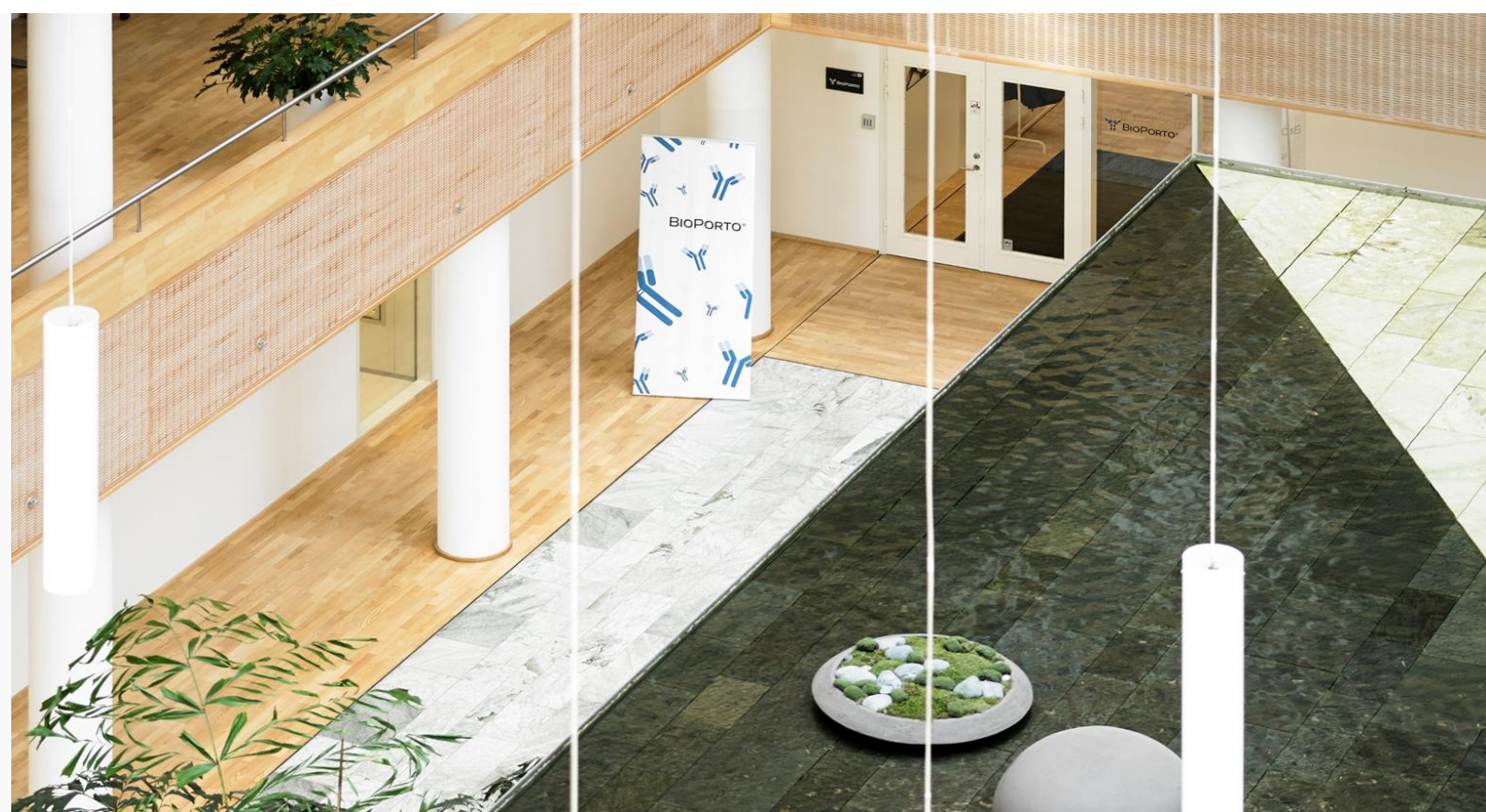
General Meeting

The Annual General Meeting of BioPorto A/S will be held on 14 April 2016 at 3:00 pm at the company's address at Tuborg Havnevej 15, ground floor, DK-2900 Hellerup, Denmark.

IR contact



Christina Thomsen, Investor Relations Manager
Tel. +45 4529 0034
Email: investor@bioporto.com



Company announcements

Nr.	Dato	Beskrivelse
3	13. feb, 2016	Scientific journal's publication of white paper on the use of NGAL marks important milestone for BioPorto
2	11. jan, 2016	BioPorto enters distribution agreement with Siemens Healthcare
1	4. jan, 2016	Announcement from major shareholder
24	16. dec, 2015	Financial Calendar 2016
23	6. nov, 2015	Interim financial report for Q3 2015 – the BioPorto Group
22	30. sep, 2015	Share Capital and Votes
21	25. sep, 2015	Submission of FDA application for The NGAL Test™
20	4. sep, 2015	Completion of rights issue and capital increase
19	31. aug, 2015	Announcement from major shareholder
18	31. aug, 2015	Insider's dealings
17	31. aug, 2015	BioPorto A/S completes cash issue, private placement
16	31. aug, 2015	Increase of the share capital through a cash issue, private placement
15	7. aug, 2015	Interim financial report for Q2 2015 – the BioPorto Group
14	3. jul, 2015	Progress in clinical trials for the FDA application for The NGAL Test™ and launch of new generic strip test
13	18. may, 2015	Announcement from major shareholder
12	5. may, 2015	Interim financial report for Q1 2015 – the BioPorto Group
11	10. apr, 2015	Passing of BioPorto A/S' Annual General Meeting
10	10. apr, 2015	Enrollment for the clinical trial of The NGAL Test™ in the US has been completed
9	29. mar, 2015	Announcement from major shareholder regarding the AGM on April 10, 2015
8	24. mar, 2015	Announcement from major shareholder
7	24. mar, 2015	Announcement from major shareholder regarding the AGM on April 10, 2015
6	22. mar, 2015	Announcement from major shareholder regarding the AGM on April 10, 2015
5	18. mar, 2015	Annual General Meeting
4	18. mar, 2015	Annual report 2014
3	28. jan, 2015	Market rumours about rejection of NGAL cut-off patent application
2	22. jan, 2015	New CFO at BioPorto A/S.
1	6. jan, 2015	Scientific journal's publication of white paper on the use of NGAL marks important milestone for BioPorto

Company details

Bank

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

Lawyer

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

Independent auditor

PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab
Strandvejen 44
DK-2900 Hellerup
Denmark

Locations

BioPorto A/S and BioPorto Diagnostics A/S



Tuborg Havnevej 15, st.
DK-2900 Hellerup
Denmark

BioPorto Inc. and BioPorto Diagnostics Inc.



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

Board of directors and management

Board members		Directorships in other companies		
	Thomas Magnussen (M) (1953) Chairman Joined the Board of Directors in 2013	Chairman of the Board of QuantumWise A/S og Zylinc. Managing Director of Therazone ApS		
	Torben A. Nielsen (M) (1960) Vice chairman Joined the Board of Directors in 2013	Partner of Linde & Partners Kapitalrådgivning A/S and Member of the Board of Wavepiston A/S. Managing Director of Arnth Advice ApS		
	Roar Bjørk Seeger (M) (1964) Joined the Board of Directors in 2013	Chairman of the Board of Modstrøm Danmark A/S. Member of the Board of Aktant Technology Denmark A/S, Aktant Technology and BRS Holding Int. ApS. Managing Director of BRS Holding Int. ApS, Seeger, Lion & Dolphin A/S and Jiawei Photovoltaic Lightning		
	Jan Kuhlmann Andersen (M) (1961) Joined the Board of Directors in 2015	Vice President, Animal health & Nutrition, Chr. Hansen A/S, Chairman of the Board of Cytovac A/S		
Management Board		Directorships in other companies		
	Peter M. Eriksen (M) (1960) CEO of BioPorto A/S since 2013	Chairman of the Board of Ocumove ApS and Medtech Innovation Center. Managing Director of PME Consult ApS and PME Holding ApS. Member of Advisory Board at Lund University.		
Holding of shares				
	31 Dec 2014	Bought	Sold	31 Dec 2015
Board of Directors				
Thomas Magnussen	-	100,000	-	100,000
Torben A Nielsen	75,000	100,000	-	175,000
Roar B. Seeger	11,533	-	-	11,533
Jan K. Andersen	-	30,000	-	30,000
Management Board				
Peter M. Eriksen	69,239	-	-	6,239

Statement by the management

The Board of Directors and the Management Board have today discussed and approved the annual report of BioPorto A/S for the financial year 1 January – 31 December 2015.

The consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) as adopted by the EU. The financial statements of the parent company, BioPorto A/S, are presented in accordance with the Danish Financial Statements Act. In addition, the annual report is presented in accordance with additional Danish disclosure requirements for annual reports of listed companies.

In our opinion, the accounting policies are appropriate, and the consolidated and parent company financial statements give a true and fair view of the Group's and the parent company's assets, liabilities and financial position as at 31 December 2015 and of the results of the Group's and the parent company's operations and the consolidated cash flows for the financial year 1 January – 31 December 2015.

In our opinion, the management's review includes a fair review of the development and performance of the business and the financial position of the Group and the parent company, the results for the year and of the financial position, together with a description of the principal risks and uncertainties that the Group and the parent company face.

We recommend the annual report for approval at the annual general meeting

Hellerup, 16 March 2016

Management Board:

Peter Mørch Eriksen
CEO

Board of directors:

Thomas Magnussen
Chairman

Torben A. Nielsen
Vice Chairman

Roar Bjørk Seeger

Jan K. Andersen

Independent Auditor's Report

To the Shareholders of BioPorto A/S

Report on Consolidated Financial Statements and Parent Company Financial Statements

We have audited the Consolidated Financial Statements and the Parent Company Financial Statements of BioPorto A/S for the financial year 1 January to 31 December 2015, which comprise income statement, balance sheet, statement of changes in equity and notes, including summary of significant accounting policies for both the Group and the Parent Company, as well as statement of comprehensive income and cash flow statement for the Group. The Consolidated Financial Statements are prepared in accordance with International Financial Reporting Standards as adopted by the EU, and the Parent Company Financial Statements are prepared under the Danish Financial Statements Act. Moreover, the Consolidated Financial Statements and the Parent Company Financial Statements are prepared in accordance with Danish disclosure requirements for listed companies.

Management's Responsibility for the Consolidated Financial Statements and the Parent Company 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 Danish disclosure requirements for listed companies and for preparing Parent Company Financial Statements that give a true and fair view in accordance with the Danish Financial Statements Act and Danish disclosure requirements for listed companies, and for such internal control as Management determines is necessary to enable the preparation of Consolidated Financial Statements and Parent Company Financial Statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on the Consolidated Financial Statements and the Parent Company Financial Statements based on our audit. We conducted our audit in accordance with International Standards on Auditing and additional requirements under Danish audit regulation. This requires that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance whether the Consolidated Financial Statements and the Parent Company Financial Statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the Consolidated Financial Statements and the Parent Company Financial Statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the Consolidated Financial Statements and the Parent Company Financial Statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Company's preparation of Consolidated Financial Statements and Parent Company Financial Statements that give a true and fair view 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 Company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by Management, as well as evaluating the overall presentation of the Consolidated Financial Statements and the Parent Company Financial Statements.

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

The audit has not resulted in any qualification.

Opinion

In our opinion, the Consolidated Financial Statements give a true and fair view of the Group's financial position at 31 December 2015 and of the results of the Group's operations and cash flows for the financial year 1 January to 31 December 2015 in accordance with International Financial Reporting Standards as adopted by the EU and Danish disclosure requirements for listed companies.

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 2015 and of the results of the Parent Company's operations for the financial year 1 January – 31 December 2015 in accordance with the Danish Financial Statements Act and Danish disclosure requirements for listed companies.

Statement on Management's Review

We have read Management's Review in accordance with the Danish Financial Statements Act. We have not performed any procedures additional to the audit of the Consolidated Financial Statements and the Parent Company Financial Statements. On this basis, in our opinion, the information provided in Management's Review is consistent with the Consolidated Financial Statements and the Parent Company Financial Statements.

Hellerup, 16 March 2016

PricewaterhouseCoopers

Statsautoriseret Revisionspartnerselskab

CVR-nr. 33 77 12 31

Torben Jensen
State Authorised Public Accountant

Allan Knudsen
State Authorised Public Accountant

Statement of comprehensive income

		2015	2014
		DKK thousand	DKK thousand
Note			
3	Revenue	20,383	18,705
4.6	Production costs	(4,902)	(5,508)
	Gross profit/loss	15,481	13,197
4.6	Sales and marketing costs	(8,876)	(9,396)
4.6	Research and development costs	(9,944)	(8,616)
4,6,7	Administrative expenses	(9,420)	(10,441)
	Profit/loss before financial items (EBIT)	(12,759)	(15,256)
8	Financial income	323	288
8	Financial expenses	(578)	(129)
	Profit/loss before tax	(13,014)	(15,097)
9	Total income taxes	2,282	2,171
	Profit/loss for the year/comprehensive income	(10,732)	(12,926)
		DKK	DKK
10	Profit/loss / comprehensive income per share (EPS & DEPS)	(0.09)	(0.11)

Balance sheet

		2015	2014
		31 December DKK thousand	31 December DKK thousand
Note	ASSETS		
	Non-current assets		
	Property, plant and equipment and intangible assets		
11	Fixtures and fittings, tools and equipment	451	612
11	Rights and software	559	199
	Total property, plant and equipment and intangible assets	1,010	811
	Financial assets		
	Deposits	666	645
	Total financial assets	666	645
	Total non-current assets	1,676	1,456
	Current assets		
12.19	Inventories	4,034	4,004
13,17,19	Trade receivables	3,967	3,310
	Income tax receivable	2,299	2,171
13,17,19	Other receivables	2,150	851
	Total inventories and receivables	12,450	10,336
	Cash	34,867	25,447
	Total current assets	47,317	35,783
	TOTAL ASSETS	48,993	37,239

Balance sheet

		2015	2014
		31 December DKK thousand	31 December DKK thousand
Note	EQUITY AND LIABILITIES		
	Equity		
14	Share capital	129,599	117,874
	Share-based payments	568	648
15	Treasury shares	0	0
	Retained earnings	(85,682)	(89,836)
	Total equity	44,485	28,686
	Liabilities		
	Non-current liabilities		
17	Lease obligation	64	87
	Non-current liabilities	64	87
	Current liabilities		
16.17	Current portion of non-current liabilities	22	18
17.19	Trade payables	1,227	1,199
17.19	Other payables	3,195	7,249
	Current liabilities	4,444	8,466
	Total liabilities	4,508	8,553
	TOTAL LIABILITIES	48,993	37,239

Statement of changes in equity

	Share capital DKK thousand	Share premium DKK thousand	Share-based payments DKK thousand	Retained ear- nings DKK thousand	Total DKK thousand
Equity 1 January 2015	117,874	0	648	(89,836)	28,686
Profit/loss for the year/ comprehensive income	0	0	0	(10,732)	(10,732)
Capital increase	11,725	16,415	0	0	28,140
Capital increase costs	0	(1,609)	0	0	(1,609)
Transferred to Retained earnings	0	(14,806)	(80)	14,886	0
Equity at 31 December 2015	129,599	0	568	(85,682)	44,485

	Share capital DKK thousand	Share premium DKK thousand	Share-based payments DKK thousand	Retained ear- nings DKK thousand	Total DKK thousand
Equity 1 January 2014	117,874	0	1,666	(77,928)	41,612
Profit/loss for the year/ comprehensive income	0	0	0	(12,926)	(12,926)
Transferred to Retained earnings	0	0	(1,018)	1,018	0
Equity at 31 December 2014	117,874	0	648	(89,836)	28,686

Cash flow statement

Note		2015	2014
		DKK thousand	DKK thousand
	Profit/loss before financial items	(12,759)	(15,256)
	Amortisation, depreciation and impairment losses	300	270
	Cash generated from operations before working capital	(12,459)	(14,986)
19	Changes in working capital	(6,012)	(1,312)
	Cash generated from operations	(18,471)	(16,298)
	Financial income, received	308	272
	Financial expenses, paid	(564)	(112)
	Tax refund	2,153	0
	Cash flows from operating activities	(16,574)	(16,138)
	Purchase of operating equipment	(50)	(542)
	Purchase of rights and software	(464)	(265)
	Purchase of financial assets	(21)	(392)
	Sale of operating equipment	18	0
	Cash flows from investing activities	(517)	(1,199)
20	Capital increase	26,531	0
	Reduction of lease obligation	(20)	(18)
	Cash flows from financing activities	26,511	(18)
	Net cash flow from operating, investing and financing activities	9,420	(17,355)
	Cash and cash equivalents at 1 January	25,447	42,802
	Cash and cash equivalents at 31 December	34,867	25,447

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. Amortisation, 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
22. Related parties and ownership

Note 1

Accounting policies

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

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

The financial statements are prepared on the basis of the historical cost convention, with the exception of share-based remuneration, which is measured at fair value.

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 2015 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 2015.

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, 2015 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 a number of 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"

IFRS 15. "Revenue"

IFRS 16. "Leases"

BioPorto expects these standards and interpretations to be implemented once they come into effect. The impact of the new and modified standards and interpretations is being examined at present, but the management does not expect them to have a significant effect on 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 so as to obtain returns or other benefits from its activities. Control is obtained when the Company directly or indirectly holds more than 50 % of the voting rights in the subsidiary or controls the subsidiary in some other way.

The consolidated financial statements have been prepared consolidating the financial statements of the parent company and the individual subsidiaries using the Group's accounting policies, eliminating intra-group income and expenses, intra-group shareholdings, intra-group balances and dividends as well as realised and unrealised gains on intra-group transactions. Unrealised gains on transactions with associates are eliminated in proportion to the Group's share of the company. Unrealised losses are eliminated in the same way as unrealised 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 recognised 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 recognised in the income statement under financial income or expenses.

Note 1, continued

Incentive programmes

The company has granted warrants to the Management Board and the employees. Share-based incentive schemes in which employees can only opt to subscribe new shares in the parent company (equity-based schemes) are measured at the equity instruments' fair value at the grant date and recognised in the income statement when the employees obtain the right to subscribe for the new shares, which is the date of grant. The balancing item is recognised directly in equity as a separate reserve until exercise.

Leasing

Leases in which the company retains all significant risks and rewards of ownership (finance leases) are recognised 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 capitalised residual lease liability is recognised 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 recognised 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 Test™
- 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 non-current assets or investments outside Denmark.

Note 1, continued

Income statement and statement of comprehensive income

Revenue

Revenue from the sale of finished goods is recognised 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 recognised 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 recognised 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 amortisation.

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, amortisation 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 recognised in the income statement, and the tax expense relating to changes directly recognised in equity is recognised in equity.

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

Note 1, continued

Balance sheet

Intangible assets

Development projects

In accordance with IAS 38 Intangible Assets, intangible assets arising from development projects must be recognised 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 capitalised 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

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:

Rights and software; 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 recognised 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 recognised 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 recognised only to the extent that it is probable that they will be utilised 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 recognised 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 recognised 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.

Note 1, continued

Inventories

Inventories are measured at cost in accordance with the FIFO method. Where the net realisable 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 realisable 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 amortised cost and net realisable 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 recognised 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 recognised 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 recognised 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 recognised under other non-current assets at the expected value of their utilisation, 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 unrealised intra-group profits and losses is adjusted on consolidation.

Deferred tax is measured on the basis of the tax regulations and rates that, according to the rules in force at the balance sheet date, will apply

Note 1, continued

at the time the deferred tax is expected to crystallise as current tax. Changes in deferred tax due to changes in the tax rate are recognised in the income statement.

Other financial liabilities

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

Other liabilities are measured at amortised 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	$\frac{\text{Revenue year 1} - \text{revenue year 0}}{\text{Revenue year 0}}$
Gross margin	$\frac{\text{Gross income} \times 100}{\text{Net revenue}}$
EBIT margin	$\frac{\text{EBIT} \times 100}{\text{Net revenue}}$
Equity ratio	$\frac{\text{Equity, closing} \times 100}{\text{Total liabilities, closing}}$
Return on equity	$\frac{\text{Result for the year} \times 100}{\text{Average equity}}$
Earnings per share (EPS)	$\frac{\text{Result for the year}}{\text{Average number of shares}}$
Cash flow per share	$\frac{\text{Cash generated by operations}}{\text{Average number of shares}}$
Net asset value per share at year end	$\frac{\text{Capital and reserves, closing}}{\text{No. of shares, closing}}$

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, with reference to IFRS, it is not sufficiently probable that the tax asset can be utilised in the foreseeable future. Management has therefore decided not to recognise 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 amount of assets or liabilities in the coming financial year.

Note 3

Segment reporting

GEOGRAPHIC DISTRIBUTION:	2015	2014
	DKK thousand	DKK thousand
Denmark	1,783	536
Rest of Europe	7,195	7,250
North America	7,634	8,568
Asia	2,448	1,672
Other countries	1,323	679
Revenue	20,383	18,705

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

PRODUCT GROUPS	2015	2014
	DKK thousand	DKK thousand
The NGAL test	3,747	2,396
ELISA Human NGAL kits	2,554	1,701
ELISA Animal NGAL kits	920	1,244
ELISA MBL kits	2,530	2,073
Antibodies*	9,489	9,113
Other products and licenses	1,143	2,178
Revenue	20,383	18,705

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

*In 2015, public innovation assistance of DKK 1.075 thousand relating to the development and production of a new antibody is included as revenue.

Note 4

Staff costs

	2015	2014
	DKK thousand	DKK thousand
Wages and salaries	15,518	16,081
Defined contribution pension plans	1,339	1,420
Other social security costs	202	221
Other staff costs	273	232
Staff costs	17,332	17,954
Average number of employees	22	24

Specification of staff costs:

	2015	2014
	DKK thousand	DKK thousand
Production costs	2,151	2,589
Sales and marketing costs	5,962	5,563
Administrative expenses	5,607	7,625
Research and development costs	3,612	2,177
Staff costs	17,332	17,954

	2015	2014
	DKK thousand	DKK thousand
Management Board		
Salaries	2,333	4,151
Pension	225	300
Management Board, Total	2,558	4,451
Board of Directors		
Remuneration	1,188	1,013

Note 5

Incentive schemes

In order to motivate and retain employees and members of the Management Board, in 2008, 2009 and 2011 BioPorto A/S established warrant programmes as incentive and bonus schemes. The schemes, which can only be exercised when new shares are issued (equity-based scheme), entitle the holders to subscribe a number of new shares in the parent company at a pre-determined price. The right to subscribe new shares vests at the date of grant. The parent company will issue the subscribed number of shares not later than at the next annual general meeting after receiving the claim, and at the same time the capital increase will be notified to the Danish Business Authority. However, this process is subject to the parent company's CEO having received the claim not later than six weeks before the annual general meeting is held. In 2015, recognised share-based remuneration, equity-based schemes, was DKK 0 (DKK 0).

Overview of existing warrant programmes:

	No. of warrants
Total at 1 January 2015	979,750
Additions during the year	0
Total at 31 December 2015	979,750
Lapsed at 1 January 2015	735,250
Lapsed during the year	30,000
Lapsed at 31 December 2015	765,250
Total at 31 December 2015	214,500

Overview of existing warrants programs:

The 214,500 outstanding warrants may be exercised until and including 6 February 2017. The average exercise price for these warrants is DKK 7.86 per warrant.

Note 6

Amortisation, depreciation and impairment

	2015	2014
	DKK thousand	DKK thousand
Property, plant and equipment	196	204
Total depreciation and impairment	196	204
Specification of depreciation and impairment:		
Production costs	82	102
Sales and marketing costs	8	7
Research and development costs	98	81
Administrative expenses	8	14
	196	204

	2015	2014
	DKK thousand	DKK thousand
Intangible assets	104	66
Total amortisation and impairment	104	66
Specification of amortisation and impairment:		
Production costs	0	0
Sales and marketing costs	104	66
Research and development costs	0	0
Administrative expenses	0	0
	104	66

Note 7

Fees to auditors appointed by the general meeting

	2015	2014
	DKK thousand	DKK thousand
Fees to auditors appointed by the general meeting	506	220
Breakdown of fees:		
Fees for statutory audit	201	200
Fees for tax consulting	142	20
Other services	163	0
Total fees to auditors appointed by the general meeting	506	220

Note 8

Financial income and expenses

FINANCIAL INCOME

	2015	2014
	DKK thousand	DKK thousand
Interest income from bank	93	210
Interest income from financial assets not measured at fair value	93	210
Exchange rate adjustments	230	78
Total financial income	323	288

FINANCIAL EXPENSES

	2015	2014
	DKK thousand	DKK thousand
Interest expenses, other debt	(279)	(15)
Interest expenses on liabilities not measured at fair value	(279)	(15)
Exchange rate adjustments	(267)	(85)
Other financial expenses	(32)	(29)
Total financial expenses	(578)	(129)

Note 9

Deferred tax

	2015 DKK thou- sand	2014 DKK thou- sand
Calculated tax asset	34,110	33,352
Writedown to assessed value	(34,110)	(33,352)
Carrying amount	0	0

A significant deferred tax asset has been calculated. However, Management has found that, with reference to IFRS, it is not sufficiently probable that the tax asset can be utilised in the foreseeable future. Management has therefore decided not to recognise the calculated tax asset in the balance sheet, cf. note 2. The tax asset is of indefinite duration.

Deferred tax assets not recognised in the balance sheet:

	2015 DKK thousand	2014 DKK thousand
Intangible assets	612	2,671
Property, plant and equipment	693	667
Current assets	356	350
Tax loss carryforwards	32,449	29,664
Deferred tax at 31 December, net	34,110	33,352

Income taxes

	2015 DKK thousand	2014 DKK thousand
Tax refund, research and development costs	2,299	2,171
Adjustment of tax from previous years	(17)	0
Total income taxes	2,282	2,171

Note 10

Earnings per share

	2015	2014
	DKK thousand	DKK thousand
Profit/loss for the period	(10,732)	(12,926)
BioPorto Group's share of profit/loss	(10,732)	(12,926)
Average number of shares	121,652	117,874
Average number of treasury shares	(13)	(13)
Average number of shares in circulation	121,639	117,861
Diluted average number of shares in circulation	121,639	117,861
Earnings per share (EPS)	(0.09)	(0.11)

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

Note 11

Fixtures and fittings, tools and equipment

	2015	2014
	DKK thousand	DKK thousand
Cost at 1 January	2,035	3,466
Additions during the year	50	542
Disposals during the year	(33)	(1,973)
Cost at 31 December	2,052	2,035
Depreciation at 1 January	(1,423)	(3,192)
Depreciation during the year	(196)	(204)
Reversed depreciation on disposals	18	1,973
Depreciation at 31 December	(1,601)	(1,423)
Carrying amount at 31 December	451	612
Of which finance leases	73	108

Rights and software

	2015	2014
	DKK thousand	DKK thousand
Cost at 1 January	265	0
Additions during the year	464	265
Disposals during the year	0	0
Cost at 31 December	729	265
Depreciation at 1 January	(66)	0
Depreciation during the year	(104)	(66)
Reversed depreciation on disposals	0	0
Depreciation at 31 December	(170)	(66)
Carrying amount at 31 December	559	199

Note 12

Inventories

	2015	2014
	DKK thousand	DKK thousand
Finished goods	3,593	3,813
Raw materials and consumables	441	191
Inventories	4,034	4,004
Writedown of slow-moving items	(140)	(33)
Inventories expected to be sold after 12 months	1,497	1,550

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

Note 13

Receivables

	2015 DKK thousand	2014 DKK thousand
Trade receivables	4,017	3,474
Other receivables	2,150	851
Provision for bad debts	(50)	(164)
	6,117	4,161

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 on the basis of 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 129,598,960 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.

	2015	2014
	Number	Number
NUMBER OF SHARES		
1 January	117,874,210	117,874,210
Issue	11,724,750	0
31. December	129,598,960	117,874,210

	Number of shares	Nominal value DKK	Share price DKK/share
CAPITAL INCREASES IN 2015			
Issue	11,724,750	1.00	2.40

	No.	DKK	DKK/share
CAPITAL INCREASES IN 2013			
Issue	70,724,526	1.00	1.00

	No.	DKK	DKK/share
CAPITAL INCREASES IN 2012			
Cash private placement	2,000,000	3.00	5.10

	No.	DKK	DKK/share
CAPITAL INCREASES IN 2011			
Conversion of bonds	64,560	3.00	6.97
Warrant exercise – Board of Directors	26,000	3.00	6.15
Warrant exercise – Management Board and employees	226,497	3.00	4.18
Cash private placement	2,700,000	3.00	5.00

Note 15

Treasury shares

	2015	2014
	DKK thousand	DKK thousand
NOMINAL VALUE		
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%

BioPorto A/S has been authorised by the shareholders in general meeting to acquire own shares for a value of up to 10 % of the share capital. BioPorto has not acquired treasury shares in 2014 and 2015.

Note 16

Current portion of non-current liabilities

	2015	2014
	DKK thousand	DKK thousand
Finance leases	22	18

Note 17

Financial risks and financial instruments

FINANCIAL INSTRUMENT CATEGORIES	2015	2014
	DKK thousand	DKK thousand
Trade receivables	3,967	3,310
Other receivables	2,150	851
Cash and cash equivalents	34,867	25,447
Total receivables and cash	40,984	29,608

	2015	2014
	DKK thousand	DKK thousand
Loans, amortised cost	86	105
Trade payables	1,227	1,199
Other payables	3,195	7,249
Total financial liabilities	4,508	8,553

Trade receivables

In 2015, BioPorto has recognised loss on bad debts of DKK 116 thousand. 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.

	2015	2014
	DKK thousand	DKK thousand
Not due	2,546	2,069
Overdue by 0-90 days	1,334	1,236
More than 90 days overdue	137	169
Total trade receivables before writedowns	4,017	3,474

Note 17, continued

Financial risks and financial instruments

Movements in receivables more than 90 days overdue	2015	2014
	DKK thousand	DKK thousand
1 January	169	3
Disposals	(215)	(3)
Additions	183	169
31 December	137	169

Cash

	Currency	Effective rate of interest	2015	2014
			DKK thousand	DKK thousand
Floating-rate loans	DKK	0%-0.5%	34,867	8,447
Fixed-rate loans	DKK	0.3%-1.0%	0	17,000
Sensitivity to change in interest rates		1%	0	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 no debt denominated in foreign currency.

Note 17, continued

Financial risks and financial instruments

	Currency	Exchange rate	2015 DKK thousand	2014 DKK thousand
Revenue settled in	EUR	7.46	14,616	16,186
Sensitivity to change in exchange rates	0.15%	0.01	164	181
Revenue settled in	USD	6.77	3,505	1,851
Sensitivity to change in exchange rates	0.15%	0.01	36	17

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

At 31 December 2015, BioPorto's cash holdings amounted to DKK 34.9 million. BioPorto thus has cash resources that are sufficient to support its organic growth strategy, which longer-term is expected to strengthen the equity by way of increasing operating income and positive cash flows.

Capital structure

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

Note 17, continued

Financial risks and financial instruments

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

2014	Less than 1 year DKK thousand	Between 1 and 5 years DKK thousand	More than 5 years DKK thousand	Total DKK thousand
Lease obligations	18	87	0	105
Trade payables and other payables	8,448	0	0	8,448
Financial liabilities	8,466	87	0	8,554

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.

	2015 DKK thousand	2014 DKK thousand
Less than 1 year	2,221	1,865
1-5 years	8,157	7,461
More than 5 years	529	2,331

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 pre-determined minimum royalty percentage.

	2015 DKK thousand	2014 DKK thousand
Less than 1 year	479	456
1-5 years	503	982
More than 5 years	0	0

Payments recognised in profit/loss for the year

	2015 DKK thousand	2014 DKK thousand
Less than 1 year	2,271	2,323

Note 19

Changes in working capital

	2015	2014
	DKK thousand	DKK thousand
Change in inventories	(30)	(375)
Change in receivables	(1,956)	(528)
Change trade payables	28	238
Change in other payables	(4,054)	(647)
	(6,012)	(1,312)

Note 20

Capital increase

	2015	2014
	DKK thousand	DKK thousand
Capital increase, gross proceeds	28,140	0
Capital increase costs	(1,609)	0
	26,531	0

Note 21

Contingent liabilities

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

Note 22

Related parties and ownership

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)

Roar Seeger, board member (elected 26.02.2013)

Jan Kuhlmann Andersen, board member (elected 10.04.2015)

Peter Mørch Eriksen, CEO (appointed 18.07.2013)

Otto Rasmussen, CFO (resigned 31.01.2015)

Group-owned companies

BioPorto Diagnostics A/S, Tuborg Havnevej 15, 2900 Hellerup

BioPorto Diagnostics Inc, Chicago, Illinois, USA (established January 2016)

BioPorto Inc, Chicago, Illinois, USA (established January 2016)

Related party transactions

In 2015, BioPorto purchased consultancy services in the amount of DKK 271,000 from Arnth Advice ApS in conjunction with the raising of capital. Arnth Advice ApS is owned by Vice Chairman Torben A. Nielsen.

Income statement

		2015	2014
		DKK thousand	DKK thousand
Note			
3	Revenue	9,600	9,600
	Gross profit	9,600	9,600
	Gross margin	100%	100%
4,5,6	Administrative expenses	(9,506)	(9,646)
	Profit/loss before financial items (EBIT)	94	(46)
	Income from investments in subsidiaries	(17,453)	(22,757)
7	Financial income	11,225	9,880
7	Financial expenses	(28)	(3)
	Profit/loss before tax	(6,162)	(12,926)
10	Total income taxes	(4,570)	0
	Profit/loss for the year	(10,732)	(12,926)
	Proposed appropriation of loss		
	To be transferred to retained earnings	(10,732)	(12,926)

Balance sheet

		2015	2014
		31 December DKK thousand	31 December DKK thousand
Note	ASSETS		
	Non-current assets		
8	Property, plant and equipment	0	0
	Financial assets		
9	Investments in subsidiaries	0	0
9	Receivables from subsidiaries	10,973	8,812
	Deposits	666	647
	Total financial assets	11,639	9,459
	Total non-current assets	11,639	9,459
	Current assets		
	Income tax receivables	2,299	0
	Other receivables	622	51
	Total receivables	2,921	51
	Cash	31,375	23,549
	Total current assets	34,296	23,600
	TOTAL ASSETS	45,935	33,059

Balance sheet

	2015	2014
	31 December DKK thousand	31 December DKK thousand
EQUITY AND LIABILITIES		
Equity		
Share capital	129,599	117,874
Retained profit/loss	(85,114)	(89,189)
Total equity	44,485	28,686
Liabilities		
Current liabilities		
Current portion of non-current liabilities	0	0
Trade payables	494	68
Other payables	956	4,305
Current liabilities	1,450	4,374
Total liabilities	1,450	4,374
TOTAL EQUITY AND LIABILITIES	45,935	33,059

Statement of changes in equity

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

	Share capital DKK thousand	Share premium DKK thousand	Retained ear- nings DKK thousand	Total DKK thousand
Equity at 1 January 2014	117,874	0	(76,262)	41,612
Profit/loss for the year	0	0	(12,926)	(12,926)
Equity at 31 December 2014	117,874	0	(89,188)	28,686

List of notes to the financial statements

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

Note 1

Accounting policies

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

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

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

Differences relative to the Group's accounting policies

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

Income statement

Income from investments in subsidiaries

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

Share-based payment

The value of share-based payment is not recognised in the income statement. Share-based remuneration of the Management is described in the notes to the financial statements.

Balance sheet

Investments in subsidiaries

Investments in subsidiaries are recognised and measured under the equity method. Subsidiaries with a negative net asset value are recognised 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 recognised in each individual company. All jointly-taxed companies are covered by the joint-taxation liability.

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

Note 2

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

	2015	2014
	DKK thousand	DKK thousand
GEOGRAPHIC DISTRIBUTION		
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.

Note 4

Staff costs

	2015	2014
	DKK thousand	DKK thousand
Wages and salaries	5,357	6,679
Defined contribution pension plans	423	520
Other social security costs	46	60
Other staff costs	0	0
Staff costs	5,826	7,259
Average number of employees	5	5

Specification of staff costs:

	2015	2014
	DKK thousand	DKK thousand
Administrative expenses	5,826	7,259

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

Amortisation, depreciation and impairment

There were no amortisation, depreciation or impairment charges in 2014 or 2015.

Note 6

Fees to auditors appointed by the general meeting

	2015	2014
	DKK thousand	DKK thousand
Fees for statutory audit	201	133
Fees for tax consulting	142	20
Other services	163	0
Total fees to auditors appointed by the shareholders	506	153

Note 7

Financial income and expenses

FINANCIAL INCOME

	2015	2014
	DKK thousand	DKK thousand
Interest income from subsidiaries	11,130	9,743
Interest income from bank	95	137
Total financial income	11,225	9,880

FINANCIAL EXPENSES

	2015	2014
	DKK thousand	DKK thousand
Other financial expenses	(28)	(3)
Total financial expenses	(28)	(3)

Note 8

Fixtures and fittings, tools and equipment

	2015	2014
	DKK thousand	DKK thousand
Cost at 1 January	0	174
Additions during the year	0	0
Disposals during the year	0	174
Cost at 31 December	0	0
Depreciation at 1 January	0	(174)
Depreciation during the year	0	0
Reversed depreciation on disposals	0	(174)
Depreciation at 31 December	0	0
Carrying amount at 31 December	0	0

Note 9

Investments in subsidiaries

	2015 DKK thousand	2014 DKK thousand
Cost at 1 January	48,000	48,000
Additions	0	0
Disposals	0	0
Cost at 31 December	48,000	48,000
Net impairment at 1 January	(170,439)	(147,682)
Income from investments in subsidiaries	(17,453)	(22,757)
Net impairment at 31 December	(187,892)	(170,439)
Negative value written down on receivable	187,892	170,439
Value at 31 December	0	0
Name of subsidiaries		
BioPorto Diagnostics A/S, Hellerup, Copenhagen 100% ownership interest	(187,892)	(170,439)
Negative equity transferred to be set off against receivables from group enterprises	187,892	170,439
Value at 31 December	0	0
Receivables from subsidiaries		
Cost at 1 January	179,280	162,203
Additions	19,614	17,077
Disposals	0	0
Cost at 31 December	198,894	179,280
Net impairment at 1 January	(170,468)	(147,711)
Negative equity transferred to be set off against receivables from group enterprises	(17,453)	(22,757)
Net impairment at 31 December	(187,921)	(170,468)
Value at 31 December	10,973	8,812

Note 9, continued

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 the subsidiary'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 the subsidiary'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

	2015 DKK thousand	2014 DKK thousand
Calculated tax asset	52	59
Writedown to assessed value	(52)	(59)
Carrying amount	0	0

A deferred tax asset has been calculated. However, Management has found that it is not sufficiently probable that the tax asset can be utilised. Management has therefore decided not to recognise the calculated tax asset in the balance sheet, cf. note 2.

DEFERRED TAX ASSETS NOT RECOGNISED IN THE BALANCE SHEET:

	2015 DKK thousand	2014 DKK thousand
Property, plant and equipment	52	59
Deferred tax at 31 December, net	52	59

TOTAL INCOME TAXES:

	2015 DKK thousand	2014 DKK thousand
Joint taxation contribution 2015	(2,656)	0
Adjustment of tax from previous years	(1,914)	0
Total income taxes	(4,570)	0

Note 11

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.

	2015 DKK thousand	2014 DKK thousand
Less than 1 year	2,221	1,865
1-5 years	8,157	7,461
More than 5 years	529	2,331

	2015 DKK thousand	2014 DKK thousand
Minimum lease payments recognised in profit/loss for the year	1,753	1,654

Note 12

Contingent liabilities

BioPorto A/S has acknowledged towards the subsidiary BioPorto Diagnostics A/S that it will finance its operations in 2016.

Note 13

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.

Glossary

Biomarker	Theoretically, any analyzable phenomenon that can be used for indicating a biological condition (e.g. pulse, body temperature). Most often used for a molecule whose level in a patient sample (blood, tissue) indicates the existence of a disease and possibly its seriousness.	IVD	"In vitro diagnostic(s)", a diagnostic procedure that takes place outside the body, e.g. by analyzing blood and urine samples in a laboratory, as opposed to "in vivo diagnostics", which are performed on the patient, such as a prick test in the skin or an X-ray.
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.	MBL	"Mannan-binding lectin", a blood protein that binds to foreign organisms and contributes to congenital (innate) immune response.
Diagnostics	Diagnostics is the process whereby a disease and possibly its cause are identified. Fast, accurate diagnostics are decisive for the subsequent treatment (therapy). Certain diagnostic tests can be used for monitoring the patient's response to treatment and possible needs for changing the treatment.	Monoclonal	Derived from a single "clone", in this case a single cell line. A monoclonal antibody thus consists of antibody molecules which are all identical, whereas a polyclonal antibody consists of many different antibody molecules produced by many different cell lines in the body.
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.	NGAL	"Neutrophil gelatinase-associated lipocalin", a biomarker that can indicate renal injury already at an early stage..
FDA approval	The "Food and Drug Administration", is the US authority that authorizes the use of medicines, including diagnostic products..	Routine diagnostics	Diagnostic analyses that are performed on a routine basis at the time of hospitalization.
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.	Specificity	The degree to which an antibody molecule, for example, binds only to a unique structure on another molecule and not to other structures or molecules, or the degree to which a diagnostic procedure only diagnoses a given pathological condition and does not give a positive result in other conditions, including the normal state.
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 on automated equipment from different manufacturers. Heterogeneous analysis typically requires a wash step and have different designs in the various automated equipment supplied by various manufacturers why a particular heterogeneous analysis typically cannot be transferred to another manufacturer's equipment.	Therapy/therapeutic ducts	pro-Treatment of diseases and the products used for this, typically medicines.
		Turbidimetry	A homogeneous analysis method by which a fluid sample from the patient mixed with a reagent fluid containing substances, often antibodies, that react with the biomarker in the sample to form a haze in the liquid (turbidity), which can be measured through radiation of light.

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

www.bioporto.com



BioPorto A/S
Tuborg Havnevej 15, st.
DK-2900 Hellerup
Denmark

Tel: (+45) 4529 0000
Fax: (+45) 4529 0001
E-mail: info@bioporto.com
Web: www.bioporto.com