



Annual Report 2012

Diagnostics - the path to better treatment

NGAL

- » NGAL is relevant for the diagnosis of Acute Kidney Injury (AKI).
- » 5 - 7% of all hospitalized patients may develop Acute Kidney Injury.
- » With present methods, kidney damage is diagnosed after 24-72 hours whereas measuring NGAL can diagnose it within few hours.
- » BioPorto offers several NGAL tests and has obtained IP rights for the diagnostic method.

Clinical application:

- » Intensive care
- » Emergency
- » Cardiopulmonary bypass surgery
- » Renal transplantation



The NGAL Test™

Turbidimetric immunoassay for Human NGAL determination in research and diagnostic procedures.

Human NGAL ELISA Kits

Human NGAL determination in research and diagnostic procedures.

Animal NGAL ELISA Kits

ELISA Kit for NGAL determination in animals for research use.

Other products

BioPorto offers a range of products to support research and development in.

Antibodies

Monoclonal antibodies for research and development.

MBL ELISA kit

A key test in the assessment of primary immunodeficiency.

APC PCI ELISA kit

A severity and prognostic marker of sepsis.

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NGAL – Do it!

Sales of NGAL products have increased by 24% in 2012 and have now surpassed the sales of BioPorto's other product categories. Expectations are very high for The NGAL Test™, BioPorto's primary test for diagnosing acute kidney injury. A number of key steps toward implementing the test have been taken, such as global diagnostics companies' recognition of the use of The NGAL Test™ on their analyzers, and the entering into of the first distribution agreement with analyzer supplier Wiener Lab. Group of Latin America. In the course of 2012 and early 2013, the kidney-injury test was registered and launched for diagnostic use in new countries and regions, including all four BRIC countries (Brazil, Russia, India and China), and targeted efforts for registration by the US FDA are currently under way. Today, The NGAL Test™ can run on eight of the major clinical chemistry analyzers. Many hospitals have validated The NGAL Test™, and the test will be set up to run on an additional number of analyzers at more hospitals in the years ahead. Routine use of The NGAL Test™ is growing and sales of the test for diagnostic purposes are growing little by little. There is still a way to go from launch to routine use, and market penetration will require additional resources for the carrying out of clinical trials and for marketing the test. Once full market penetration has been achieved, sales are expected to exceed 200 million NGAL tests a year, the majority of which are expected to be BioPorto's *The NGAL Test™*.

NGAL analysis for diagnosing acute kidney injury

Based on laboratory preferences, BioPorto has developed a kidney injury test that enables doctors to determine a patient's condition in a short time. As the test is designed as an application for automated analyzers already found in the laboratory, hospitals do not have to invest in new equipment in order to start using The NGAL Test™. In this way, the test creates potential access to the NGAL market for most major vendors of clinical chemistry analyzers.

The building up and optimization of sales channels is crucial, and BioPorto's sales strategy for The NGAL Test™ involves establishing sales channels via global diagnostics companies which market their own analyzers and by optimizing the network of distributors, which currently market The NGAL Test™ at national level. In addition to signing a contract with Wiener Lab. Group, the biggest diagnostics companies in the world have started to recognize BioPorto's The NGAL Test™. Both Roche Diagnostics and Siemens Diagnostics, market leaders in the field of analyzers on which The NGAL Test™ is used, have issued information to their local divisions and subsidiaries about The NGAL Test™. This recognition is expected to be the first step toward collaborating on the proliferation of The NGAL Test™.

Market penetration is influenced by many factors, including laboratories' possibility of being reimbursed for the test; results of health-economic calculations; clinical validation; drafting of guidelines for how to use the test; marketing efforts; the competitive situation, and therapeutic possibilities. In particular, other players' marketing—and thus a market acceptance of NGAL—has not generated the progress expected in 2012, and this has had an effect on the implementation of The NGAL Test™. This explains why sales of the test did not reach the rate predicted, and the estimation of market

penetration, and thus sales forecasts for The NGAL Test™ in the years ahead, is still subject to great uncertainty.

The NGAL cut-off patent for protecting The NGAL Test™ as a method of measuring acute kidney injury was issued in China, one of BioPorto's high-priority markets, in 2012. The European Patent Office rejected the patent issued in Europe in a first instance decision. This decision has been appealed, and BioPorto expects the appeal to be decided in BioPorto's favor. BioPorto's European patent is fully valid, also during the appeal. The NGAL patent owned by the company Phadia was ruled invalid in terms of its principal claims, as a result of a case filed by BioPorto in Denmark. Phadia has appealed this case to Denmark's Supreme Court.

BioPorto sold its first patent license in 2011. The licensing agreement gives Instrumentation Laboratories non-exclusive access to BioPorto's NGAL IP rights to develop and market NGAL tests in all non-homogeneous assay formats. The first installment fell due for payment on the date of entering into the agreement; the second installment for access in 2012 has been received; and regular milestone payments comprising EUR 2 million have been agreed, as well as a 5.5% royalty if a new NGAL assay is launched.

As part of the process of recognizing a new biomarker, it is important to influence the greatest number of prospective users of the test. For this reason, BioPorto also aims its marketing of The NGAL Test™ at the pharmaceutical industry, which can use the test in the developing and testing of new medicines. The NGAL Test™ has been used in a clinical trial where the final trial design was prepared under the influence of the US FDA, which has encouraged the use of NGAL as part of assessing the reliability of a new therapy. The inclusion of NGAL as an efficacy marker in future clinical trials will have a major impact on the use of NGAL and The NGAL Test™.

The cost of developing new medicine can be reduced if the proper tools are available at an early phase of development to weed out prospective medicines which are ineffective or produce undesirable side-effects such as harming the kidneys. This means that there is an important market for NGAL for the testing of animals. By comparison with present methods, the NGAL test could reduce the number of laboratory animals used per prospective medicine, which would benefit the pharmaceutical industry both ethically and economically. For this reason, BioPorto has developed and now markets a number of animal NGAL products, thus enabling the company to market an NGAL portfolio of high-quality products for both animal and human testing. BioPorto's portfolio includes NGAL ELISA kits for mice, rats, pigs and dogs, and a planned launch of a Monkey NGAL ELISA kit in 2013 will complete the series of kits for experimental animals.

Other products

In addition to products for measuring NGAL, BioPorto also markets a number of other products for use in both diagnostics and research. Under the AntibodyShop® trademark, BioPorto markets about 300 different monoclonal antibodies, primarily for the basic-research market. Sales of these products still account for a large share of the combined revenues and amounted to DKK 8.7 million in 2012.

Mannose-binding lectin (MBL) is an important molecule of innate immunity, and MBL deficiency can affect the efficacy with which the body can ward off a foreign organism such as a virus or bacterium. BioPorto markets diagnostics products to measure MBL levels in human beings. The revenue generated by MBL products amounted to DKK 2.1 million in 2012.

BioPorto is the only company to commercially offer a method for measuring the APC-PCI complex. BioPorto has applied for a patent concerning the diagnostic use of the marker for selecting patients with severe septicemia for special treatment. The first US patent was issued in January 2012. BioPorto continues its efforts to obtain clinical validation of the APC-PCI test and is looking into the possibility of entering into collaboration agreements with central players in the septicemia field concerning further development.

BioPorto—and what the future will bring

BioPorto is still expecting growth in the diagnostic market. The most important factors contributing to this growth are longer life expectancy and the pronounced growth in the BRIC countries (Brazil, Russia, India and China) due to overall improvements of the health sector in these markets. Expansion arising from the establishment of new diagnostic markers, like BioPorto's The NGAL Test™, also contributes to this growth. Another important factor for continued growth is the wish to customize medical treatment to meet the needs of the individual patient, intensifying the demand for more accurate comprehensive diagnoses—by using BioPorto's APC-PCI assay, for instance. The market is not very sensitive to cyclical fluctuations, as patients need to be diagnosed regardless of financial developments. However, the crisis of recent years has put pressure on the economic situation of public health services, which is why increasingly lower-cost products are required, and the speed with which new products are being implemented is slowing at the same time.

BioPorto's board of directors was infused with new expertise in early 2013. The board has decided to retain the current strategy and to redirect focus to using BioPorto's leading position in the NGAL market to initiate additional activities aimed at increasing market penetration, to retain crucial IP rights, and, within a few years, to implement The NGAL Test™ as an essential marker for analyzing acute kidney injury. Some of the principal goals are to qualify for US FDA registration, and to maintain the validity of the European cut-off patent. BioPorto is planning to increase activities aimed at implementing additional clinical trials and to widen its marketing efforts, particularly as regards advising and assisting hospital laboratories and doctors in the implementation phase to increase market penetration.

For the purpose of financing the planned operation in the coming years of the group and its current liabilities, funding possibilities have been considered. At the end of February, 2013, cash in the form of bank deposits totaled DKK 5.2 million, which is expected to finance BioPorto's activities until June 2013. The management estimates the funding needs by the end of May 2013 to be DKK 5-10 million and by third quarter at the latest an additional DKK 15-20 million in order to finance the activities of the group in 2013 and settle the convertible debt due in September 2013. Also, the

management estimates a need for DKK 35-45 million to fund the activities planned for 2014 and 2015.

After considering the options available, management has decided to attempt to carry out a rights issue to existing shareholders. The issue, planned for third quarter 2013, is expected to provide BioPorto with funds in the range of DKK 60-70 million, which is deemed sufficient to implement the planned activities over the next three years.

The group's continued status as a going concern is dependent on a supply of DKK 5-10 million in May, and that net proceeds of at least DKK 25 million are raised in connection with the issue. See also the section on capital resources in the report.

All our employees have coordinated and persistently driven the company towards a common goal: to pave the way for the use of The NGAL Test™ in routine diagnostics. In 2012, BioPorto enlarged its expertise in the area of technical validation of the test on several analyzers, which, in collaboration with Siemens, resulted in further validation of The NGAL Test™ on the ADVIA 1800 and the ADVIA 2400. From 2013 onwards, BioPorto expects a heightened level of activity in sales and marketing; the design of clinical trials; further widening of and support for our important IP rights; additional IVD registrations; continued optimization of our production quality; and the establishment of partnerships and contracts. This expansion will require an increase in staff, including the influx of additional intellectual resources, which is included in our organizational planning.

The first ground has been broken: little by little, doctors are realizing how they can use NGAL. Many trials have been carried out all over the world and the results show by far that NGAL is the right marker for measuring acute kidney injury. BioPorto has developed the marker in the right format—The NGAL Test™—and launched it for the most widely used analyzers. The method of use is patent protected, also in China. The test could potentially be used more than 200 million times a year, however, this use must be well-documented before doctors begin to use the test on a routine basis. For this reason, BioPorto will carry out additional trials in 2013 to document the diagnostic value of the test and thus support the use of NGAL. Furthermore, BioPorto will be instrumental in preparing information about the use of NGAL and clinical guidelines, which is intended to inspire and guide doctors and encourage them to use the test. In this way, we can proliferate the use of The NGAL Test™, which will improve the plight of kidney-injury patients all over the world. NGAL, do it!



*Thea Olesen,
CEO*

Highlights

Strategic developments in 2012

- » BioPorto is in the process of establishing collaborative agreements with major diagnostics companies concerning the registration, distribution and/or marketing of The NGAL Test™. In 2012 an agreement was entered into with Wiener Lab. Group concerning distribution and marketing in Latin America. Both Siemens Diagnostics and Roche Diagnostics have informed about The NGAL Test™ to all their local divisions, directly referring to the technical validation on Siemens' and Roche's respective analyzers and providing contact details for BioPorto's sales team for buying the test. This is expected to be the first step towards more comprehensive collaboration.
- » Sales of NGAL products increased by 24% to DKK 6.5 million, of which sales of The NGAL Test™ amounted to DKK 1.8 million. Sales forecasts for The NGAL Test™ have been revised downward due to delays in the test's qualification for reimbursement in China and registration in Brazil.
- » The NGAL Test™ is continuously being developed for existing analyzers; as part of this, application notes have been achieved for Siemens' ADVIA 1800 and ADVIA 2400.
- » The NGAL Test™ was approved for registration in China, Russia and other countries in 2012. The test was also approved for registration in Brazil in March 2013. With a view to being approved for registration in the US, the first required trial to identify the normal range of NGAL levels has begun and the trial protocol for the actual clinical trial has been finalized.
- » A decisive factor for implementing The NGAL Test™ into routine diagnostics is to determine the clinical guidelines for the use of NGAL analyses for diagnostic purposes. The initial indications of use comprise diagnosing/monitoring kidney injury resulting from antibiotic treatment and ruling out kidney injury before release from hospital, both of which are used in practice at selected hospitals.
- » The NGAL cut-off patent was issued in China in 2012, which is one of BioPorto's high-priority markets, and the NGAL ratio patent was approved for issuance in the US. In a first instance decision, the European Patent Office rejected the already issued cut-off patent, but the ruling has been appealed and BioPorto expects a favorable outcome. The European patent is fully valid during the appeal. The NGAL ratio patent is BioPorto's first NGAL patent to be issued in the US. Following a case filed by BioPorto against Phadia's NGAL patent in Denmark, the patent was declared invalid insofar as principal claims 1 and 2 are concerned. Phadia has appealed this case to Denmark's Supreme Court.
- » Licensing income of DKK 0.6 million has been received for Instrumentation Laboratories' access to the NGAL IP rights in 2012.

Financial trends in 2012

- » The group's net revenues amounted to DKK 17.9 million in 2012 (2011: DKK 18.3 million). The net revenues are on a par with the most recently announced expectations. Product sales rose 5.5% from DKK 16.4 million to DKK 17.3 million.
- » The net loss for the year in 2012 was DKK 13.9 million (2011: DKK -12.9 million). The loss is in line with the most recently announced expectations.
- » A private placement cash issue was carried out and generated proceeds of DKK 9.6 million.
- » By December 31, 2012, the group's equity amounted to DKK -1,2 million.

Forecast for 2013

- » BioPorto expects its 2013 revenues to be on a par with 2012.
- » A loss is expected in 2013 and is expected to be slightly greater than in 2012 due to the initiation of clinical trials.
- » The most important task in 2013 is to ensure wider routine use and implementation of The NGAL Test™:
 - by continuing the registration process, focusing on the US market;
 - by collaborating with distributors and hospitals concerning the implementation of trials aimed at establishing clinical guidelines and preparing health-economic analyses;
 - by continuing to enter into partnerships with distributors of analyzers.
- » It is expected that further resources will be earmarked to protect the group's technologies by obtaining patent rights and to defend, optimize and expand these rights.
- » At the end of February, 2012, cash in the form of bank deposits totaled DKK 5.2 million, which is expected to finance BioPorto's activities until June 2013. The management estimates the funding needs by the end of May 2013 to be DKK 5-10 million and by third quarter at the latest an additional DKK 15-20 million in order to finance the activities of the group in 2013 and settle the convertible debt due in September 2013. After considering the options available, management has decided to attempt to carry out a rights issue to existing shareholders. The issue, planned for third quarter, is expected to provide BioPorto with funds in the range of DKK 60-70 million

This annual report contains statements regarding forecasts for future developments, including in particular future revenues and net financial results. Such statements are uncertain and risky as many factors, some of which are out of BioPorto's control, may cause actual trends to deviate from the forecasts contained in this report.

Financial Highlights

| | 2012 DKK thousand | 2011 DKK thousand | 2010 DKK thousand | 2009 DKK thousand | 2008 DKK thousand |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|
| Net revenues | 17,858 | 18,584 | 13,802 | 11,008 | 9,875 |
| Earnings before Interest and taxes | (13,870) | (12,858) | (13,411) | (18,017) | (15,477) |
| Income/loss from net linancilas | (2,080) | (1,980) | (796) | 63 | 735 |
| Earnings before taxes | (15,950) | (14,838) | (14,207) | (15,954) | (14,742) |
| Net income/loss for the period | (14,700) | (14,838) | (14,207) | (15,954) | (14,742) |
| Long-term assets | 470 | 572 | 763 | 882 | 1,206 |
| Short-term assets | 17,708 | 20,680 | 20,209 | 19,336 | 17,951 |
| Total assets | 18,178 | 21,252 | 20,973 | 20,218 | 19,157 |
| Capital stock | 141,449 | 135,449 | 126,398 | 126,398 | 114,908 |
| Equity | (1,150) | 3,940 | 3,307 | 15,410 | 15,501 |
| Long-term liabilities | 0 | 12,186 | 11,924 | 0 | 0 |
| Short-term liabilities | 19,328 | 5,126 | 5,741 | 4,807 | 3,655 |
| Total liabilities | 18,178 | 21,252 | 20,972 | 20,218 | 19,156 |
| Cash generated by operations | (15,280) | (13,508) | (13,379) | (13,288) | (13,717) |
| Cash generated by investment, net | (87) | (30) | (207) | (21) | (363) |
| Of which tor investment in property, plant and equipmen | (82) | (23) | (201) | (14) | (1) |
| Cash generated by financing | 9,611 | 13,815 | 13,168 | 14,746 | (507) |
| Total cash flow | (5,756) | 179 | (418) | 1,438 | (14,587) |
| Revenue growth | 4% | 35% | 25% | 11% | 18% |
| Gross margin ratio | 82% | 57% | 81% | 57% | 54% |
| Operating margin | -78% | -69% | -97% | -145% | -157% |
| Equity interest (equity ratio) | -6% | 19% | 16% | 76% | 81% |
| Return on equity | Negativ | Negativ | Negativ | Negativ | Negativ |
| Average no. of employees | 25 | 25 | 23 | 22 | 20 |
| Average no. of shares (1,000) | 45,308 | 43,084 | 42,133 | 39,245 | 38,290 |
| Earnings per share (EPS) DKK | -0.32 | -0.34 | -0.34 | -0.41 | -0.39 |
| Equity value per share, closing, DKK | 0.03 | 0.09 | 0.08 | 0.39 | 0.40 |
| Listed price, closing, DKK | 4.82 | 7.05 | 7.85 | 7.05 | 5.25 |

The routine diagnostics market

BioPorto develops *in vitro* diagnostic (IVD) assays. IVD diagnoses take place outside the body, for instance by analyzing blood and urine samples in a laboratory, as opposed to *in vivo* diagnostics that take place on the patient, e.g. by means of skin prick tests, X-rays, etc. IVD is an essential, objective source of information that can help doctors to detect disease, select appropriate treatments and monitor the patient's response to treatment. In addition, scientists can use new assays to better understand the causes of a specific disease and to discover and develop new treatment methods.

The IVD market is estimated to be around USD 45 billion. More than 50% of all *in vitro* diagnoses take place at hospitals, and other assays are carried out in general practitioners' offices or at home. Clinical laboratories—targeted by BioPorto's The NGAL Test™—comprise the biggest segment. The financial crisis, large national debt (particularly in Europe and the US), but continued growth in the BRIC countries (Brazil, Russia, India and China) were the dominant influences on the healthcare sector in 2012. Therefore, it is assessed that there is still a large appetite for risk in the BRIC countries in terms of investment and the introduction of new technologies, including new biomarkers like NGAL. The healthcare sectors in these countries are generally being improved on an ongoing basis, and the introduction of NGAL is expected to be more progressive than in many European countries, for instance. At the same time, the European market is expected to be marked by the continuing financial crisis which generally puts pressure on public-sector health expenditures. Overall, only slight growth is expected in the global IVD market.

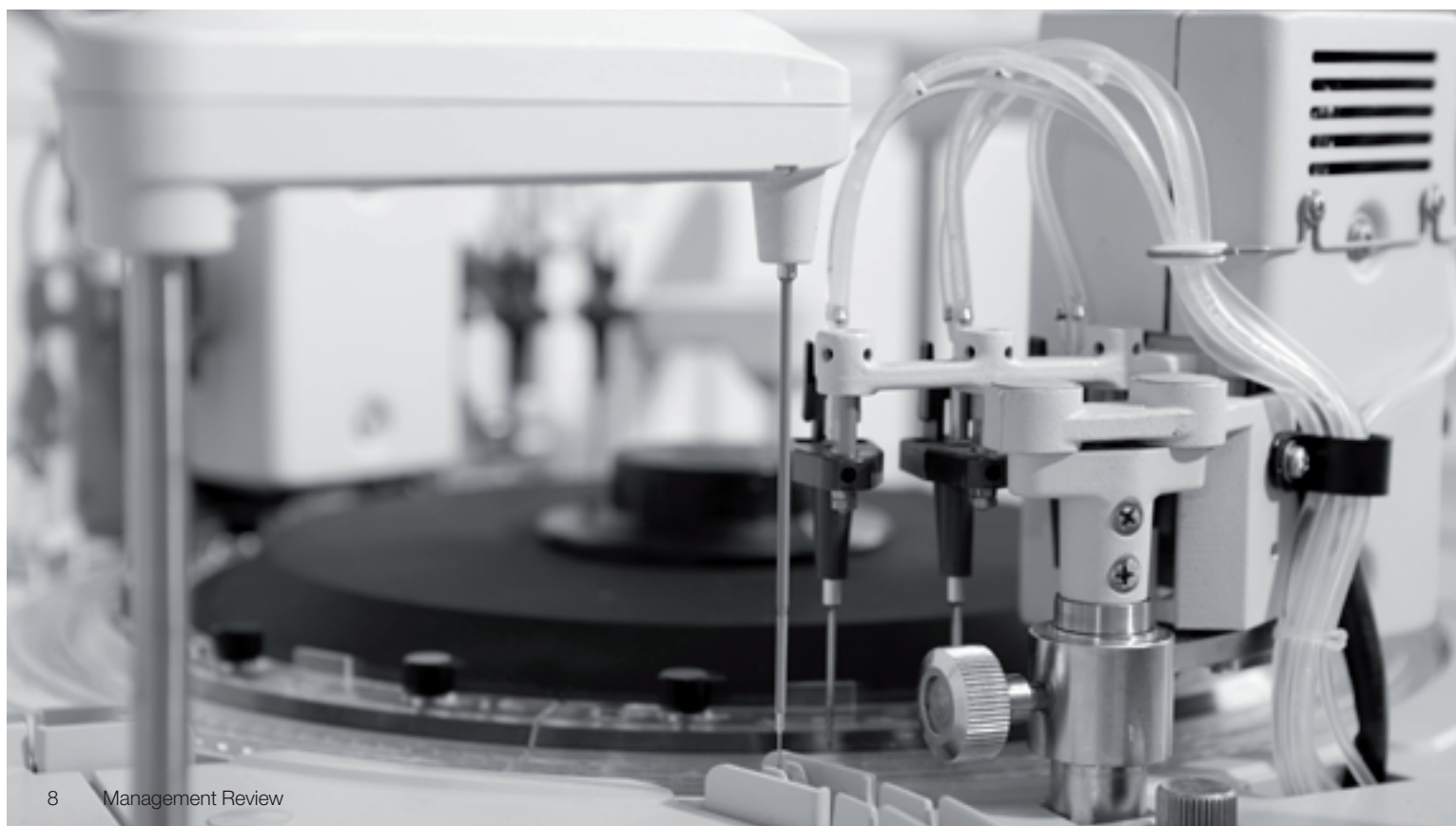
Furthermore, the pharmaceutical and diagnostics industries are currently encountering major challenges in the form of new statu-

tory requirements for higher quality and safety, which increases the cost of R&D and quality-assurance; at the same time, there is an incessant demand for lower-priced diagnostics and medicines. This increases the need for documentation that verifies that costs can be reduced by introducing a new test.

In recent years, the diagnostics industry has been heavily influenced by the consolidation of the largest companies which gain access to new technologies and products through mergers and corporate acquisitions. A natural and alternative method for these companies to grow is by acquiring the sales and marketing rights to innovative new diagnostic assays—such as BioPorto's NGAL Test™—through partnerships, or the rights to new technologies and the development of products—such as BioPorto's IP rights—via licensing agreements.

From launch to implementation in routine diagnostics

The road is long, from the marketing of a new biomarker until it is finally implemented in routine diagnostics. First and foremost, clinical acceptance and the biomarkers' value must be recognized by key scientific experts in the market. After launch, the test method with which the marker is offered must be approved by the health authorities for diagnostic use. Next, the test must be technically and clinically validated, the financial consequences of using the test must be determined, reimbursement must be obtained from authorities/insurance companies in order to perform the test, but, most of all, the individual user/hospital staff must be trained in how to use the test.



NGAL for human diagnostics

NGAL (neutrophil gelatinase-associated lipocalin) is a protein secreted by the kidneys when exposed to harmful action. NGAL is also secreted to a lesser extent by other organs or tissue in the presence of other illnesses, but in the event of kidney injury, the level of NGAL rises sharply and quickly. Today, there is no competing technology for early diagnosis of acute kidney injury. The existing methods for measuring kidney injury, including the most frequently used measurement of serum creatinine, do not indicate kidney failure as a consequence of a previous kidney injury until much later (24 to 72 hours). By comparison, a measurement of NGAL can indicate a harmful kidney effect only a few hours after the effect occurs.

The patient base for NGAL utilization encompasses all critically ill patients, as well as post-operative patients after major surgery, including heart operations. 5–7% of all hospitalized patients will experience acute kidney failure during hospitalization. The NGAL test market is estimated to be more than 200 million tests a year. The use of NGAL tests for diagnosing acute kidney injury will strikingly improve treatment and make it possible to perfect new therapies.

Since 2004, BioPorto has focused on NGAL for the production and sale of NGAL antibodies, the development and production of NGAL ELISA Kits (both human and animal NGAL), carried out trials and studies and filed patent applications, and, in 2011, BioPorto launched The NGAL Test™, which in 2012 obtained recognition for use on the analyzers of several diagnostics companies, including Siemens and Roche.

The NGAL Test™

Sales

The NGAL Test™, BioPorto's homogeneous kidney-injury test, makes it possible for doctors to quickly obtain analysis results concerning a patient's condition, and, as the test is designed as an application for analyzers already found in the laboratory, the hospital does not have to invest in new equipment to start using The NGAL Test™. In this way, the test provides rapid access to the attractive NGAL market for most major vendors of assay systems.

Since the launch of The NGAL Test™, the test has been tested and validated at many different hospitals all over the world. The NGAL Test™ has already been implemented at many hospitals, and it only takes 10 to 15 minutes to measure NGAL using The NGAL Test™ to diagnose acute kidney injury. Most of the analyses sold by BioPorto today are still used for clinical trials, not routine diagnostics. This is because only a limited number of guidelines have been drawn up thus far for the use of this early diagnosis of kidney injury and/or for other uses of NGAL. As a result, only a few doctors have begun to base their decisions on NGAL analyses.

Total sales of NGAL products increased by 24% to DKK 6.5 million, and this product category is now bigger than BioPorto's other product categories. Sales of The NGAL Test™ amounted to DKK 1.8 million of total NGAL sales, which is a 16% sales increase. In the European market, where the test has been sold for IVD use since early 2011, test sales increased 62%, in spite of general

downward trends in Europe in this same period. Sales forecasts for The NGAL Test™ have been revised downwards due to factors such as delays in the test's qualifying for reimbursement in China and registration in Brazil.

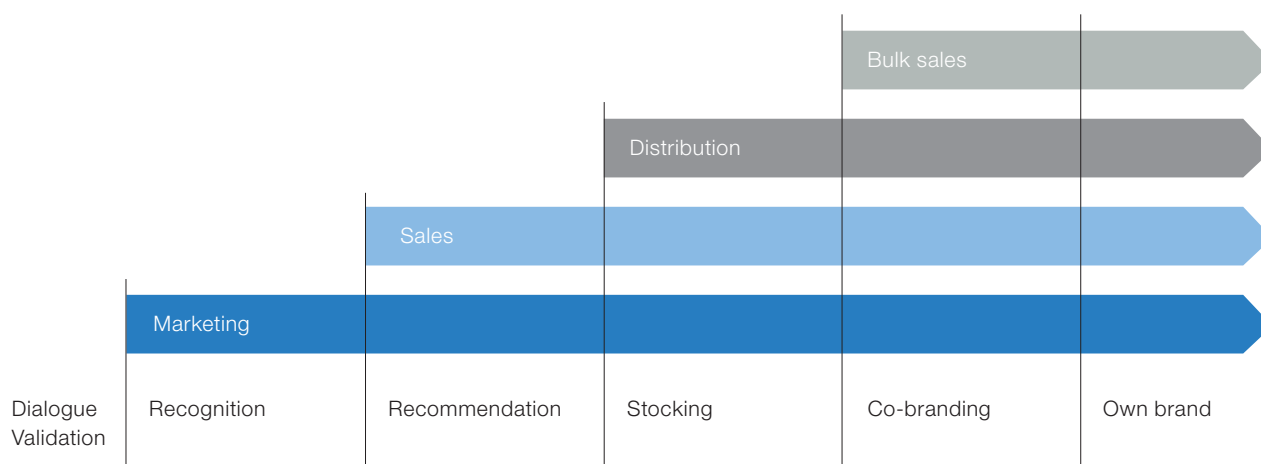
Market penetration is influenced by many factors, including laboratories' possibilities of being reimbursed for the test; results of health-economic calculations; clinical validation; drafting of guidelines for how to use the test; marketing efforts; the competitive situation, and therapeutic possibilities. In particular, other players' marketing—and thus a market acceptance of NGAL—has not generated the expected increase in 2012, and this has had an effect on the implementation of The NGAL Test™. This explains why sales of the test did not reach the rate predicted, and the estimation of market penetration, and thus sales forecasts for The NGAL Test™ in the years ahead, is still subject to great uncertainty. However, BioPorto is planning to increase its activities aimed at carrying out additional clinical trials and to widen its marketing efforts, particularly as regards advising and assisting hospital laboratories and doctors in the implementation phase to increase market penetration.

Sales channels

BioPorto's sales strategy for The NGAL Test™ is based on establishing sales channels via global diagnostics companies marketing their own analyzers and building up a network of distributors to market The NGAL Test™ at national level. The national distributors benefit from their thorough knowledge of local conditions and hospitals, whereas the multinationals benefit from higher sales volumes and the fact that they are marketing combined portfolios of diagnostic products for their own analyzers.

In 2012, BioPorto focused on establishing partnerships with global and regional diagnostics companies/analyzer suppliers to increase the use and implementation of The NGAL Test™. An analyzer supplier can collaborate with an test supplier on several levels. This collaboration can develop in stages over several years (see figure) particularly as part of the implementation of new biomarkers and analyses. BioPorto can benefit from this type of collaboration by gaining direct access to hospital analyzers, increased technical support, heightened awareness and sales, recognition of The NGAL Test™ and NGAL, and consolidation of IP rights. The analyzer supplier gains a competitive advantage by being able to include NGAL in its portfolio and to use this to maintain/enlarge the number of analyzers at the hospitals. Analyzer suppliers will also be able to take part in public tenders concerning tests and analyzers. Even though NGAL tests are still not widely used in routine diagnostics, a number of hospitals include NGAL among the preferred tests in their tender documents.

Collaboration with analyzer suppliers



The first partnership with an analyzer supplier was entered into with Wiener Lab. Group in the spring of 2012. This agreement concerns the registration, distribution and marketing of NGAL test reagents in Latin America. Wiener Lab. Group has existed for more than 50 years and is a market leader in analyzers for small and medium-sized laboratories in core Latin American markets, such as Brazil and Argentina. Wiener Lab Group has initiated the registration process to obtain certification of The NGAL Test™ in Argentina and will subsequently register and market the test in the rest of Latin America.

In addition, Roche Diagnostics and Siemens Diagnostics, the world's largest diagnostics companies and market leaders in the field of analyzers, on which The NGAL Test™ can be used; have issued information to their local divisions and subsidiaries about The NGAL Test™. These marketing letters acknowledge the use of NGAL in the diagnosis of acute kidney injury, provide information about BioPorto's The NGAL Test™ and contact details for BioPorto's sales team. This recognition is expected to be the first step toward collaborating on the proliferation of The NGAL Test™.

In addition to collaborating with global analyzer suppliers, it is important that BioPorto can market The NGAL Test™ through a national distribution network. National distributors are faster at marketing a new marker than global diagnostics companies, and this cultivates the market for a more general proliferation of The NGAL Test™ as well. During 2012, BioPorto did not significantly increase the number of markets in which the test is marketed by national distributors. On the other hand, focus and resources were applied to boosting close collaboration with distributors concerning the implementation of The NGAL Test™ in the existing markets. In 2013, there are plans to widen this type of sales channel to include regions like the Middle East, Eastern Europe and selected markets in Asia.

Market penetration

New diagnostic markers with NGAL's potential of more than 200 million tests a year are rarely introduced into the market. BioPorto has made great strides since it submitted its first NGAL patent

application in 2004 and the first NGAL ELISA kit was launched in 2005, up to the present where the proper format of the test—The NGAL Test™—has been launched and CE-marked. There is still a way to go before NGAL is generally accepted as a marker and The NGAL Test™ is implemented for full routine diagnostic use. There are several factors affecting market penetration, the most important of which are dealt with in the following:

Registration

In order to be able to market a diagnostic product, the product must undergo a registration process with the health authorities in each individual market. The process of registering The NGAL Test™ began with CE marking in Europe. In 2012, two registration approvals of The NGAL Test™ were obtained from China's State Food and Drug Administration (SFDA) through two of BioPorto's distribution partners. The NGAL Test™ has also been approved for registration in Russia, Taiwan and Chile. An import license has also been obtained in Columbia. An application for the registration of The NGAL Test™ was submitted in Brazil in 2012 and approved in March 2013.

As the US constitutes roughly 45% of the combined IVD market, substantial resources are being expended on achieving registration of The NGAL Test™ with the US Food and Drug Administration (FDA). The FDA recommended having a clinical registration trial carried out in the US to verify the use of the test under American conditions. In 2012, BioPorto initiated dialogue with the FDA through the Pre-IDE Program concerning the design of the clinical trial protocol to obtain the clinical data required. The FDA issued a statement about the protocol and the FDA proposals have been incorporated into the commission for the clinical trial sites. Collaboration is under way with specialists aimed at the entering into contracts both with US contract research organizations and with hospitals that will take part in carrying out the clinical trial. Once these are in place, the protocol must be reviewed and approved by the ethics committees affiliated with the individual participating hospital units. Once the ethics committees have issued positive statements, the collection of samples can begin. The trial is expected to be carried out in 2013 and will lay the basis for a revised registration application. Concurrent with the clinical trial, a smaller

and faster trial will be carried out to determine the normal range of NGAL levels. The collection of samples for this trial began in January 2013.

Reimbursement

Diagnostic assays are often eligible for economic reimbursement via the public healthcare system or private health insurance. Naturally, an test can be marketed and sold without obtaining such reimbursement, but in order for an test to become a widely-used routine marker, reimbursement is an important incentive for this implementation. More widespread use of the test as a result of being eligible for reimbursement is also expected to lead to further clinical validation and drafting of guidelines for use (see the discussion of this on page 14). By way of several distributors, BioPorto has initiated applications for reimbursement for The NGAL Test™, a process which could take up to several years. In 2013, reimbursement is expected to be obtained in several provinces of China as well as from Czech authorities. If other players in the NGAL market qualify for reimbursement for their test, this will have a positive impact on BioPorto's reimbursement process, because comparable tests already qualified for reimbursement could ease the application process.

Health-economic consequences

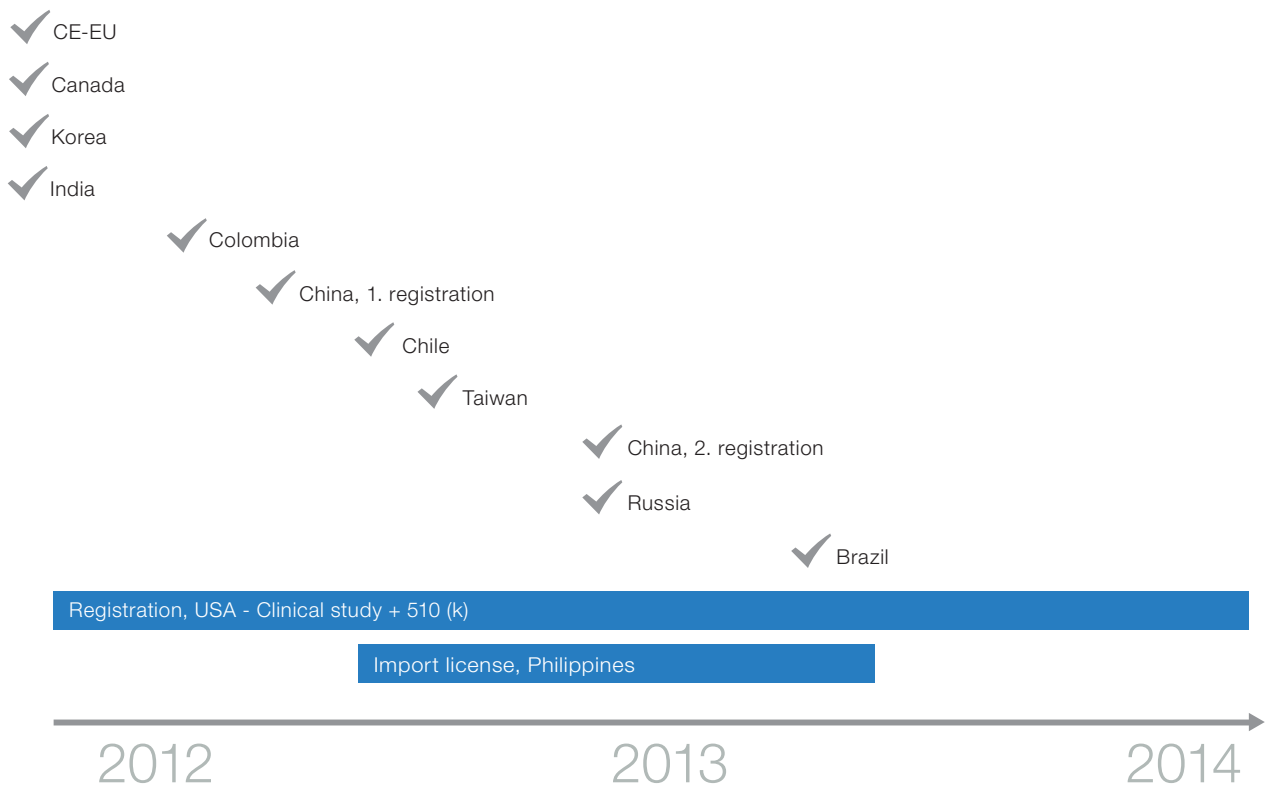
Another significant factor is being able to document the health-

economic aspects for the use of the test. The first theoretical cost-benefit analyses published show a clear financial advantage of using NGAL for diagnosing acute kidney injury. Even so, it is important to carry out additional and actual analyses based on the clinical use of the test.

In the UK, BioPorto's distributor has applied to the National Institute for Health and Clinical Excellence (NICE) Medical Technologies Evaluation Programme (MTEP), for an evaluation of The NGAL Test™. NICE MTEP assesses new methods and technologies primarily with a view to the financial advantages and, on this basis, makes recommendations to the National Health Service to enable the healthcare authorities in the UK to implement new methods and technologies more efficiently. In late 2012, BioPorto received NICE's assessment of the applicability of NGAL and The NGAL Test™. Basically, NICE MTEP expects there to be substantial advantages related to early diagnosis of acute kidney injury. Insofar as the use of NGAL and The NGAL Test™ is concerned, NICE MTEP assesses that there is a need for further clinical trials which, among other things, could lay the basis for clinical guidelines for treating patients diagnosed using NGAL. As a follow-up to this assessment, BioPorto and the UK distributor have entered into dialogue with NICE MTEP to identify the exact specifications of requirements for performing these trials.

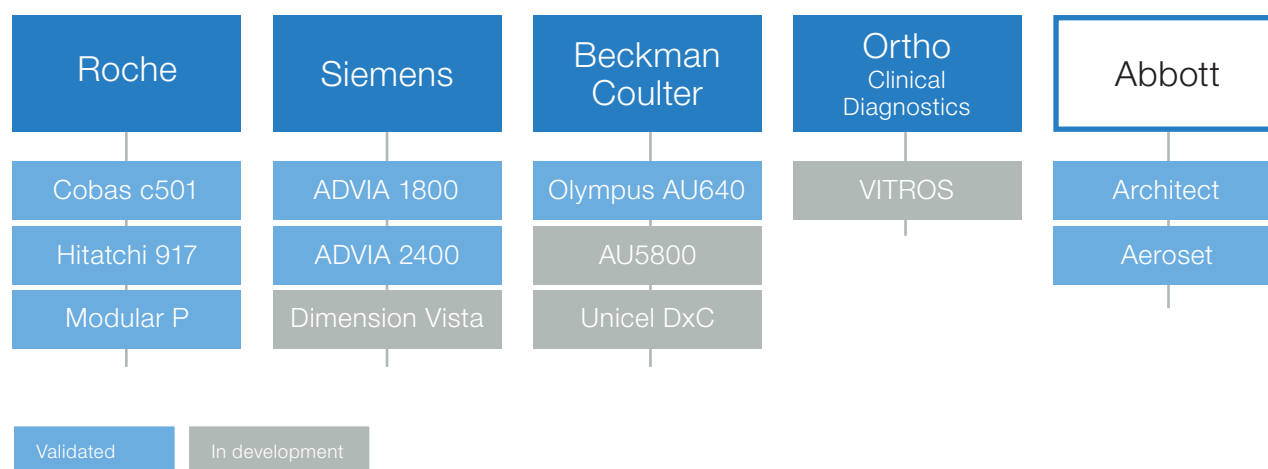
BioPorto will work with distributors and hospitals to motivate the implementation of cost-benefit analyses.

Registration Proces



Registration/official certification is under way in a number of other countries and is on schedule in order of priority. The present status of diagnostic availability of The NGAL Test™ is shown in the outline.

Technical validation – application notes



Overview of application notes – validated and in development.

Technical validation

The NGAL Test™ is designed as an application for analyzers already found in the laboratories of just about every hospital. The test has been adapted to the most widely used systems, but there will always be analyzers on which it is more complicated to get the test to work than others. Furthermore it is essential for several of the analyzer suppliers to carry out their own validations of the test, a process which can take several months. BioPorto is continuously and ambitiously working to increase the number of analyzers on which The NGAL Test™ can be used. This takes place in close collaboration with distributors, customers and analyzer suppliers. In 2012, BioPorto earmarked additional resources for the technical validation of the test on several analyzers, which, in collaboration with Siemens, resulted in further validations of The NGAL Test™ on the analyzers ADVIA 1800 and ADVIA 2400.

In 2012, a number of articles were published in international scientific journals which validate and verify the technical application of The NGAL Test™, in part on analyzers for which BioPorto has prepared application notes and in part on analyzers still awaiting validation, such as professor G. Lippi's article on the use of The NGAL Test™ on Beckman Coulter's new flagship the AU5800 and Dr. A. Bakker's documentation of performance on Roche's Modular P analyzers.

A number of additional application notes for analyzers from Ortho Clinical Diagnostics, Beckman Coulter and Siemens are being prepared and expected completed in the course of 2013.

Clinical validation and guidelines for use

For several years, doctors around the world have been studying the clinical use of NGAL as a diagnostic marker for acute kidney injury. Trials studying NGAL's efficacy and use, and articles published by doctors on the topic of acute kidney injury are crucial

for the implementation of NGAL for diagnostic use. Such clinical validation and guidelines for use will lay the groundwork for training and informing other doctors, which will pave the way for widespread, routine implementation.

BioPorto presented its own scientific results at the annual meeting of the American Society of Nephrology in 2012. The scientific results document that BioPorto's The NGAL Test™ is optimal for diagnosing acute kidney injury and that any input which interferes with NGAL levels, such as from infection, septicemia or cancer, does not change the diagnosis of kidney injury when The NGAL Test™ is used. BioPorto also expects to publish results relating to NGAL in 2013 and these results are expected to bolster the clinical validation of The NGAL Test™.

This topic is described in more detail in the section on page 14.

Marketing

In 2012, BioPorto primarily focused its marketing of The NGAL Test™ in markets where an IVD registration process has been carried out. A significant effort is being made to support the company's distributors, and The NGAL Test™ is also marketed at conventions and trade fairs. In addition, the marketing of The NGAL Test™ increasingly uses doctors and professors who are knowledgeable in the field of kidney-injury diagnostics, as it is crucial to support the information provided with scientific documentation.

At present, there are two other vendors of NGAL assays for the diagnostics market: Abbott (heterogeneous assay) and Alere/Biosite (point-of-care assay). Abbott's and Alere's marketing of their respective NGAL assays helps to engender acceptance of NGAL as a valid kidney-injury marker, and these two companies are also expected to expedite The NGAL Test™ through various registration and reimbursement processes. In terms of competitive pa-

rameters, BioPorto has both the most applicable test in the homogeneous format and the IP rights to NGAL (see p. 16 for further details). Other players' marketing—and thus market acceptance of NGAL—did not generate the expected increase in 2012, however, and this had an effect on the implementation of The NGAL Test™.

Therapy and treatment

The use of NGAL assays for diagnosing acute kidney injury will strikingly improve treatment and make it possible to perfect new therapies. Diagnostics and therapy are mutually interdependent, and the lack of an outright kidney-injury therapy is deemed to be closely related to the previously limited options for detecting kidney injury in time. Great strides have been made in developing therapies in this area, and the possibility of earlier diagnosis already enables several other options for treating kidney-injury patients (see further details in the section "Clinical Use of NGAL", page 14).

With a view to developing therapies, in 2012 Abbott obtained the rights to the medicine AP214 for the prevention of acute kidney injury during heart surgery. The product can presumably also be used to treat acute kidney injury in critically ill patients if treatment is initiated early in the process, e.g. when an NGAL increase is indicated.

Expectations and risks

There are many unknowns in the equation concerning the anticipated market penetration of The NGAL Test™. The test is new to the market and must undergo registration and reimbursement processes in the various markets; the major diagnostics companies must first include the test in their portfolio, and the test must gain widespread acceptance as a kidney-injury marker by hospitals and doctors. In the years ahead, tests will be submitted for validation and trial set-ups, but at the same time, the initial routine set-up of the test is also expected.

The NGAL market is expected to exceed 200 million tests a year, of which BioPorto expects to achieve a market share of more than

50%, once The NGAL Test™ is fully implemented. Eventually, the price level is expected to decline concurrent with increasing implementation and use. When fully implemented, the price per unit for the end user is estimated at DKK 50–100 in the industrialized countries and somewhat lower in other markets. Sales of the test are expected to grow exponentially.

The following prerequisites are expected to be achieved in the near future and are expected to have a positive impact on test sales and possibly on entering into licensing agreements:

- » Reimbursement schemes for The NGAL Test™ are obtained in several European countries;
- » Registration and reimbursement approval are obtained in China and Brazil for use of the test;
- » The NGAL Test™ qualifies for FDA approval and can be launched in the US market;
- » Agreement is entered into concerning the distribution of The NGAL Test™ through major global analyzer suppliers.
- » The Phadia case is decided in BioPorto's favor (alternatively, the patent expires in 2015);
- » The appeal brought before the European Patent Office concerning the cut-off patent being decided in BioPorto's favor.
- » A number of trials involving NGAL being carried out for the purpose of cost-benefit analyses and establishing clinical guidelines.

Significant risk factors could delay this penetration:

- » Failed or delayed registration of The NGAL Test™ on the important markets;
- » Delay of reimbursement schemes for The NGAL Test™;
- » Insufficient clinical acceptance of NGAL as a kidney injury marker, including the failure to establish clinical guidelines;
- » Inadequate healthcare-economics analyses for the use of NGAL in routine diagnostics;
- » Unanticipated competition from existing or new NGAL tests;
- » IP rights of BioPorto/other companies in important markets.

Clinical Use of NGAL

In order for a new biomarker to be successfully and widely implemented as part of routine diagnostics, it is crucial to define the clinical procedures describing a patient's care pathway after diagnosis is made.

From the time the first examples of clinical use are available until an test has achieved full market penetration, comprehensive educational and implementation efforts relating to clinical practice are involved. Achievement of higher volumes is expected after doctors and/or clinical forums have drawn up guidelines for the recommended use of an assay at the specific hospital/ in the specific country (specifying patients, number of analyses per patient, etc.). Once such guidelines have been prepared, training and informing doctors in the individual departments can commence, thus paving the way for widespread, routine implementation.

Since the launch of The NGAL Test™, BioPorto has worked intensely with the company's distributors to have the test sent out for trials at hospitals all over the world. The first NGAL workshop was held in the Czech Republic for clinicians and laboratory managers as early as May 2011, only three months after the official launch of The NGAL Test™.

There is sustained interest in NGAL in the Czech Republic and validation processes have been carried out at 20 hospitals so far. At several of these, clinical trials involving NGAL are now under way, and a Prague hospital has gone one step further and become the very first hospital to implement The NGAL Test™ for routine use.

At the hospital's affiliated intensive care unit, NGAL was used on selected patients on an ongoing basis during 2012. It was not used in a formalized clinical trial but on a case-by-case basis. The purpose was not to demonstrate that NGAL can prove the existence of kidney injury, as this was proven by clinical research long ago. Instead, the purpose was to find the proper way to use NGAL in day-to-day routines in the intensive care unit. Even though heaps of scientific articles are available concluding that NGAL is a good marker for diagnosing acute kidney injury, written clinical guidelines for the actual use of NGAL are still few and far between. In this case, therefore, the unit had no choice other than to proceed by the method of trial and error.

NGAL as a marker of kidney injury caused by antibiotics

The intensive care unit specializes in nephrology and, based on the unit's affiliation with the hospital's internal medicine ward, the unit receives many patients with infectious diseases requiring antibiotic treatment. Many of these patients are treated with particularly strong

antibiotics which have the unfortunate side effect that they are nephrotoxic and can thus injure the kidneys.

One of the most frequently used antibiotics for severe bacterial infection is gentamicin. Gentamicin has a narrow area of concentration within which the substance is both reliable and effective. The administration of high concentrations over a long period of time can cause kidney injury, among others. It is therefore crucial that patients with impaired kidney function or who are at risk of kidney injury are closely monitored while being treated with gentamicin, as nephrotoxicity caused by gentamicin can be difficult to differentiate from symptoms of the underlying kidney disease.

Therefore, it is common clinical practice to monitor gentamicin levels in the patient's blood while treatment is in progress. A routine assay which is technically reminiscent of The NGAL Test™ is used for this purpose.

Research in the area has established direct correlation between the measurable level of NGAL in urine or blood and the extent of kidney injury. Therefore, by contrast with current guidelines where the dose administered is adjusted in proportion to the level of gentamicin in the blood, daily NGAL measurements provide an additional means of adjusting the dose administered in proportion to the extent of kidney impact. This is because kidney sensitivity is highly individual. Some patients can withstand a high dose of the substance whereas others experience kidney injury at doses below the level commonly used. Some patients have a very low tolerance for gentamicin, and if they have a higher level of NGAL this could indicate to the doctor that the treatment should be stopped or that a different medicine should be considered.

Initial trials have proven the efficacy of this treatment approach. This is exemplified by a patient who—even after the gentamicin dose had been reduced due to an excessively high level of gentamicin in the blood—still had a high NGAL level, which is a sign of ongoing kidney injury. The high NGAL level (660 ng/mL) prompted the doctor to stop the gentamicin treatment.

Another example is a patient with a chronic kidney disease. NGAL is an injury marker which is also fully applicable in instances where an acute injury occurs on top of an existing kidney disease. Patients with chronic kidney disease have constant or only slowly rising levels of serum creatinine, which is higher than the normal values. The NGAL level is also fairly constant but increases to high levels in the event of a newly occurring injury.

In this case, the patient had sharply increased levels of both NGAL and serum creatinine. Therefore, the doctor decided there was no other option than to put the

patient on dialysis and stop further injury by replacing the nephrotoxic gentamicin with another antibiotic.

These cases clearly show how patients can benefit from the use of a marker like NGAL which provides real-time information about the kidney's condition. NGAL is very useful for guiding antibiotic treatment, especially for groups of patients already at risk of kidney injury. On the basis of this, NGAL can help the doctor take critical decisions earlier on and thus stop the ongoing kidney injury before it develops into potentially fatal kidney failure.

In a wider perspective, these lessons learned are yet another example of the apparent shortcomings of the current tradition of kidney-injury diagnostics based on serum creatinine. Serum creatinine simply does not react quickly enough to be suitable for guiding treatment, which is possible with NGAL.

Other use of NGAL

NGAL has also been used in other countries. In Finland, a major hospital has just started to use NGAL on a routine basis in conjunction with heart surgery, and two more Finnish hospitals are expected to follow suit soon afterwards. NGAL has already been used for some time in France and Germany, primarily as an exclusion marker for kidney transplants.

It should be noted that although this involves relatively limited routine use, this does not make these initiatives any less important. An experience base must be created at the hospitals to show the value attributable to NGAL for selected patient groups, one at a time.

In Denmark, Hvidovre Hospital is in the process of preparing just such a quality assurance trial using NGAL, aimed at improving the quality of treatment of patients with septicemia and SIRS.

At a university hospital in Germany, the use of the test has been evaluated in relation to a wide selection of the hospital's areas of clinical specialization, including intensive care, surgery, accident and emergency care, pediatrics, cardiology, gynecology, hematology and gastroenterology, all of which have used the test. Most analyses (50% of the total number) were requested by the nephrology ward which uses NGAL analyses in conjunction with all kidney transplants where these analyses are used to guide the immunosuppressive treatment with steroids. This has been instrumental in preventing the acute rejection of the transplanted kidney. In this context, urine NGAL levels have successfully differentiated between rejection-based acute kidney injury and other causes—at a very high level of diagnostic sensitivity and specificity. Based on this practical experience, the doctors conclude that NGAL

analysis is an important tool for increasing diagnostic accuracy and ensuring correctly dosed treatment in the event of kidney failure after transplantation.

The clinical chemical unit of an Athens hospital uses measurements of lower NGAL levels to exclude the presence of kidney injury. This negative predictive value of NGAL is absolutely certain. A low level of NGAL is a powerful tool for clinical decision-making and can be reliably used as a diagnostic exclusion criterion, e.g. for assessing whether a patient can be released from hospital.

In addition to a comprehensive number of scientific articles, NGAL was also included in a 2012 handbook for doctors concerning new biomarkers, edited by Dr. Alan Maisel, a recognized professor of medicine at the University of California, San Diego. An entire section of the chapter "Assessing Kidney Injury in Heart Failure: The Role of Biomarkers" is devoted solely to describing the effects of NGAL. The section's first line states that "Arguably the most analyzed and promising novel biomarker for AKI is neutrophil gelatinase-associated lipocalin (NGAL)." Both scientific articles and textbooks such as this constitute important elements of disseminating NGAL-related knowledge and early diagnosis of acute kidney disease.

Although published guidelines concerning the specific use of NGAL are few and far between, the use of NGAL in practice is definitely in the process of being documented. These trials and new, substantiated methods of use will be promulgated in the form of recognized guidelines as the message is gradually disseminated and doctors all over the world begin to use the marker on a routine basis.

NGAL - manual methods

Manual analysis methods, such as ELISA kits, require more technical expertise of a laboratory employee than is the case for using The NGAL Test™, as the former methods are used to carry out the analysis manually. In addition, this analysis method is more time-consuming per analysis and is best suited for carrying out many analyses at exactly the same time, such as when analyzing frozen patient samples from a clinical trial.

BioPorto was the first player to enter the NGAL market when it launched an NGAL ELISA kit in 2005, and a fast-track version (one-hour procedure) of the kit was launched in 2006. The marketing and sale of BioPorto's NGAL ELISA kits have been crucial for

analyzing samples from clinical trials and clinical documentation for NGAL as a fast, specific biomarker of acute kidney injury. Over the years, the number of competing products for research has increased and there are currently 10 or 12 different NGAL ELISA kits on the market.

BioPorto's NGAL ELISA kits are frequently cited in scientific articles, and BioPorto's total sales increased by 28% for the two NGAL ELISA kits in 2012. The reason for this growth is that in 2012 a number of coordinators of major international clinical trials chose to use BioPorto's ELISA kits to analyze NGAL in clinical samples. The analysis of the biomarker NGAL as part of clinical trials is expected to continue for many years to come.

Intellectual property rights

The group expends much of its resources on continuously seeking to protect the group's technologies by acquiring patent rights and defending, optimizing and extending these patent rights.

BioPorto has obtained a number of patent rights within the NGAL field. The group's NGAL cut-off patent is the principal patent in BioPorto's portfolio of NGAL IP rights and is crucial to the group's strategy in the promising NGAL market. The NGAL patents make it possible to guarantee higher sales of BioPorto's own products and to exercise BioPorto's rights vis-à-vis competitors in the event that competitors sell NGAL tests for acute kidney-injury diagnosis without having licensing access to these patents. Obtaining a patent is not a prerequisite for enabling BioPorto to sell its products, however. The NGAL IP strategy is to retain the patent rights to the homogeneous test format, but to grant licenses for NGAL tests developed in the heterogeneous test format.

The group's NGAL cut-off patent is the principal patent in BioPorto's portfolio of NGAL IP rights and is an important asset for achieving the largest share of the future NGAL market. The NGAL cut-off patent describes the cut-off of 250 ng/mL or higher that can be used for diagnosing acute kidney injury. As actual use of NGAL as a diagnostic marker gradually increases, it is considered that the patented cut-off will be borne out.

Several other stakeholders, including major diagnostics companies like Abbott, Alere and the Cincinnati Children's Hospital (CCH), have found the NGAL cut-off patent to be so decisive that they have tried to have the patent invalidated. This occurred in 2009, for instance, where CCH filed a lawsuit against BioPorto with an unfounded claim that BioPorto had encroached on the invention comprising the NGAL cut-off patent. This case was withdrawn after about six months, after which the patent was issued in Europe.

After the issuance of the NGAL cut-off patent, Abbott, Alere, Phadia and Getica sought to eliminate the patent in Europe by filing an opposition case with the European Patent Office (EPO). In February 2012, the EPO made a first-instance decision stating that the patent does not describe the invention with sufficient clarity for the method to be carried out as specified in claim 1 (Art. 83, EPC), by citing the following reasons for its decision:

- 1) The cut-off limit of 250mg/mL is not sufficiently substantiated. The EPO has incorrectly calculated the specificity, and this

leads to an erroneous conclusion in the decision. Moreover, it is worth noting that Alere, which took part as an opponent in the case, has published data on its own insert slip which substantiates BioPorto's cut-off limit of 250 mg/mL; this has been submitted as evidence in the pending appeal.

- 2) It has not been rendered probable that the method can diagnose all types of kidney injury, e.g. that BioPorto has not proven on a balance of probabilities that chronic kidney injury, for instance, can be diagnosed using this method. The EPO has misunderstood the purpose of the patent. The purpose is to diagnose kidney injury, regardless of the type of injury, with sufficient probability for a diagnostic assay.

As BioPorto clearly expects to be able to reverse the decision, an appeal has been filed with a court of second instance (Board of Appeal). The patent is fully valid and the patent rights can continue to be enforced during the appeal. A ruling in the case by the EPO is expected in the course of 2014.

In December 2012, BioPorto's NGAL cut-off patent was certified for issuance in China, one of BioPorto's high-priority markets. Obtaining patent protection is crucial for the marketing of The NGAL Test™ in China. BioPorto has now obtained essential IP rights to NGAL as a test method for diagnosing acute kidney injury in China, Europe, India, Japan, New Zealand, Singapore, Hong Kong, South Africa, South Korea, Australia and Israel. All that remains is the final processing for the cut-off patent applications submitted in the US and Canada.

In addition to the cut-off patent, BioPorto continues to develop its patent portfolio to ensure broad, strong protection of its NGAL technology platform. So far, the portfolio includes:

- » The NGAL-exclusion patent application, which is complementary to the cut-off patent and involves lower NGAL levels, which rule out an immediate risk of kidney injury. Patent applications have been submitted in Europe, the US and Japan, and all are being processed.
- » The NGAL-ratio patent application, which involves the use of a ratio between NGAL concentrations in urine and plasma for increasing the diagnostic specificity and sensitivity for 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. On the basis of this application, BioPorto achieved its first patent in the US in 2012. The final processing of submitted applications is still under way in Europe and India.

- » The NGAL-trauma patent application deals with NGAL analysis of plasma or urine to assess the severity of physical traumas. The European patent was issued in 2011 but was countered by an opposition case filed by an unknown third party in September 2012. This opposition was expected as opposition cases are usually filed in an effort to limit other companies' patent rights in areas of commercial interest. BioPorto's NGAL trauma patent is strong, and the opposition case is not expected to result in any changes to the patent rights obtained. This patent constitutes a significant protection of the company's rights in the utilization of NGAL in Europe's expanding point-of-care market, including NGAL measurements at emergency care units, trauma centers and, potentially, in ambulances. The patent is fully valid in Europe during the opposition case. In addition, BioPorto has submitted a patent application in the US and is awaiting the final processing of this.
- » The NGAL-forms patent application deals with an analysis of individual molecular forms of NGAL in urine and blood to increase the diagnostic specificity of illnesses characterized by different increases in the levels of these forms, including acute kidney injury. Patent applications have been submitted in Europe, the US, China and India, and the applications are being processed in the first three areas.

In March 2012 the US Supreme Court issued its decision in the case of *Prometheus v. Mayo Labs*, whereby Prometheus' patent no. 6,355,623 was ruled invalid, by citing that the patent describes a natural phenomenon. In the wake of this, the United States Patent and Trademark Office (USPTO) published guidelines in July 2012 for US patent examiners handling diagnostic patent applications. BioPorto's patent consultant, Susanne Høiberg, has analyzed both the ruling and the guidelines and concludes that diagnostic patent applications in the US should generally expect to be met with Prometheus objections. Susanne Høiberg assesses, however, that it is possible to counter Prometheus-based objections to BioPorto's diagnostic patent applications because the guidelines published include specific and relevant examples of what is acceptable. To obtain the best possible results for BioPorto's US patent applications by, among other things, obtaining as much knowledge as possible on how to avoid the Prometheus issue, BioPorto has decided to file continuations in those US patent applications submitted by BioPorto which have been met with objections from the USPTO. A continuation postpones the case processing, but patent rights may continue to be enforced from the date of the publishing of the application. So far, continuations have been filed in the US NGAL exclusion application and the NGAL forms application.

Other parties' NGAL rights

NGAL is widely accepted as a kidney injury marker and has great market potential, which also explains the existence of patents and patent applications from other sector players.

CCH's NGAL-related patents and patent applications in Europe and the US are not expected to affect BioPorto's market access, even if, contrary to expectation, they were to be issued (or upheld after opposition or appeal). However, to dispel any doubt about the use of CCH's rights, opposition cases have been filed against the patents issued to CCH in Europe. CCH's European NGAL-urine patent was

withdrawn in 2011 as a result of a ruling in the opposition case by the EPO. The ruling was appealed by CCH to the second instance in March 2012 and the case is currently being processed. Abbott has licensing access to this patent. BioPorto has also filed an opposition case against CCH's European NGAL-serum patent and a ruling in this case is expected in 2013. Alere has licensing access to this patent.

Alere was issued with a patent in the US in 2012. The patent concerns the use of NGAL for diagnosing the risk of kidney injury in conjunction with the cardiorenal syndrome, characterized by heart and kidney failure. BioPorto has analyzed the patent and believes that the patent will not obstruct BioPorto's access to the market. Irrespective of this assessment, however, BioPorto will initiate an inter partes patent review before the USPTO, as the patent lacks both novelty value and inventive step. An inter parties patent review is equivalent to filing an opposition case with the EPO.

In December 2006, BioPorto filed a patent invalidity case against Phadia's European patent DK/EP 0 756 708 in Denmark, particularly focusing on rendering invalid the patent's claim 1 which cites the use of HNL (another designation of NGAL) as a diagnostic marker of human illness. BioPorto's assertion that the patent's claims 1 and 2 are invalid in Denmark was upheld by the Maritime and Commercial Court in its ruling of June 2012. At the same time, the Court did not accept Phadia's claim for a ban against and damages in tort for BioPorto's sales of NGAL kits. Phadia appealed this decision to Denmark's Supreme Court in July 2012, and the court hearing will take place in June 2014. Phadia's patent expires on April 21, 2015.

BioPorto is constantly monitoring existing and new patent applications in the sector and assessing their potential impact on BioPorto's market access.

Licensing access to BioPorto's IP rights

With the products and IP rights in the NGAL field that BioPorto has today, the group expects to follow two routes towards achieving shares of the routine diagnostics market: namely by marketing The NGAL Test™ and by entering into licensing and collaboration agreements with other diagnostics companies concerning the marketing of NGAL tests in other formats: POC and heterogeneous. BioPorto is willing to enter into licensing agreements for NGAL IP rights for test formats other than homogeneous.

The first licensing agreement concerning access to the group's NGAL IP rights was entered into with Instrumentation Laboratory in February 2011. The overarching financial terms comprise payments totaling EUR 2 million, divided into several milestone payments, and a royalty rate of 5.5%. The first installment of EUR 250,000 fell due for payment on the date of entering into the agreement; the second installment of EUR 75,000 for access in 2012 has been received. As the licensing agreement is non-exclusive, BioPorto may enter into additional licensing agreements concerning access to NGAL IP rights, thereby ensuring that the market gets the widest possible access to NGAL. There have been ongoing negotiations with other prospective licensees, but the negotiations in process have been influenced by the important patent cases. Negotiations are expected to be resumed as soon as there are favorable developments in the patent situation in Europe and the US.

BioPorto believes that an NGAL test for diagnosing kidney injury in relevant patients cannot be marketed without the manufacturer having to pay for licensing access to BioPorto's patent rights. Competitive vendors without a license who violate BioPorto's patent rights could face an injunction and claim for damages.

NGAL for the pharmaceutical industry

Today, the NGAL biomarker is in the process of becoming a recognized routine diagnostic marker of kidney injury. As part of the process of recognizing a new biomarker, it is important to influence the greatest number of prospective users of the test. Exerting influence on several different market segments (the IVD market and the pharmaceutical industry) at the same time increases the likelihood of achieving widespread market acceptance more quickly. For this reason, BioPorto also aims its marketing of The NGAL Test™ at the pharmaceutical industry, which can use the test in the developing and testing of new medicines. Sales to the pharmaceutical industry can provide a quicker route to recognition, because of this industry's enthusiasm for trying out new cost-saving methods.

The cost of developing a new medicine can be reduced if the proper tools are available in an early development phase to weed out prospective medicines that are ineffective or produce undesirable side-effects such as being harmful to the kidneys. This means that there is a potentially large and important market for NGAL for testing experimental animals. By comparison with present methods, the NGAL test could reduce the number of laboratory animals used per prospective medicine, which would benefit the pharmaceutical industry both ethically and economically. For this reason, BioPorto

has also developed and markets a number of animal NGAL products, thus enabling the company to market a complete NGAL portfolio of high quality products for both animal and human experiments. In 2013, BioPorto expects to complete the animal NGAL product portfolio by launching an ELISA kit for the measurement of NGAL in monkeys.

Preliminary clinical results from experiments on monkeys have demonstrated a good dose-response ratio between the administering of a nephrotoxic substance and the level of NGAL in monkey urine. These results sparked the interest of the US FDA and the Predictive Safety Testing Consortium (PSTC), and have resulted in the initiation of additional technical and clinical validation as regards the measurement of NGAL in both dogs and monkeys.

In 2012, The NGAL Test™ was also used for clinical trials involving humans as part of testing a new medicine. BioPorto has been informed that NGAL was included in these trials following encouragement for its inclusion by the US FDA as part of working out the final trial design. If it is deemed useful to include NGAL as an efficacy marker in future clinical trials, this will have a major impact on the use of NGAL and The NGAL Test™.

Other products

In addition to products for measuring NGAL, BioPorto also markets a number of other products for use in both diagnostics and research.

APC-PCI ELISA Kits

APC-PCI stands for "Activated Protein C with Protein C Inhibitor Complex", tiny amounts of which form in the blood once the blood coagulation process is triggered and Protein C (blood-coagulant regulator) is also activated. Activated Protein C (APC) has coagulating and anti-inflammatory effects.

BioPorto markets an APC-PCI ELISA Kit for research use that measures APC-PCI in blood plasma. Studies in this area have spurred great expectations for the use of APC-PCI as a biomarker for septicemia (blood-poisoning) patients with a view to selecting patients suitable for specific treatment. Severe septicemia is a complex, dangerous condition with a very high mortality rate. There are approximately 2.3 million cases of severe septicemia a year in the industrialized world.

BioPorto is the only company to commercially offer a method for measuring APC-PCI in human plasma samples. BioPorto has applied for a patent in Europe, the US, Japan and Canada concerning the diagnostic use of the marker for selecting patients with severe septicemia for special treatment. In January 2012, this patent was issued in the US and approved for issuance in Europe. In 2013 BioPorto is continuing its efforts to clinically evaluate the APC-PCI assay and explore its options for entering into licensing agreements with central players.

MBL Oligomer ELISA Kit

Mannose-binding Lectin (MBL) is an important molecule in the innate immune response. MBL deficiency can affect a patient's effective ability to combat a foreign organism such as a virus or a bacterium. For genetic reasons, 12% of the population of the industrialized countries is fully or partially deficient in MBL. This is of no importance, provided that the adaptive immune response functions optimally, but during chemotherapy, for instance, the presence or lack of MBL can be crucial, as one's immune response is severely weakened during such treatment. From the age of 0 to 2, children can in some instances be affected by MBL deficiency, which manifests itself as recurring severe or unusual infections. In addition to the two categories already mentioned, the list of patient categories affected by MBL deficiency includes transplant patients, patients with cystic fibrosis and people suffering from other genetic immune deficiencies. The primary MBL market is estimated to be around 440,000 tests a year.

Since 2000, BioPorto has marketed an ELISA kit for measuring the level of MBL in humans, and the kit is the most frequently used product of the five or six similar products on the market. The revenue generated by the MBL products amounted to DKK 2.1 million in 2012.

Antibody portfolio: AntibodyShop®

Under the AntibodyShop® trademark, BioPorto markets several hundred different monoclonal antibodies, primarily for the basic-research market. BioPorto's antibody portfolio contains highly specialized antibodies, including a number aimed at peptide hor-

mones such as GLP-1. Sales of monoclonal antibodies comprise roughly half of BioPorto's total revenues and amounted to DKK 8.7 million in 2012.

BioPorto is continuously monitoring antibody sales and compares these with new scientific publications and feedback received from

the basic-research market. This feedback helps to ensure that BioPorto can follow up on new markers in the areas of focus, create a continuous influx of new products into the market and form the basis on which to develop new biomarkers for routine diagnostics. In 2013, only a few new antibody launches are expected, as the company's NGAL R&D resources have higher priority.

Intellectual Resources

BioPorto is operating in a highly complex, changeable and competitive sector. Thus, the group's success depends on having the appropriate intellectual resources. The management has identified and follows up on the four key areas of importance to future development:

Scientific areas of focus

The group's scientific expertise must identify the types of product that should be developed and must also possess the knowledge required for successfully developing the product or finding a suitable partner. In addition, it must be possible to assess the accessibility of intellectual property rights protection and the consequences of existing patent protection.

Development, production and quality-assurance processes

The group's development, production and quality-assurance expertise must ensure that the finished product conforms with official specifications of requirements, that the development and production processes are focused and cost-effective, and that the development processes are reproducible.

Commercialization

Knowledge of the diagnostics market, including knowledge of registration and reimbursement processes, is required for commercializing new markets, including the estimation of market prospects and penetration, and for optimizing sales. In addition, marketing and sales knowledge relating to major diagnostics companies is crucial for being able to establish the right partnership agreements with these players. Insight into the sale of licenses for the company's own rights or products is essential for being able to negotiate the proper terms and conditions for such licenses.

Financing and IR

The group's financing expertise must enable the group to plan and act in relation to the scientific development process characterized by high complexity and low predictability—as well as the group's commercialization of new markers, including expected market potential and penetration—which may lead to significant deviations in relation to the budget. Knowledge of IR and communications should at the same time strengthen the relationship with investors, analysts, the media and other stakeholders.

The group's existing intellectual resources are focused in the following areas: scientific development processes; methods for developing diagnostic analyses; negotiating and concluding contracts; financing and investment; commercialization; processes for registration and the granting of reimbursement; communications; disseminating information; quality and certification requirements, clinical relevance; immunology; antibody development; immunochemical analysis; molecular biology; protein chemistry; and manufacturing processes. In addition to the group's own expertise, the group's activities are conducted in close cooperation with permanently employed scientific employees and an external staff of senior researchers and alliance partners, as well as external consultants in business development, IP rights, licensing, communications, etc., which thus increases the organization's knowledge base.

The group needs to continue developing, retaining and actively applying its knowledge. The group keeps an account of its intellectual resources for internal use; this is part of the management tools. To ensure that The NGAL Test™ achieves the best starting point for sales for routine diagnostics, the group expects to see a higher level of activity within almost every area in 2013 onwards. This expansion will lead to requirements for a staff increase, including the acquisition of additional intellectual resources.



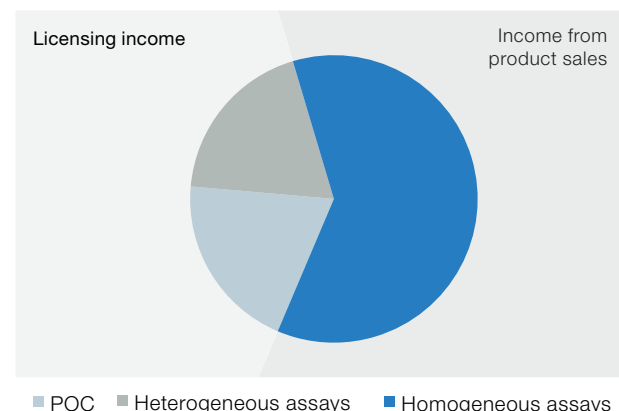
Strategy

The group's goal for 2013 and the years ahead is to gain a major share of the routine diagnostics market—a market which is lucrative because, once a new diagnostic test has achieved market acceptance and implementation, the market share is upheld for a long time, providing the basis for a stable, large-scale sales volume. With the launch of The NGAL Test™, BioPorto has come closer to this goal and further paved the way to achieving it. In light of the NGAL s market potential of more than 200 million tests a year, BioPorto's strategy will naturally be concentrated on moving forward and following up within this specific area.

In 2013, the strategy is focused on the exploitation of BioPorto's leading position in the NGAL market to initiate additional activities aimed at increasing market penetration, to retain crucial IP rights, and within a few, to implement The NGAL Test™ as an essential marker for analyzing acute kidney injury.

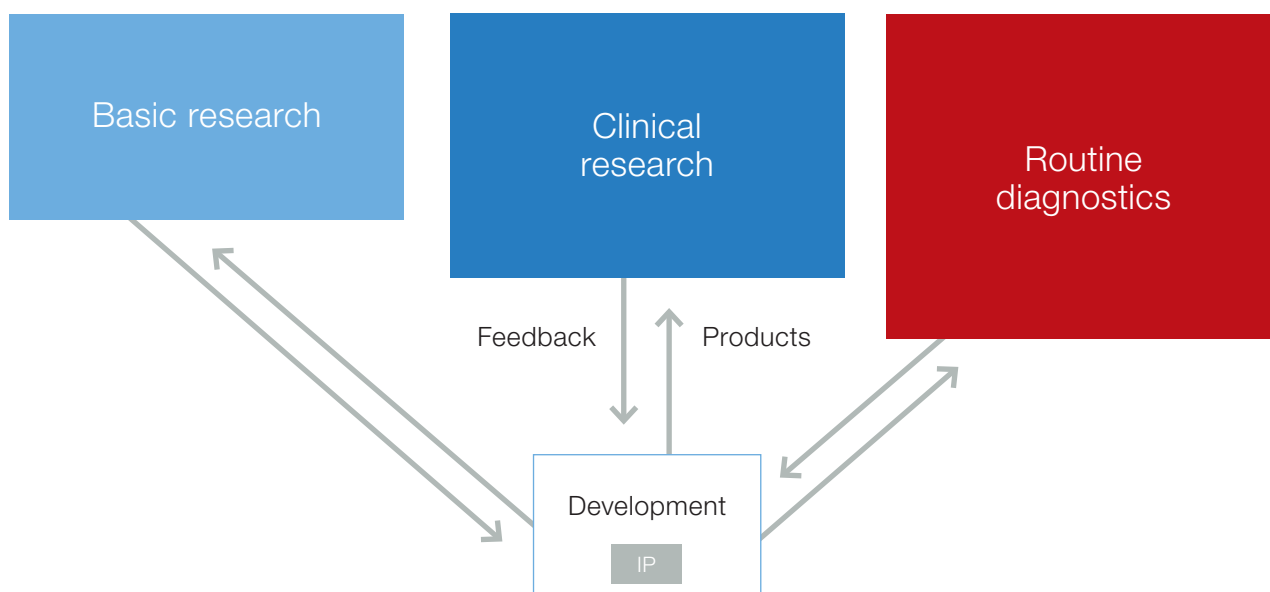
In the event of major activity in the basic research market and the clinical research market and in the event that new knowledge emerges in the routine diagnostics market, BioPorto will be kept continually informed of the group's existing markers and areas of focus from all three markets. By collecting data from all three markets, BioPorto seeks to develop, validate and market new and better markers in the proper test formats. The selection will be made by taking account of market potential and the option of protecting intellectual property rights or any other competitive advantage.

By virtue of BioPorto's current products and IP rights, the group expects to follow two routes for obtaining shares of the routine diagnostics market, notably via sales of its own products and by entering into licensing and collaboration agreements with major diagnostics companies.



Anticipated income breakdown from sales, after NGAL has been established on the routine diagnostics market.

Income from sales on the routine-diagnostics market is expected to be generated by direct sales of NGAL IVD products and by licensing agreements concerning partners' sales of either NGAL IVD products in other test formats or APC-PCI assays. The profits from sales of the group's own assays are estimated to be higher than the royalties that could be generated by selling licenses. At the same time, The NGAL Test™ is expected to be capable of gaining the largest share of the combined NGAL market, as the test is suitable for already existing analyzers and because it will be possible to produce and market it at competitive prices. In addition, it is assumed that the NGAL test will be marketed in other formats, such as heterogeneous and POC tests.



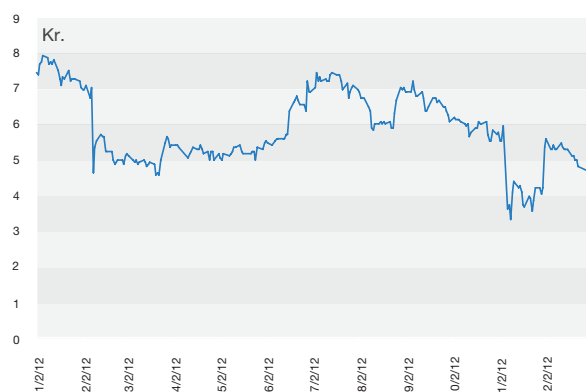
Shareholder Information

ISIN, capital share and price trends

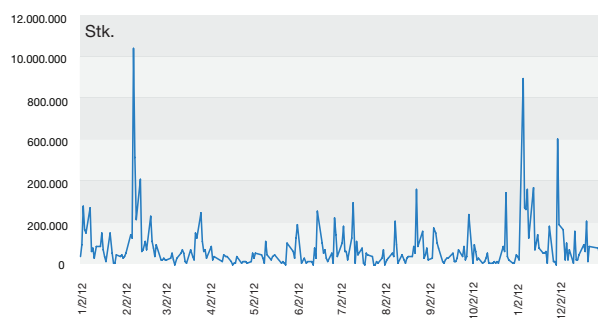
On December 3, 2012, the share capital was increased by the nominal amount of DKK 6,000,000, as a result of a private placement cash issuance. After this, the share capital constitutes the nominal amount of DKK 141,449,052, and is allotted in shares with a nominal value of DKK 3.00, equivalent to 47,149,684 shares and an equal number of voting rights. BioPorto A/S's shares are listed on NASDAQ OMX Copenhagen under the symbol "BIOPOR". The ISIN is DK0011048619.

BioPorto's share ended at a price of DKK 4.82 on December 28, 2012, which equals a price drop of -35% in the fiscal year. With a price of DKK 4.82, BioPorto had a market value of DKK 227 million at the end of 2012. Share turnover totaled 21 million for the whole year, equivalent to transactions worth DKK 118 million.

Share price development



Turnover



Ownership situation

As at December 31, 2012, BioPorto had 3,301 registered shareholders, who in the aggregate owned 78% of the share capital.

As at March 25, 2013 the following shareholder has announced ownership of 5% or more of the share capital: Media-Invest Danmark A/S

Convertible bonds

In 2010, BioPorto issued convertible bonds that were subsequently listed on NASDAQ OMX Copenhagen: 8% BioPorto Convertible 2013 is listed under ISIN DK0030263454.

In 2012, no bonds were converted. As at December 31, 2012, the bond loan constitutes the nominal amount of DKK 13,500,000, distributed over 90 bonds with a nominal value of DKK 150,000.

For full exercise of the conversion right, a total of 1,936,800 new shares with a nominal value of DKK 3.00 would be issued.

Warrant program

For the purpose of creating an incentive for retaining current employees to actively work for the company and for attracting prospective new employees, the board established a warrant program in 2011. The warrant program also works as an incentive for the company's management. At the end of the fiscal year, a total of 1,244,753 warrants remain, which amounts to 2.64% of the existing nominal share capital.

Dividend

BioPorto A/S's policy is that shareholders should receive a return on their investment in the form of a price increase based on the group's growth. The payment of dividend must consider the requisite consolidation of equity as the basis of the group's continued expansion.

As a result of the group's need for capital to market and register The NGAL Test™, and to continue the securing and widening of crucial NGAL IP rights, the payment of dividend is not expected in 2013.

Investor relations (IR)

BioPorto aims to give the market open, satisfactory 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 sector in terms of both products and market conditions. Insofar as possible, the group endeavors to strike a balance so that the information it communicates is both technically correct and understandable to laypersons. All stakeholders should have fast, equal access to important information about BioPorto's development and growth. This means, among other things, that in-house knowledge is published in company announcements via NASDAQ OMX Copenhagen 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 to everyone 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 company announcements; press releases and other news are published.

To ensure an efficient, expedient dialog with our shareholders, BioPorto encourages its shareholders to let their shareholding be registered and to participate in shareholders' meetings. The IR Department is also responsible for ensuring that information from the group's IR stakeholders is passed on to the management and the board of directors.

Company announcements

| Date | Announcement |
|------------|---|
| 10.01.2012 | Announcement from major shareholder |
| 08.02.2012 | BioPorto's NGAL cut-off patent rejected following a decision in the opposition case |
| 19.03.2012 | Annual report 2011 |
| 19.03.2012 | The NGAL test registered for diagnostic use in China |
| 22.03.2012 | Annual General Meeting |
| 17.04.2012 | Development of Annual General Meeting |
| 22.05.2012 | BioPorto's NGAL cut-off patent: written decision in the opposition case |
| 22.05.2012 | BioPorto's NGAL cut-off patent: assessment of the decision in the opposition case |
| 25.05.2012 | Interim report Q1 2012 |
| 01.06.2012 | BioPorto enters into an agreement with Wiener Lab Group – Status for the distribution of The NGAL Test |
| 15.06.2012 | BioPorto wins lawsuit filed against Phadia |
| 27.06.2012 | BioPorto obtains its first NGAL patent in the US |
| 02.07.2012 | Ruling on NGAL patent appealed to the Supreme Court |
| 23.08.2012 | Interim report for Q2 2012 |
| 23.08.2012 | Increase of the share capital through a cash issue, private placement |
| 24.08.2012 | Insider's dealings |
| 21.09.2012 | Cash issue, private placement to be carried out |
| 25.09.2012 | BioPorto's patent rights for NGAL - opposition to the European trauma patent |
| 24.10.2012 | Cash issue, private placement delayed |
| 31.10.2012 | Decision on cash issue, private placement postponed to November 2, 2012 |
| 05.11.2012 | Cash issue, private placement cancelled, the company in an economically critical state |
| 12.11.2012 | Interim financial report for Q3 |
| 29.11.2012 | BioPorto enters agreement on sales cooperation with Siemens |
| 30.11.2012 | Announcement from major shareholder |
| 03.12.2012 | Increase of the share capital through a cash issue, private placement |
| 05.12.2012 | BioPorto's The NGAL Test TM registered for diagnostic use in Russia – status on progress in the BRIC countries |
| 07.12.2012 | BioPorto completes cash issue, private placement |
| 11.12.2012 | New shares admitted to trading, the company's financial situation restored |
| 11.12.2012 | BioPorto's NGAL cutoff patent is issued in China |
| 20.12.2012 | Financial calendar 2013 |
| 28.12.2012 | Share Capital and Votes |

Financial calendar

| Date | Announcement |
|------------|--|
| 19.03.2013 | Annual report for the year January 1 – December 31, 2012 |
| 16.04.2013 | Annual general meeting |
| 23.04.2013 | Quiet period before Q1 begins |
| 07.05.2013 | Interim financial report for Q1 2012 |
| 26.07.2013 | Quiet period before Q2 begins |
| 09.08.2013 | Interim financial report for H1 2012 |
| 25.10.2013 | Quiet period before Q3 begins |
| 08.11.2013 | Interim financial report for Q3 2012 |

Contact

Additional information is available on the company's website, www.bioporto.com.

For Investor Relations, please contact:

Christina Thomsen

Tel.: (+45) 4529 0000

Fax: (+45) 4529 0001

E-mail: investor@bioporto.com

General meeting

The annual shareholders' meeting will be held on April 16, 2013, at 3 p.m. at the company's address.

Corporate Governance

The management and board of directors of BioPorto A/S focus on investor relations, and the company's board of directors gives high priority to exercising good corporate governance. Following the recommendations for good corporate governance generates value for the company in the long term and ensures the immediate publicizing of information to shareholders and the share market. The Statutory Report on Corporate Governance, cf. Section 107(b) of the Danish Financial Statements Act, regards the period from January 1 to December 31, 2012 and is available on the company's website:

www.bioporto.com/content/download/1902/44721/version/9/file/Corporate+Governance+2012.pdf

13 board meetings were held in 2012, including a strategy meeting, and seven conference calls. Six meetings and three conference calls are planned for 2013, in accordance with the board's annual schedule, which can be changed at any time to allow for additional meetings, if the need arises.

On February 26, 2013, an extraordinary general meeting was held for election to the board as requested by a group of shareholders. The following candidates were elected: Carsten Lønfeldt, Marianne Weile, Roar Bjørk Seeger, Laura von Kobyletzki and Thomas Mag-nussen. Torben A. Nielsen and Claus Crone Fuglsang were elected deputy members. After the meeting, the board constituted itself with Carsten Lønfeldt as chairman.

The members of the board are selected and put up for election on the basis of their specific qualifications and experience that are relevant to BioPorto. Thus, the board is composed with a view to ensuring an optimal combination of professional experience in the sector in general, in research and development, in IP rights and conclusion of contracts, in sales and marketing, as well as in finance and economics. All board members are assessed by the board as being independent. The election term is one year at a time and the age limit is set at 70 years. The unique expertise of each member is shown on the company's website:

www.bioporto.com/about_us/board_of_directors

The chairman of the board is responsible for evaluating the management and the board of directors every year. The evaluation also includes the working relationship with the management. The result of the evaluation process is subsequently presented to and discussed at a board meeting.

Diversity

The aim of the company is to provide equal opportunity to both genders, but without stipulating quantitative targets for this. In employment situations and in the composition of the management, the best qualified candidates are selected, and gender is not a part of this assessment. For some years, the company has had and still seeks to have a somewhat equal number of men and women in



managerial positions, which attests to compliance in practice with this goal. The board's composition also complies with the recommendation for diversity with a reasonable age spread and gender proportion.

BioPorto's internal control and risk-management systems

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

The management and board assess that all significant elements of risk have been identified and addressed. The board has discussed the need for internal audit and deems that the company, with only 25 employees, does not have a need for this, nor is it possible in practice.

A review of the company's risk management is available on the company's website:

www.bioporto.com/content/download/1908/44807/version/1/file/Risk_Management.pdf

Management committees

Until February 26, 2013, BioPorto's board had four members, and for this reason the management committee tasks have been performed by the entire board at board meetings already scheduled. The chairman of the board is the chairman of the audit committee, as the chairman possesses the expert knowledge and experience required. The board has drawn up terms of reference describing the audit committee's tasks. Insofar as the nomination and remuneration committees' tasks are concerned, these are included in the board's annual schedule. The terms of reference for the audit committee are also available on the company's website:

www.bioporto.com/content/download/2066/46624/version/2/file/Audit+committee.pdf

Remuneration of the management and board of directors

The basic fee of the board is set at a level assessed as being competitive and reasonable compared to the sector in general and the Company's current situation. The annual board fee in 2012 was DKK 150,000 and the chairman of the board receives twice this fee.

The management consists of one person, employed on a contract basis. In 2012, the management was paid DKK 1,553,000 in salary, inclusive of pension (contribution-based), bonus and share-based remuneration. An already concluded bonus agreement will continue in 2013 so that the payment of a bonus takes place if down-payment or milestone payments are achieved in connection with negotiations concerning access to the group's NGAL IP, or if marketing/distribution agreements with major diagnostics companies are established for The NGAL Test™ and the sales of the test is increased. The management takes part in the company's warrant program (see note 5). The company has not assumed any obligation to disburse severance pay to the management at the time of the termination of the employment relationship, besides possible remuneration for the conclusion of a non-competition clause. The employment relationship may be terminated by the company by giving twelve months' notice to the end of a month and in special instances by giving twenty-four months' notice.

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

www.bioporto.com/content/download/1905/44762/version/4/file/Remuneration+Policy.pdf

Social responsibility

BioPorto is aware of its social responsibility and endeavors to improve its social and environmental conditions. BioPorto has acceded to the Global Compact, and the recent *communication on progress*, which also constitutes the company's report on corporate social responsibility, is available on the company's website:

www.bioporto.com/content/download/1904/44747/version/7/file/COP+for+2012+English.pdf

Management and board of directors

The company's members of the board and management own securities in BioPorto A/S and hold the following directorships in other companies as specified in the following overview. Directorships in wholly owned subsidiaries are not included.

| Board of directors | | Directorships in other companies | |
|---|---------|---|-------------|
| Carsten Lønfeldt (b.1947) Chairman of the board Director, KCBL Management ApS Joined the board in 2007 | | Chairman of the board in Investeringforeningen Nykredit Invest, Investeringsforeningen Nykredit Invest Engros, Placeringsforeningen Nykredit Invest, Specialforeningen Nykredit Invest, Dandrit Biotech, A/S, LHK Stil-lads A/S, GoMinisite ApS, Pirutech ApS and Fonden Dansk Standard. Vice chairman in Professionel Forening Institutionel Investor. Member of the board in ATP Invest III F.M.B.A., EMDInvest F.M.B.A., Emerging Mar-kets Long-term Economic InvestmentFund (L.E.I.F.) F.M.B.A., Global volu-tion InvestF.M.B.A., Investeringsforeningen Investin, Investin ProF.M.B.A., Investin professionel forening, Nykredit AIDA IIF.M.B.A., Nykredit KOB-RA F.M.B.A., Nykredit KOBRA IIF.M.B.A., Nykredit KOBRA III F.M.B.A., Nykredit Mira IIIF.M.B.A., Pro-Target Invest F.M.B.A., Polaris Management A/S with affiliates, Carmo A/S, Bolux A/S with affiliates og Labflex A/S. Judge in Landsskatteretten, Member of NASDAQ OMX Copenhagen ad-visory board, Member of repræsentantskabet i Foreningen Nykredit. | |
| | Shares | Warrants | Bonds |
| Quantity | 101,000 | 52,000 | DKK 300,000 |
| Change, 2012 | +8,000 | - | - |
| Marianne Weile (b.1960) Director, Patent & Licensing, Novozymes A/S Joined the board in 2009 | | | |
| | Shares | Warrants | Bonds |
| Quantity | 44,000 | 0 | DKK 300,000 |
| Change, 2012 | +9,000 | - | - |
| Roar Bjørk Seeger (1964) Director of Lion & Dolphin A/S and Vidis GmbH Joined the board in 2013 | | Chairman of the board in Modstrøm Danmark A/S. Board member in Ak-tant Technology Denmark A/S, Aktant Technology and BRS Holding Int. ApS. Director of BRS Holding Int. ApS and Seeger. | |
| | Shares | Warrants | Bonds |
| Quantity | 0 | 0 | 0 |
| Thomas Magnussen (1953) Director of Therazone APS Joined the board in 2013 | | Chairman of the board in QuantumWise A/S and Zylinc. | |
| | Shares | Warrants | Bonds |
| Quantity | 0 | 0 | 0 |
| Laura von Kobyletzki (1971) Head of County Councils Department of R&D and Edu-cation, Karlstad. Joined the board in 2013 | | | |
| | Shares | Warrants | Bonds |
| Quantity | 0 | 0 | 0 |

Deputy members**Directorships in other companies****Torben A. Nielsen (b.1960)**

Former CEO of BankInvest

Joined the board in 2013

| | Shares | Warrants | Bonds |
|----------|--------|----------|-------|
| Quantity | 0 | 0 | 0 |

Claus Crone Fuglsang (b.1968)

Vice President AD BioEnergy, Novozymes

Joined the board in 2013

| | Shares | Warrants | Bonds |
|----------|--------|----------|-------|
| Quantity | 0 | 0 | 0 |

Management**Directorships in other companies****Thea Olesen (b.1966)**

CEO of BioPorto A/S since 2005

Chairman of the board in Olesens A/S, Board member in Larix A/S

| | Shares | Warrants | Bonds |
|--------------|---------|----------|-------------|
| Quantity | 265,064 | 151,675 | DKK 300,000 |
| Change, 2012 | +4,400 | - | |

Financial Statements

Income statement

Net Revenues

In 2012, the group generated net revenues totaling DKK 17.9 million compared with DKK 18.6 million in 2011 (-4%).

Sales of kits for human diagnostics rose 4% to a total of DKK 4.5 million (DKK 4.3 million). Sales of other kits and reagents rose 3% to a total of DKK 12.0 million (DKK 11.7 million).

The NGAL product portfolio contributed combined sales of DKK 6.5 million (DKK 5.3 million) equivalent to a 24% increase. The

growth is primarily attributable to increasing use of the group's NGAL ELISA kits for clinical development. In 2012, BioPorto's turbidimetric NGAL test, The NGAL Test™, achieved sales of DKK 1.8 million compared with DKK 1.5 million the year before.

Licensing income, primarily from Instrumentation Laboratories, amounted to DKK 0.6 million in 2012, compared with DKK 1.9 million in 2011.

BioPorto increased its product sales (excluding licensing income) in Europe and North America by 7%. Product sales in Asia declined by 46%, as a direct result of sharply declining deliveries of NGAL tests to the group's OEM partners in China.

Figure 1: Growth in revenues for products, including licenses

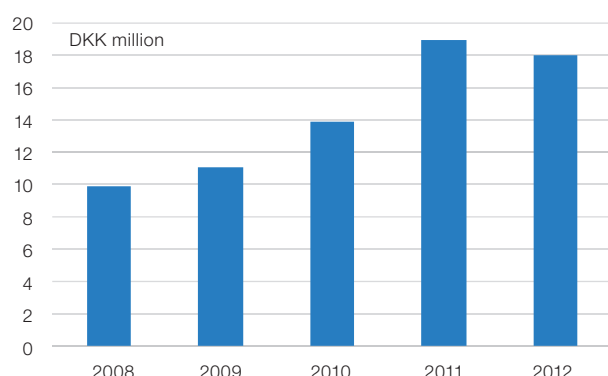


Figure 2: Revenue growth broken down by main segments

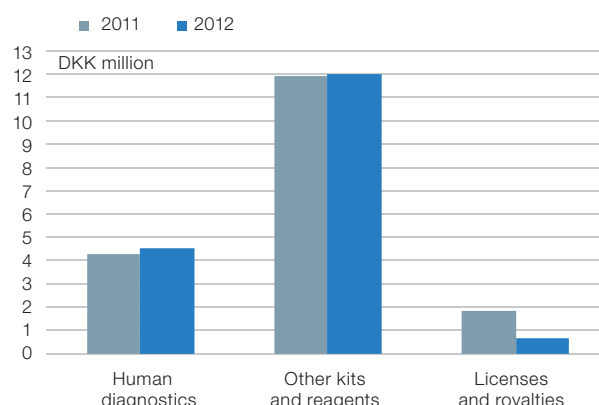


Figure 3: Revenue growth broken down by product category

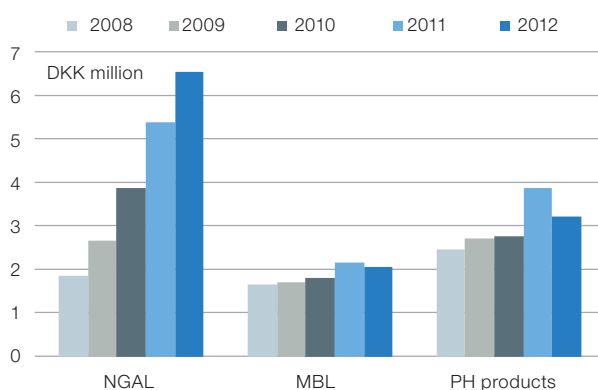
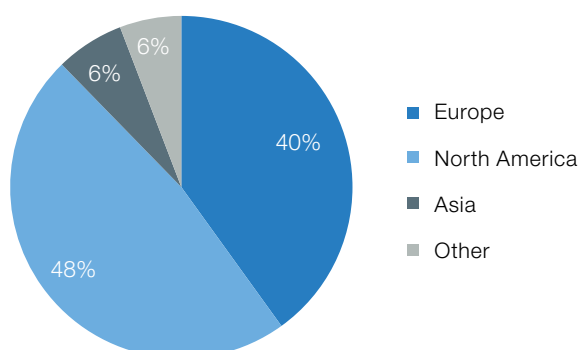


Figure 4: Geographic breakdown of product sales in 2012



Operating costs

Total operating costs (excluding financial costs) rose 1% to DKK 31.7 million (DKK 31.4 million).

Production overheads totaled DKK 6.8 million in 2012, equivalent to a 16% reduction compared with 2011 (DKK 8.1 million). Production overheads were positively affected by a reduction in staff and a decline in licensing overhead.

The gross profit in 2012 was DKK 11.1 million (DKK 10.5 million), equivalent to a 5% increase over 2011. The gross margin rose to 62%, compared to 57% in 2011.

Sales and marketing costs amounted to DKK 6.0 million in 2012 (DKK 6.5 million).

R&D costs amounted to DKK 9.9 million in 2012 (DKK 8.1 million). The costs of developing and defending the group's IP rights, including the patent invalidity case filed against Phadia's NGAL patent, increased sharply in 2012.

Administration costs amounted to DKK 9.0 million in 2012, equating to a 3% increase (DKK 8.8 million).

Result for the year before interest

The result for the year before interest (EBIT) was a loss of DKK 13.9 million compared with a loss of DKK 12.9 million in 2011.

Financial income and expenses

Financial income amounted to DKK 49,000 in 2012 (DKK 68,000).

Financial expenses amounted to DKK 2.1 million (DKK 2.0 million), primarily interest expenditure and amortized transaction costs concerning convertible bonds.

Income tax expense

In connection with the Finance Act for 2012, a way for companies to receive 25% of losses derived from experimental and research expenses was introduced, with a maximum of EUR 5.0 million, however. The new option is applicable from the 2012 income year. A tax income of DKK 1.25 million corresponding to 25% of DKK 5.0 million is contained.

Net loss for the year

The net loss for the year in 2012 was DKK -15.9 million (DKK -14.8 million).

Balance Sheet

At the end of 2012, the balance sheet total was DKK 16.8 million (DKK 21.2 million).

In 2012, a private placement was carried out for a total of 2.0 million shares at a price of DKK 5.10 per share (nominal value: DKK 3.00 per share). After deducting the costs of issuance, the gross proceeds of the issuance amounted to DKK 9.6 million.

Assets

Again in 2012, no significant investments were made in property, plant or equipment. At the end of 2012, the book value of property, plant and equipment amounted to DKK 0.2 million (DKK 0.3 million).

At the end of 2012, inventories totaled DKK 4.2 million (DKK 3.7 million). Indirect production overhead totaling DKK 0.5 million is recognized in the inventories (DKK 0.4 million). Slowly marketable products were written down by DKK 53,000 (DKK 186,000) in 2012.

At the end of the fiscal year, receivables from sales and other receivables amounted to DKK 3.7 million (DKK 2.9 million). BioPorto had bad debts of DKK 29,000 in 2012.

Equity

The capital structure consists of convertible bonds and equity, including share capital, other reserves and retained earnings.

At December 31, 2012, the consolidated equity was DKK -1.2 million. Restoration of equity is expected to be achieved through a planned rights issue, see Capital structure for details. In the longer term, the equity is expected to be strengthened through increased operating income.

At year end, the share capital amounted to DKK 141.4 million, dispersed over 47,149,684 shares. The group owns the nominal amount of 13,000 shares of treasury share, equivalent to 0.03% of the share capital.

Liabilities

At the end of the fiscal year, short-term liabilities amounted to DKK 19.1 million (DKK 5.1 million).

DKK 13.2 million relating to the convertible bond loan is entered under short-term liabilities. Interest due for convertible bonds is calculated at DKK 1.9 million, DKK 0.3 million of which falls due for payment in September 2013.

The group's liabilities are otherwise composed of trade payables, provisions for salary and holiday pay obligations, and outstanding debts, including accountants and lawyers. The group has not taken on any lease obligations or bank debt.

Cash flow statement

The cash flow from the group's working capital during the fiscal year was DKK -15.2 million (DKK -13.6 million).

The cash flow from the group's investment activities was DKK -82,000 (DKK -23,000).

The cash flow from the group's financing activities was DKK 9.6 million (DKK 13.8 million).

At the end of 2012, the group had cash and cash equivalents (primarily as bank deposits) totaling DKK 8.3 million (DKK 14.1 million).

BioPorto A/S – parent company

In 2012, BioPorto's revenue was DKK 1.9 million (DKK 1.8 million). Administrative expenses amounted to DKK 6.6 million (DKK 5.8 million). The increase is related to costs incurred by the private placement in December 2012. In 2012, financial income amounted to DKK 7.2 related to interest from loans to the subsidiary BioPorto Diagnostics A/S (DKK 6.3 million). In 2012, financial expenses amounted to DKK 1.4 million (DKK 1.4 million), primarily from interest on convertible bond loans. In 2012, BioPorto A/S' earnings before tax amounted to DKK 1.1 million (DKK 1.0million). It is proposed to transfer the amount to next year.

BioPorto A/S' assets amounted to DKK 187.9 million at December 31, 2012. The company's assets consist primarily of an equity interest in BioPorto Diagnostics A/S, corresponding to DKK 48.0 million (DKK 48.0 million) and receivables from the same company. The management has assessed that there is no motive for carrying out an impairment of the equity share in BioPorto Diagnostics A/S or the parent receivables in the same company. The share capital was DKK 172.1million in 2012 (DKK 161.4 million).

Capital Resources

Financing

At the end of February, 2013, cash in the form of bank deposits totaled DKK 5.2 million, which is expected to finance BioPorto's activities until June 2013. The management estimates the funding needs by the end of May 2013 to be DKK 5-10 million and by third quarter at the latest an additional DKK 15-20 million in order to finance the activities of the group in 2013 and settle the convertible debt due in September 2013. Also, the management estimates a need for DKK 35-45 million to fund the activities planned for 2014 and 2015.

After considering the options available, management has decided to seek to carry out a rights issue to existing shareholders. The issue, planned for third quarter 2013, is expected to provide BioPorto with funds in the range of DKK 60-70 million, which is deemed sufficient to implement the planned activities over the next three years. Three of the major shareholders have given notice that they will participate in a rights issue and, if necessary, lend funds in the period leading up to the completion of the rights issue.

The group's capital requirements are subject to uncertainty related to the expected development in sales of its products, and the actual costs, and maintenance of existing IP rights, cf. note 2, Significant accounting estimates and assessments. The management monitors actual revenues and expenditures closely in order to install corrective actions.

Capital structure

The management and board regularly assess whether the group's capital structure complies with the interest of the group and the shareholders. The overarching goal is to secure a capital structure that underpins long-term economic growth and at the same time maximizes the returns for the group's stakeholders by optimizing the debt/equity ratio.

The capital structure comprises convertible bonds and equity, including capital stock, other reserves and retained income/loss.

As of December 2012, the group's consolidated equity amounted to DKK -1.2 million. The equity is expected to be re-established as a result of the planned rights issue. In the long term, equity is expected to be further strengthened by increased revenues.

Activities in 2012 to ensure capital resources and optimization of capital structure

In 2012 a private placement at a total of 2.0 million shares at a price of DKK 5.10 each (nominal value of DKK 3.0 per share) was completed. The net proceeds after deduction of issue costs amounted to DKK 9.6 million.

Statement by the Management and Board of Directors

As of today's date, the management and board of directors have discussed and approved the annual report for BioPorto A/S for January 1 – December 31, 2012.

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

In our opinion, the selected accounting policies are appropriate, so that the annual report presents a true and fair view of the company's assets, liabilities and financial position as at December 31, 2012, and of the financial result of the group's and parent company's activities and cash flow for the fiscal year from January 1 to December 31, 2012.

In our opinion, the statement by the management and the board of directors on the annual report presents a true and fair account of developments in the group's and the parent company's activities, economic factors, financial result and financial position, and also describes the most significant risks and elements of uncertainty currently facing the group and the parent company.

At the end of February, 2013, cash in the form of bank deposits totaled DKK 5.2 million, which is expected to finance BioPorto's activities until June 2013. The management estimates the funding needs by the end of May 2013 to be DKK 5-10 million and by third quarter at the latest an additional DKK 15-20 million in order to finance the activities of the group in 2013 and settle the convertible debt due in September 2013. Also, the management estimates a need for DKK 35-45 million to fund the activities planned for 2014 and 2015.

After considering the options available, management has decided to attempt to carry out a rights issue to existing shareholders. The issue, planned for third quarter 2013, is expected to provide BioPorto with funds in the range of DKK 60-70 million, which is deemed sufficient to implement the planned activities over the next three years. The group's continued status as a going concern is dependent on a supply of DKK 5-10 million in May, and that net proceeds of at least DKK 25 million are raised in connection with the issue. See also the section on capital resources in the report.

The annual report is hereby submitted to the annual general meeting for approval.

Gentofte, Denmark, March 25, 2013

Management:

Thea Olesen
CEO

Board of Directors:

Carsten Lønfeldt
Chairman

Marianne Weile

Roar Bjørk Seeger

Laura von Kobyletzki

Thomas Magnussen

Statement of the Independent Auditor

To the shareholders of BioPorto A/S

Report on the consolidated financial statements and the parent financial statements

We have audited the consolidated financial statements and the parent financial statements of BioPorto A/S for the fiscal year January 1 – December 31, 2012, which comprise the income statement, the balance sheet, and the statement of changes in equity and notes, including the accounting policies applied for both the group and the parent company and the 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 approved by the EU and Danish disclosure requirements for listed companies, and the parent financial statements are prepared in accordance with the Danish Financial Statements Act.

Management's responsibility for the consolidated financial statements and parent financial statements

The management is responsible for preparing consolidated financial statements which give a true and fair view in accordance with International Financial Reporting Standards as approved by the EU and with Danish disclosure requirements for listed companies, as well as the preparation of parent financial statements which give a true and fair view in accordance with the Danish Financial Statements Act. The management is also responsible for the internal controls which the management deems necessary for preparing the consolidated financial statements and the parent financial statements without material misstatement, regardless of whether the misstatement is due to fraud or error.

Auditor's Responsibility

We are responsible for submitting our opinion of the consolidated financial statements and the parent financial statements on the basis of our audit. We have performed our audit in accordance with international auditing standards and additional requirements in accordance with Danish audit legislation. This requires us to comply with ethical standards and to plan and perform our audit to achieve a high degree of certainty that the consolidated financial statements and the parent financial statements are free of material misstatement. An audit includes the performance of audit procedures to obtain audit evidence of amounts and information in the consolidated financial statements and the parent financial statements. The audit procedures chosen depend on the auditor's assessment, including the assessment of risk of material misstatement in the consolidated financial statements and the parent financial statements, regardless of whether this is due to fraud or error. In making the assessment of risk, the auditor considers internal controls that are relevant to the company's preparation of consolidated financial statements and parent financial statements that give a true and fair view. The purpose of this is to draw up audit procedures that are suitable under the circumstances, but not for the purpose of expressing a conclusion regarding the effectiveness of the company's internal controls. Our audit also includes an assessment of whether the management's choice of accounting policies is appropriate, whether the management's accounting estimates are reasonable, and an assessment of the overall presentation of the consolidated financial statements and the parent financial statements.

Disclaimer

Basis for disclaimer of Opinion conclusion

It is evident in the consolidated financial statements, Note 2 "Significant accounting estimates and assessments" that the assumption of continued operation (going concern) requires a significant cash injection in May 2013 and in third quarter 2013, and that there are significant risks associated with those requirements and with the company's cash flow forecast in general. Included in this risk is a significant adverse effect on liquidity, and thus the assumption of going concern, if expectations about the supply of liquidity in May 2013 and a cash injection in third quarter 2013 are not met. We are unable to assess whether the temporary financing in May 2013, as assumed by management, and cash injection in third quarter 2013 can be implemented, and therefore, we qualify our opinion.

The value of the investments in the subsidiary and receivables in the subsidiary recognized as assets with a total value of DKK 180 million in the financial statements for the parent company are subject to the execution of the cash injection as planned by the company's management, and of the group's operations developing as expected, cf. note 2 of the consolidated financial statements. We are unable to assess whether these conditions are met and accept no liability.

Disclaimer of Opinion

Due to the significance of the conditions described in "Basis for Disclaimer of Opinion", we have not been able to obtain sufficient appropriate audit evidence to provide a basis for an audit opinion. Accordingly, we do not express an opinion on the consolidated financial statements and parent financial statements.

Opinion on the Management Review

In accordance with the Danish Financial Statements Act, we have read the Management Review. We have not taken other measures in addition to the audit of the consolidated financial statements and the parent financial statements.

Due to the significance of the conditions described in "Disclaimer", we have not been able to submit an opinion on whether the Management Review is in conformity with the consolidated financial statements and parent financial statements.

Copenhagen, Denmark, March 25, 2013

Deloitte

Statsautoriseret Revisionspartnerselskab

Jens Sejer Pedersen

Jens Rudkjær

State Authorized

State Authorized

Public Accountant

Public Accountant

Comprehensive Income Statement

The BioPorto Group

January 1 – December 31, 2012

| | 2012 | 2011 |
|--|-----------------|-----------------|
| | DKK thousand | DKK thousand |
| 3 Net Revenues | 17,858 | 18,584 |
| 4,5,6 Production costs | (6,803) | (8,064) |
| Gross income | 11,054 | 10,521 |
| Gross margin | 62% | 57% |
| 4,5,6 Sales and marketing costs | (5,970) | (6,458) |
| 4,5,6 Research and development costs | (9,911) | (8,129) |
| 4,5,6 Administration expenses | (9,043) | (8,792) |
| Earnings before interest (EBIT) | (13,870) | (12,858) |
| EBIT margin | -78% | -69% |
| 8 Financial income | 49 | 68 |
| 8 Financial expenses | (2,130) | (2,048) |
| Earnings before tax | (15,950) | (14,838) |
| 15 Income taxes relating to net loss | 1,250 | 0 |
| Net income/loss for the period / comprehensive income ... | (14,700) | (14,838) |
| | | |
| Earnings per share (eps/deps) | -0.32 | -0.34 |

Balance Sheet

The BioPorto Group

December 31, 2012

| ASSETS | | 2012 Dec. 31 DKK thousand | 2011 Dec. 31 DKK thousand |
|--|---|---------------------------------|---------------------------------|
| Long-term assets | | | |
| Tangible assets | | | |
| 10 | Other plant, operating equipment and fixtures | 222 | 328 |
| Tangible assets | | 222 | 328 |
| Other long-term assets | | | |
| | Deposits | 248 | 244 |
| Other long-term assets, total | | 248 | 244 |
| Long-term assets, total | | 470 | 572 |
| Short-term assets | | | |
| 11 | Inventories | 4,228 | 3,658 |
| 12 | Receivables, sales | 2,638 | 1,576 |
| 15 | Receivables, income tax | 1,250 | 0 |
| 12 | Other receivables | 1,243 | 1,341 |
| Receivables | | 9,359 | 6,575 |
| | Cash resources | 8,349 | 14,105 |
| Short-term assets, total | | 17,708 | 20,680 |
| ASSETS, TOTAL | | 18,178 | 21,252 |

Balance Sheet

The BioPorto Group

December 31, 2012

| LIABILITIES | | 2012 Dec. 31 DKK thousand | 2011 Dec. 31 DKK thousand |
|-------------------------------|---|---------------------------------|---------------------------------|
| Equity | | | |
| 13 | Capital stock | 141,449 | 135,449 |
| 16 | Other reserves | 2,036 | 2,036 |
| 5 | Share-based payment | 2,844 | 2,844 |
| 14 | Treasury stock | (44) | (44) |
| | Retained income/loss | (147,435) | (136,346) |
| | Equity, total | (1,150) | 3,940 |
| Liabilities | | | |
| Long-term liabilities | | | |
| 16 | Convertible Bond Loans | 0 | 12,186 |
| | Long-term liabilities, total | 0 | 12,186 |
| Short-term liabilities | | | |
| 16 | Short-term segment of long-term liabilities | 13,226 | 302 |
| | Suppliers of goods and services | 2,608 | 1,757 |
| | Other debt | 3,494 | 3,067 |
| | Short-term liabilities, total | 19,328 | 5,126 |
| | Liabilities, total | 19,328 | 17,312 |
| | EQUITY AND LIABILITIES, TOTAL | 18,178 | 21,252 |

Statement of Changes in Equity

The BioPorto Group

January 1 - December 31, 2012

| | Capital stock | Treasury stock | Premium | Share-based payment | Other reserves | Retained income/loss | Total |
|---|----------------|----------------|--------------|---------------------|----------------|----------------------|-----------------|
| | DKK thousand | DKK thousand | DKK thousand | DKK thousand | DKK thousand | DKK thousand | DKK thousand |
| Equity, January 1, 2012 | 135,449 | (44) | 0 | 2,844 | 2,036 | (136,346) | 3,940 |
| Comprehensive income for the period | 0 | 0 | 0 | 0 | 0 | (14,700) | (14,700) |
| Capital increase, directed issue | 6,000 | 0 | 4,200 | 0 | 0 | 0 | 10,200 |
| Issue costs | 0 | 0 | (589) | 0 | 0 | 0 | (589) |
| Transferred to "retained income" | 0 | 0 | (3,611) | 0 | 0 | 3,611 | 0 |
| Equity December 31, 2012 | 141,449 | (44) | 0 | 2,844 | 2,036 | (147,435) | (1,150) |

| | Capital stock | Treasury stock | Premium | Share-based payment | Other reserves | Retained income/loss | Total |
|---|----------------|----------------|--------------|---------------------|----------------|----------------------|-----------------|
| | DKK thousand | DKK thousand | DKK thousand | DKK thousand | DKK thousand | DKK thousand | DKK thousand |
| Equity, January 1, 2011 | 126,398 | (44) | 0 | 1,985 | 210,450 | (127,135) | 3,308 |
| Comprehensive income for the period | 0 | 0 | 0 | 0 | 0 | (14,838) | (14,838) |
| Capital increase, directed issue | 8,100 | 0 | 5,400 | 0 | 0 | 0 | 13,500 |
| Issue costs | 0 | 0 | (800) | 0 | 0 | 0 | (800) |
| Exercised warrants and convertible bonds | 951 | 0 | 606 | 0 | 0 | 0 | 1,557 |
| Equity component of convertible bond loan | 0 | 0 | 0 | 0 | (69) | 0 | (69) |
| Share-based payment | 0 | 0 | 0 | 1,274 | 0 | 0 | 1,274 |
| Transferred to "retained income" | 0 | 0 | (5,206) | (415) | 0 | 5,629 | 8 |
| Equity December 31, 2010 | 135,449 | (44) | 0 | 2,844 | 2,036 | (136,345) | 3,940 |

Other reserves relate to the equity component of the convertible bond

Cash Flow Statement

The BioPorto Group

January 1 – December 31, 2012

| | 2012 | 2011 |
|--|-----------------|-----------------|
| | DKK thousand | DKK thousand |
| Earnings before interest (EBIT) | (13,870) | (12,858) |
| Depreciation, amortization, write-downs and impairment | 189 | 221 |
| Share-based payment | 0 | 1,274 |
| Cash generated by primary operations before change in working capital | (13,681) | (11,363) |
| 19 Change in working capital | (469) | (1,058) |
| Cash generated by primary operations | (14,150) | (12,421) |
| Interest income, included | 49 | 68 |
| Interest expenses, paid | (1,178) | (1,254) |
| Cash generated by operating activities | (15,280) | (13,606) |
| Purchase of tangible assets | (82) | (23) |
| Prepayment | (5) | (7) |
| Cash generated by investment activities | (87) | (30) |
| Cash issue, direct placement | 10,200 | 14,615 |
| Issue cost | (589) | (800) |
| Cash generated by financing activities | 9,611 | 13,815 |
| Cash flow for the period | (5,756) | 179 |
| Cash resources at the beginning of the year | 14,105 | 13,926 |
| Cash resources at the end of the period | 8,349 | 14,105 |

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Note 1

Accounting Policies

The financial statements for the BioPorto Group is presented in accordance with International Financial Reporting Standards (IFRS) as approved by the EU and in accordance with additional Danish disclosure requirements for the annual reports of listed companies as per the Executive Order on IFRS issued pursuant to the Danish Financial Statements Act.

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

The financial statements are presented on the basis of historical costs, except for share-based payment, which is measured at fair value.

The accounting policies, which remain unchanged, compared to last year, are otherwise as described below.

Implementation of new and modified standards and interpretations

The 2012 Annual Report is presented in accordance with new and modified standards (IFRS/IAS) and new interpretations (IFRIC) that apply to fiscal years beginning on or after January 1, 2012.

These standards and interpretations are as follows:

- » Changes to IAS 12, Income Taxes: recovery of the carrying amount of assets.
- » Changes to IFRS 7, Financial instruments: disclosures (offsetting financial assets and financial liabilities).

The implementation of the new and modified standards and standards in the 2012 Annual Report did not result in changes to accounting policies and did not affect the figures or information reported in present or previous periods but could affect the accounting-related processing of future transactions or agreements.

Standards and interpretations not yet in force

At the time of publication of this annual report a number of new or amended standards and interpretations that have not yet entered into force and are therefore not included in the annual report. Management believes that these will not have a material impact on the consolidated financial statements for the coming year.

General principles of recognition and measurement

Earnings are recognized in the income statement concurrent with their realization. In addition, all costs incurred to achieve the income for the year are recognized in the financial statements, including depreciation, amortization, write-downs, impairment and provisions, as well as carry backs resulting from modified accounting estimates of amounts previously recognized in the financial statements.

Assets are recognized on the balance sheet when it is likely that future financial benefits will accrue to the company and the asset's value can be measured reliably.

Liabilities are recognized on the balance sheet when it is likely that future economic benefits will flow from the company and the liability's value can be measured reliably.

Assets and liabilities are measured at the cost on initial recognition. Subsequently assets and liabilities are measured as described below for each item.

For recognition and measurement, predictable gains, loss and risk occurring before the submission of the annual report and which confirm or disprove the situation on the balance sheet date are taken into consideration.

Consolidated financial statements

The consolidated financial statements include the parent company, BioPorto A/S, and the subsidiaries in which BioPorto A/S has a controlling interest, i.e. controlling influence on financial and operating policies for achieving returns or other benefits for its activities. Controlling interest is achieved by directly or indirectly owning or having at one's disposal more than 50% of the voting rights or otherwise controlling the company concerned. Companies in which the group exercises significant but not controlling influence are regarded as affiliated companies. Significant influence is typically achieved by directly or indirectly owning or having at one's disposal more than 20% but less than 50% of the voting rights. The assessment of whether BioPorto A/S has controlling or significant influence considers potential voting rights that could be exercised on the balance sheet date.

The consolidated financial statements integrate the financial statements for the parent company and the individual subsidiaries, which are accounted for in accordance with the group's accounting policies, with the elimination of intercompany income and expenses, intercompany share holdings, intercompany balances and dividends, as well as realized and unrealized earnings for transactions between the consolidated companies. Unrealized earnings from transactions with affiliated companies are eliminated in proportion to the group's ownership interest in the company. Unrealized losses are eliminated according to the same procedure as unrealized earnings to the extent that an impairment has not occurred.

Foreign currency translation

A functional currency is determined for each of the group's reporting companies. The functional currency is the currency used in the primary financial environment in which the specific reporting company operates. Transactions in other currencies than the functional currency are transactions in foreign currency.

Transactions in foreign currency are translated on initial recognition to the functional currency according to the exchange rate prevailing on the date of the transaction. Currency differences arising

between the rate on the date of the transaction and the rate on the date of payment are recognized in the income statement under financial income or expenses.

Receivables, debt and other monetary items in foreign currency are translated into the functional currency according to the exchange rate prevailing on the balance sheet date. The difference between the rate on the balance sheet date and the rate on the date on which the receivable or debt arose or was recognized in the most recent annual report is included in the income statement under financial income and expenses.

Incentive programs

The company has granted warrants (share subscription rights) to the board of directors, the management and employees. Share-based incentive programs in which the employees alone have the option of choosing to subscribe to new shares in the parent company (equity-settled share-based payment arrangements) are measured at the fair value of the equity instruments on the date of granting and are recognized in the income statement when the employees acquire the right to subscribe to the new shares. The set-off for this is recognized directly in the equity as a separate reserve until utilized.

Leases

Payments in conjunction with operating leases are recognized in the income statement over the term of the lease.

Segment information

Segmentation reflects the main product groups in the group. Segment reporting has not been changed compared to the previous report. A distinction is made between the following segments:

- a. Products sold for use in human diagnostics, including The NGAL Test™ and ELISA kits for measuring human NGAL and MBL.
- b. Products primarily intended for research and development, including monoclonal antibodies and other ELISA kits.
- c. Licenses and royalties stemming from the group's IP rights.
- d. Other (primarily reimbursed freight and packaging expenses).

The product groups are measured primarily on gross margin level as distribution, sales and marketing, research and development, and administration relates to both segments. There is no internal settlement between the segments.

As previously, information is included on the breakdown of net revenues into geographical and therapeutic areas.

There are no long-term assets or investments outside Denmark.

Comprehensive Income Statement

Revenues

Revenues from sales of finished goods are recognized in the income statement if the goods have been delivered and the risk has been passed on to the customer before the end of the year, and if said income can be reliably accounted for and receipt of payment is expected.

Net revenues from development and cooperation contracts are recognized in the income statement if the general criteria for revenue recognition are observed.

This is considered to be the case when:

- » delivery has taken place before the end of the fiscal year;
- » a binding sales agreement exists;
- » the selling price is fixed; and
- » payment has been received or is expected to be received with reasonable certainty.

The revenues are recognized exclusive of VAT and after the deduction of any discount connected to the sale.

Production costs

Production costs include costs incurred for achieving the year's net revenues, including fixed and indirect overhead for raw materials and consumables, wages and salaries, freight, royalties, rent and leasing as well as depreciation of plant.

Sales and marketing costs

Costs recognized under sales and marketing costs are those incurred for marketing products sold during the year and sales campaigns, etc., that have been carried out. Costs for sales staff, advertising and exhibition costs, as well as depreciation and amortization are included here.

Research and development costs

Wages and salaries, laboratory materials, patent expenses, rent, leasing and other costs relating to the company's research and development activities are recognized under research and development costs.

Administration expenses

Costs incurred during the year for the management and administration of the company, including costs for administrative staff, management, office facilities and office costs, depreciation, amortization, etc., are recognized under administration expenses.

Financial income and expenses

Financial income and expenses include interest, capital gains and losses, as well as write-downs and impairment concerning debt, securities and foreign currency transactions, amortization of financial assets and liabilities, as well as charges and refunds under the tax prepayment scheme, etc.

Income taxes relating to the net loss

The tax for the year, consisting of the year's current tax and the change in the deferred tax, is recognized in the income statement

by the amount attributable to the net loss and directly to the equity by the amount attributable to entries under equity.

To the extent the group obtains deductions by means of the accounting of the taxable income resulting from share-based payment, the tax effect of the schemes is recognized under income taxes relating to net income. If the total tax deduction exceeds the total accounting cost, the tax effect of the surplus deduction is recognized directly to the equity, however.

Balance Sheet

Intangible assets

Development projects

In accordance with "IAS 38, Intangible Assets", intangible assets arising from development projects must be recognized on the balance sheet when the development project is clearly defined and identifiable where technical utilization options are demonstrated and adequate resources can be documented for completing the development work and marketing or using the product, and the company's management has acknowledged its intention to manufacture and market or use the product.

Finally, it must be possible to document with adequate certainty that the future earnings from the development project will exceed the costs of production and development as well as for selling and administering the product. Development costs concerning individual projects are only recognized as assets in the event it is adequately certain that the future income of the individual projects will exceed not only the production, selling and administration costs, but also the development costs for the product.

In the opinion of the management and board of directors, a large risk is generally associated with the company's products and for this reason it is not possible to obtain adequate certainty for future earnings at present. The future financial advantages associated with product development cannot be calculated with reasonable certainty until the development activities have been completed. As a result of this, development costs are expensed concurrent to being incurred during the year.

Tangible assets

Other plant, machinery and equipment are measured at the original cost, minus the accumulated depreciation, amortization, write-downs and impairment.

The cost includes the acquisition price as well as expenses directly associated with the acquisition up to the date on which the asset is ready for use.

Depreciation and amortization are carried out on a straight-line basis over the expected useful life of the assets, which are assessed as having the following terms of years:

| | |
|---|-----------|
| Other plant, operating equipment and fixtures | 3–5 years |
|---|-----------|

The basis for depreciation and amortization is the original cost, minus the expected residual value at the end of the useful life. The original cost of a total asset is divided into smaller components that are depreciated/amortized separately if their useful life differs. Depreciation and amortization methods, useful lives and residual values are reassessed each year.

Depreciation and amortization are recognized in the income statement under production costs, research and development costs, selling and marketing costs and administration expenses respectively to the extent the depreciations/amortizations are not included in the original cost for inventory as indirect production overhead (IPO).

Impairment of assets

Intangible assets with an indefinable useful life are reviewed at least once a year for impairment, the first time before the end of

the year of acquisition. Ongoing development projects are similarly reviewed for impairment once a year.

The accounting value of intangible assets with an indefinable useful life and development projects in process is reviewed at least once a year for impairment together with the other qualifying assets belonging to the cash-generating unit to which the asset is allocated and written down to the recoverable amount in the income statement, in the event the accounting value is higher. The recoverable amount is usually accounted for as the present value of the anticipated future net cash flow from the enterprise or activity (cash-generating unit) to which the asset is associated.

Deferred tax assets are assessed yearly and recognized only to the extent it can be rendered probable that they will be utilized in the near future.

The book value of other qualifying assets (including investments in subsidiaries) is assessed annually to determine whether there is an indication of impairment. If an indication is present, the asset's recoverable value is calculated. The recoverable value is the highest value of the asset's fair value, minus the expected costs of disposal and the value in use.

An impairment loss is recognized when the book value of an asset or a cash-generating unit respectively exceeds the asset's or the cash-generating unit's recoverable value. Impairment loss is recognized in the income statement under production, selling and distribution costs respectively or administration costs.

Write-downs relating to other assets is reversed to the extent changes occur in the prerequisites and estimates that led to the impairment. Impairment is only reversed to the extent that the asset's new book value does not exceed the book value the asset would have had after depreciation or amortization if the asset had not been impaired.

Inventories

The cost of inventories is measured according to the FIFO method. If the net realizable value is lower than the cost, the inventory in question is written down to this lower value.

The cost for raw materials and consumables is calculated at cost with the addition of transportation and similar costs.

The cost of finished goods and goods in progress includes the cost of raw materials, consumables, direct wages and indirect production overhead (IPO). Indirect production overhead includes indirect costs such as materials and wages, as well as costs for maintenance of and depreciation/amortization of machinery and equipment used in the production process, as well as costs for production administration and management.

The net realizable value of inventories is calculated as the selling price minus completion costs and costs incurred to effectuate sales and are determined under consideration of marketability, obsolescence and developments relating to the loss expected.

Receivables

Receivables are measured at the amortized cost or a lower net realizable value, which usually equates to the nominal value, minus impairment for meeting a loss.

A provision account is used to reduce the carrying value of re-

ceivables from sales, impaired due to risk of loss. Write-downs for bad and doubtful debts are based on an individual assessment of each receivable.

Prepaid expenses

Prepaid expenses recognized under assets include expenses to be incurred in the subsequent fiscal year. Prepaid expenses are measured at cost.

Equity

Treasury stock

Acquisition and disposal costs as well as the dividend for treasury stock are recognized directly in equity. The capital reduction by cancelling treasury stock reduces the share capital by an amount equivalent to the nominal value of the equity investment.

Warrants

Proceeds received from the exercise of warrants are booked directly under equity.

Payable and deferred tax

Current tax liabilities and payable current tax are recognized in the balance sheet as the tax calculated for the year's taxable income, adjusted for the tax on taxable earnings of previous years and for tax paid on account.

Deferred tax is measured according to the balance-sheet liability method by temporary differences between the book value and the tax value of assets and liabilities. However, deferred tax is not recognized for temporary differences concerning tax-related non-deductible goodwill and other entries in which temporary differences – apart from corporate acquisitions – have occurred after the date of acquisition without affecting the financial results or the taxable income. In the cases where the determination of the tax value can be performed according to different taxation rules, deferred tax is measured on the basis of the utilization of the asset or repayment of the debt respectively as planned by the management.

Deferred tax assets, including the tax value of tax losses allowed to be carried forward, are recognized under other qualifying assets by the value at which they are expected to be used, either by means of an elimination in tax of future earnings or by offsetting in deferred tax liabilities within the same legal tax unit or jurisdiction (joint taxation).

Deferred tax concerning eliminations of unrealized intercompany profits and losses is adjusted.

Deferred tax is measured on the basis of the tax rules and rates of income tax that will apply when the deferred tax is expected to create a tax liability as a current tax according to the law in force on the balance sheet date. Any change to the deferred tax resulting from changes to rates of taxation is recognized in the income statement. The tax rate used for the current fiscal year is 25%.

Financial liabilities

Convertible bonds

Convertible bonds are considered as compound instruments, consisting of a financial liability measured at amortized cost, and an equity instrument in the form of the embedded conversion option.

At the date of issue, the fair value of the financial liability is determined by using a market rate for similar non-convertible debt. The difference between the proceeds from the issuance of the convertible bond and the fair value of the financial liability, representing the embedded option to convert the obligation to equity, is recognized in equity.

Issue costs are allocated between the liability component and equity component of the convertible debt based on their relative carrying amounts at the date of issue. The part relating to the equity component is recognized directly in equity.

Interest expense on the liability component is calculated using the prevailing market rate for similar non-convertible debt. Any difference between the estimated interest cost and the actual interest paid under the bond's coupon rate is attributed to the carrying value of the liability. The financial liability is subsequently measured at amortized cost.

Other financial liabilities

Debts to banks etc., are recognized at the time of taking out the loan at the fair value of the obligation component, minus the transaction costs incurred. In subsequent periods, the financial liabilities are measured at the amortized cost by applying the effective interest method so the difference between the proceeds and the nominal value is recognized in the income statement under financial expenses during the term of the loan.

Other liabilities are measured at net realizable value.

Advance receipts

Advance receipts recognized under liabilities include payments received for income in subsequent years. Advance receipts are measured at cost.

Cash Flow Statement

The cash flow statement is presented according to the indirect method and shows cash flow broken down by operating, investment and financing activities for the year, the year's change in cash and cash equivalents and the company's cash and cash equivalents at the beginning and end of the year.

The cash flow from operating activities is accounted for as EBIT, adjusted for non-cash operating items, changes in working capital and corporate income tax paid.

Cash generated by investment activity includes the purchase and sale of intangible, tangible and financial assets.

Cash generated by financing activity includes changes to the amount or composition of BioPorto A/S's share capital and costs connected with this, as well as the raising of loans, payments on interest-bearing debt and the payment of dividends to shareholders.

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

Financial Ratios

Earnings per share (eps) and diluted earnings per share (deps) are accounted for in accordance with IAS 33.

The financial ratios stated under the key financial data are calculated as follows:

| | |
|--|---|
| Revenue growth | $\frac{\text{Revenue year 1} - \text{revenue year 0}}{\text{Revenue year 0}}$ |
| Gross margin ratio | $\frac{\text{Gross income} \times 100}{\text{Net revenues}}$ |
| Operating margin | $\frac{\text{EBIT} \times 100}{\text{Net revenues}}$ |
| 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 | $\frac{\text{Cash generated by operations}}{\text{Average number of shares}}$ |
| Equity value per share, closing | $\frac{\text{Capital and reserves, closing}}{\text{No. of shares, closing}}$ |

The financial ratios were prepared in accordance with “Anbefalinger & Nøgletal 2010” (Recommendations & Financial Ratios 2010) by the Den Danske Finansanalytikerforening (Danish Association of Financial Analysts).

Note 2

Significant Accounting Estimates and Assessments

An assessment of how future events will affect the value of certain assets and liabilities on the balance sheet date is required for determining the book value of these assets and liabilities. Assessments significant to the financial reporting are performed by determining development costs, convertible bonds, incentive schemes, inventories, deferred tax, etc.

The assessments used are based on assumptions deemed justifiable by the management and the board of directors, but which are inherently uncertain and unpredictable. The assumptions may be incomplete or inaccurate, and unforeseen events or circumstances may occur. In addition, the company is subject to risks and uncertainties that could cause the actual results to deviate from the estimates.

Going concern and financing of the group

At the end of February, 2013, cash in the form of bank deposits totaled DKK 5.2 million, which is expected to finance BioPorto's activities until June 2013. The management estimates the funding needs by the end of May 2013 to be DKK 5-10 million and by third quarter at the latest an additional DKK 15-20 million in order to finance the activities of the group in 2013 and settle the convertible debt (DKK 13.5 million) due in September 2013. Also, the management estimates a need for DKK 35-45 million to fund the activities planned for 2014 and 2015.

After considering the options available, management has decided to seek to carry out a rights issue to existing shareholders. The issue, planned for third quarter 2013, is expected to provide BioPorto with funds in the range of DKK 60-70 million, which is deemed sufficient to implement the planned activities over the next three years. Three of the major shareholders have given notice that they will participate in a rights issue and, if necessary, lend funds in the period leading up to the completion of the rights issue.

The group's capital requirements are subject to uncertainty related to the expected development in sales of its products, and the actual costs, and maintenance of existing IP rights, cf. below. The management monitors actual revenues and expenditures closely in order to install corrective actions.

The estimated net proceeds from the rights issue is also uncertain. The group's continued status as a going concern is dependent on a supply of DKK 5-10 million in May, and that net proceeds of at least DKK 25 million are raised in connection with the issue.

Intellectual property rights

BioPorto has obtained a number of patent rights within the NGAL field. The group's NGAL cut-off patent is the principal patent in BioPorto's portfolio of NGAL IP rights and is crucial to the group's strategy in the promising NGAL market. The NGAL patents make it possible to guarantee higher sales of BioPorto's own products

and to exercise BioPorto's rights vis-à-vis competitors in the event that competitors sell NGAL tests for acute kidney-injury diagnosis without having licensing access to these patents. Obtaining a patent is not a prerequisite for enabling BioPorto to sell its products, however. The NGAL IP strategy is to retain the patent rights to the homogeneous test format, but to grant licenses for NGAL tests developed in the heterogeneous test format.

The group's NGAL cut-off patent is the principal patent in BioPorto's portfolio of NGAL IP rights and is an important asset for achieving the largest share of the future NGAL market. The NGAL cut-off patent describes the cut-off of 250 ng/mL or higher that can be used for diagnosing acute kidney injury. As actual use of NGAL as a diagnostic marker gradually increases, it is considered that the patented cut-off will be borne out.

After the issuance of the NGAL cut-off patent, Abbott, Alere, Phadia and Getica sought to eliminate the patent in Europe by filing an opposition case with the European Patent Office (EPO). In February 2012, the EPO made a first-instance decision stating that the patent does not describe the invention with sufficient clarity for the method to be carried out as specified in claim 1 (Art. 83, EPC).

As BioPorto clearly expects to be able to reverse the decision, an appeal has been filed with a court of second instance (Board of Appeal). The patent is fully valid and the patent rights can continue to be enforced during the appeal. A ruling in the case by the EPO is expected in the course of 2014.

In December 2006, BioPorto filed a patent invalidity case against Phadia's European patent DK/EP 0 756 708 in Denmark, particularly focusing on rendering invalid the patent's claim 1 which cites the use of HNL (another designation of NGAL) as a diagnostic marker of human illness. BioPorto's assertion that the patent's claims 1 and 2 are invalid in Denmark was upheld by the Maritime and Commercial Court in its ruling of June 2012. At the same time, the Court did not accept Phadia's claim for a ban against and damages in tort for BioPorto's sales of NGAL kits. Phadia appealed this decision to Denmark's Supreme Court in July 2012, and the court hearing will take place in June 2014. Phadia's patent expires on April 21, 2015. The management does not expect that the patent appeal will lead to financial obligations for the group.

The NGAL Test™'s market penetration

The BioPorto Group's long-term financing structure is considerably interrelated with sales of The NGAL Test™. There are several unknown factors in the equation concerning the anticipated market penetration of The NGAL Test™. The assay is new in the market and must undergo registration and reimbursement processes in the various markets; the major diagnostics companies must first include the assay in their portfolio, and the assay must gain widespread acceptance as a renal-injury marker among hospitals and doctors. See also the section concerning market penetration and IP rights (see page. 12-14 and page 14-16).

Convertible bonds

Convertible loans are regarded as a combined financial instrument classified as an equity component and a debt component. Both components are recognized and presented separately. Interest for the debt component (effective rate of interest) is calculated over the term of the bond so that the debt specified on the balance sheet on the maturity date reflects the total debt. The effective rate of interest for the convertible debt included is calculated at 14.87%. The determination of the equity component and the effective rate of interest is based on discretionary assessments. If the assumptions applied are changed, this will influence the recognized interest expenses and the proportion between the equity component and the debt component.

Deferred tax

A significant deferred tax asset has been calculated (see Note 15). In the view of the management and the board of directors, however, the option of using the tax asset in the near future is not sufficiently plausible, based on IFRS. For this reason, the management and board of directors have chosen not to recognize the calculated tax asset on the balance sheet.

In connection with the Finance Act for 2012, a way for companies to receive 25% of losses derived from experimental and research expenses was introduced. The new option can be used from the 2012 income year. A maximum payment of DKK 1.25 million, corresponding to 25% of DKK 5 million, can be obtained, and the company must apply for this payment. The application is filed concurrently with the filing of tax returns. Included are expenses written off as experimental and research activities according to the Assessment Act 8B or the Depreciation Act 6.1.3. The group intends to apply for payment of part of the companies' tax losses, but the management has chosen not to recognize any income before tax authorities has approved the current application (see also note 15).

Note 3

Segment information

| 2012 | Human diagnostics DKK thousand | Other kits and reagents DKK thousand | Licenses and royalties DKK thousand | Other revenues DKK thousand | Total DKK thousand |
|--------------------------------|--------------------------------------|--|---|-----------------------------------|-----------------------|
| Net revenues | 4,510 | 12,033 | 652 | 663 | 17,858 |
| Production costs | (2,114) | (4,039) | 0 | (650) | (6,803) |
| Gross income/loss | 2,396 | 7,993 | 652 | 14 | 11,054 |
| 2011 | Human diagnostics DKK thousand | Other kits and reagents DKK thousand | Licenses and royalties DKK thousand | Other revenues DKK thousand | Total DKK thousand |
| Net revenues | 4,320 | 11,709 | 1,870 | 685 | 18,584 |
| Production costs | (2,543) | (4,853) | 0 | (668) | (8,064) |
| Gross income/loss | 1,777 | 6,856 | 1,870 | 18 | 10,521 |

Note 3

Segment information, continued

| The geographical dispersion of the net revenues | 2012 | 2011 |
|---|---------------|---------------|
| | DKK thousand | DKK thousand |
| Denmark | 799 | 236 |
| EU Member States | 6,090 | 5,869 |
| North America | 8,848 | 9,589 |
| Asia | 1,113 | 2,000 |
| Other | 1,008 | 890 |
| Net revenues, total | 17,858 | 18,584 |

The customer's registered office is the bases for the geographical dispersion.

| Allocation of net revenues: | 2012 | 2011 |
|----------------------------------|---------------|---------------|
| | DKK thousand | DKK thousand |
| NGAL products | 6,531 | 5,178 |
| Peptide hormone products | 3,226 | 3,887 |
| MBL products | 2,070 | 2,194 |
| Other products | 6,031 | 7,326 |
| Net revenues, total | 17,858 | 18,584 |

Major customers

Revenues from the largest customer in BioPorto Diagnostics A/S totals 16% of the total revenue (12% in 2011) and this revenue is included in all product segments.

Note 4

Staff costs

| | 2012 | 2011 |
|-----------------------------------|---------------|---------------|
| | DKK thousand | DKK thousand |
| Wages and salaries | 12,776 | 12,582 |
| Contribution based pensions | 1,867 | 1,790 |
| Other social security costs | 190 | 177 |
| Other staff costs | 451 | 348 |
| Share-based payment | 0 | 1,274 |
| Staff costs | 15,284 | 16,170 |
| Average number of employees | 26 | 25 |

Dispersed as follows:

| | 2012 | 2011 |
|--------------------------------------|---------------|---------------|
| | DKK thousand | DKK thousand |
| Production costs | 2,377 | 3,267 |
| Sales and marketing costs | 4,295 | 4,238 |
| Administration expenses | 4,902 | 5,239 |
| Research and development costs | 3,710 | 3,426 |
| Staff costs | 15,284 | 16,170 |

| | 2012 | 2011 |
|-----------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Management | | |
| Salaries and pensions | 1,535 | 1,735 |
| Share-based payment | 0 | 157 |
| Board of directors | | |
| Salaries and pensions | 750 | 625 |

Note 5

Incentive schemes

For the purpose of motivation and retaining staff and management, BioPorto A/S has set up warrant programs in 2008, 2009 and 2011 as incentive and bonus schemes. The schemes, which may only be exercised by issuing new shares (equity scheme), confers the right to subscribe a number of new shares in the parent company at a pre-agreed price. The right to subscribe new shares will take place on the date of grant. The parent company will issue the number of shares subscribed not later than at the next ordinary annual general meeting after receiving the claim and, not later than at the same time, the Danish Commerce and Companies Agency shall be notified of the capital increase for registration, both elements contingent, however, on the receipt of the claim by the parent company's CEO not later than six (6) weeks prior to the annual general meeting. In 2012, recognized share-based compensation, equity schemes, was DKK 0 (DKK 1,274 thousand).

Overview of current warrant programs:

| | Exercise period | Subscription price each DKK | No. of warrants No. | Fair value per warrant DKK |
|---|--------------------|-----------------------------------|---------------------------|----------------------------------|
| Total, December 31, 2007 | | | 771,160 | |
| Board of Directors | 31.03.10-31.03.13 | 6.15 | 130,000 | 1.21 |
| Management | 31.03.10-31.03.13 | 4.18 | 45,000 | 1.69 |
| Employees | 31.03.10-31.03.13 | 4.18 | 342,500 | 1.69 |
| Total, December 31, 2008 | | | 1,288,660 | |
| Management | 16.04.11-16.04.14 | 3.50 | 56,675 | 2.31 |
| Employees | 16.04.11-16.04.14 | 3.50 | 426,575 | 2.31 |
| Lapsed | | | -771,160 | |
| Total, December 31, 2009 | | | 1,000,750 | |
| Total, December 31, 2010 | | | 1,000,750 | |
| Management | 06.02.14-06.02.17 | 9.82 | 75,000 | 2.09 |
| Employees | 06.02.14-06.02.17 | 7.86 | 421,500 | 2.65 |
| Exercised, Board of directors | | 6.15 | -26,000 | 1.21 |
| Exercised, Management and employees | | 4.18 | -226,497 | 1.69 |
| Total, December 31, 2011 | | | 1,244,753 | |
| Total, December 31, 2012 | | | 1,244,753 | |

| The granting of warrants breaks down as follows: | No. of shares 2012 | Fair value 2012 DKK thousand | Fair value 2011 DKK thousand |
|--|-----------------------|------------------------------------|------------------------------------|
| Outstanding warrants, December 31 | 1,244,753 | 2,844 | 2,844 |

Note 6

Depreciation, amortization, write-downs and impairment

| | 2012 | 2011 |
|--|--------------|--------------|
| | DKK thousand | DKK thousand |
| Tangible assets | 189 | 221 |
| Depreciation, amortization, write-downs and impairment, total ... | 189 | 221 |
| Depreciation, amortization, write-downs and impairment are recognized in the income statement as follows: | | |
| Production costs | 89 | 109 |
| Sales and marketing costs | 0 | 0 |
| Research and development costs | 89 | 109 |
| Administration expenses | 11 | 3 |
| | 189 | 221 |

Note 7

Fee for auditors elected by the general meeting

| | 2012 | 2011 |
|--|--------------|--------------|
| | DKK thousand | DKK thousand |
| Total fees, Deloitte State authorized partnership of public accountants | 278 | 295 |
| Itemized as follows: | | |
| Audit | 253 | 253 |
| Assurance engagements | 25 | 25 |
| Tax consultancy | 0 | 17 |
| Other services and regulation relating to previous years | 0 | 0 |
| Total fees for auditors elected by the general meeting | 278 | 295 |

Note 8

Financial income and expenses

Financial income

| | 2012 | 2011 |
|---|--------------|--------------|
| | DKK thousand | DKK thousand |
| Interest income from bank | 0 | 28 |
| Interest income, financial activities not measured at fair value | 0 | 28 |
| Exchange rate adjustments | 49 | 40 |
| Other financial income | 0 | 0 |
| Financial income, total | 49 | 68 |

Financial expenses

| | 2012 | 2011 |
|--|----------------|----------------|
| | DKK thousand | DKK thousand |
| Interest expenses, convertible bonds | (1,818) | (1,742) |
| Interest costs, financial activities not measured at fair value | (1,818) | (1,742) |
| Exchange rate adjustments | (37) | (35) |
| Other financial expenses | (273) | (271) |
| Financial expenses, total | (2,128) | (2,048) |

Note 9

Earnings per share (eps)

| | 2012 | 2011 |
|--|-----------------|-----------------|
| | DKK thousand | DKK thousand |
| Net income/loss for the year | (14,700) | (14,838) |
| BioPorto A/S' shareholders' share of the net income/loss for the year | (14,700) | (14,838) |
| Average number of shares | 45,308 | 43,084 |
| Average number of treasury stocks | (13) | (13) |
| Average number of shares in circulation | 45,295 | 43,071 |
| Diluted average number of shares in circulation | 45,295 | 43,071 |
| Earnings per share (eps/deps) | (0.32) | (0.34) |

There is no difference between earnings per share (eps) and diluted earnings per share (deps) as the net earnings for the year are negative. Warrants and convertible bonds are not included in the calculation of eps and deps. In the long term, warrants and convertible bonds may have a diluting effect on both financial ratios. Further details about the incentive scheme are found in note 5.

Note10

Other plant, operating equipment and fixtures

| | 2012 | 2011 |
|--|----------------|----------------|
| | DKK thousand | DKK thousand |
| Cost, January 1 | 3,225 | 3,201 |
| Addition during the year | 82 | 24 |
| Disposals during the year | 0 | 0 |
| Cost, December 31 | 3,307 | 3,225 |
| Depreciation and amortization, January 1 | (2,896) | (2,675) |
| Depreciation and amortization for the year | (189) | (221) |
| Reverse depreciation and amortization of disposals during the year | 0 | 0 |
| Depreciation and amortization, December 31 | (3,085) | (2,896) |
| Book value, December 31 | 222 | 328 |

Note 11

Inventories

| | 2012 | 2011 |
|--|--------------|--------------|
| | DKK thousand | DKK thousand |
| Finished products | 3,586 | 3,134 |
| Raw materials and semi-finished products | 133 | 90 |
| Indirect production overhead | 509 | 434 |
| Inventory | 4,228 | 3,658 |
| Write-downs for slowly marketable products | (53) | (186) |

All product categories have been individually assessed with a view to historical marketability and future sales potential. A product category has been written down if the category is deemed not to contribute substantially to the company's future revenues. Products that are deemed marketable within the next three years are written down to zero.

| | | |
|---|-------|-------|
| Inventory that is expected to be sold after twelve months | 1,241 | 1,357 |
|---|-------|-------|

Note 12

Receivables

| | 2012 | 2011 |
|---|--------------|--------------|
| | DKK thousand | DKK thousand |
| Receivables from sales and services | 2,688 | 1,626 |
| Other receivables | 2,493 | 1,341 |
| Write-downs for meeting loss | (50) | (50) |
| | 5,131 | 2,917 |

For receivables that fall due for payment within one year after the end of the fiscal year, the nominal value is deemed equivalent to the fair value

| | 2012 | 2011 |
|--|--------------|--------------|
| | DKK thousand | DKK thousand |
| Opening balance of write-down account for meeting loss | (50) | (50) |
| Change during the year | 0 | 0 |
| Closing balance or write-down account for meeting loss | (50) | (50) |

A provision account is used to reduce the carrying value of receivables from sales, impaired due to risk of loss. Writedowns for loss are based on an individual assessment of each receivable.

Note 13

Share capital

The share capital is made up of 47,149,684 shares at DKK 3.00. The shares are fully paid. The shares are not divided into classes and there are no specific rights attached to shares.

| No. of shares | 2012 | 2011 |
|------------------------------------|-------------------|-------------------|
| | No. | No. |
| January 1 | 42,132,627 | 42,132,627 |
| Exercised, convertible bonds | 64,560 | 0 |
| Exercised, warrants | 252,497 | 0 |
| Directed share issue | 2,700,000 | 0 |
| December 31 | 45,149,684 | 42,132,627 |

| Capital increase in 2012 | No. of shares | Nominally | Subscription price |
|----------------------------|---------------|-----------|--------------------|
| | No. | DKK | DKK/share |
| Directed share issue | 2,000,000 | 3.00 | 5.10 |

| Capital increase in 2011 | No. | DKK | DKK/share |
|---|-----------|------|-----------|
| | No. | DKK | DKK/share |
| Conversion of bonds | 64,560 | 3.00 | 6.97 |
| Capital increase from exercising warrants - Board of Directors | 26,000 | 3.00 | 6.15 |
| Capital increase from exercising warrants - management and employees .. | 226,497 | 3.00 | 4.18 |
| Directed share issue | 2,700,000 | 3.00 | 5.00 |

| Capital increase in 2009 | No. | DKK | DKK/share |
|----------------------------|-----------|------|-----------|
| | No. | DKK | DKK/share |
| Directed share issue | 3,830,000 | 3.00 | 3.97 |

Note 14

Treasury stock

| Nominal value | 2012 | 2011 |
|--------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| January 1 | 39 | 39 |
| December 31 | 39 | 39 |

| No. of shares | 2012 | 2011 |
|--------------------------|---------------|---------------|
| | no. | no. |
| January 1 | 13,000 | 13,000 |
| December 31 | 13,000 | 13,000 |

| % of share capital | 2012 | 2011 |
|--------------------------|--------------|--------------|
| | % | % |
| January 1 | 0.03% | 0.03% |
| December 31 | 0.03% | 0.03% |

Pursuant to the annual general meeting's mandate, BioPorto A/S may acquire treasury stock equivalent to not more than 10% of the share capital. BioPorto A/S has not acquired treasury stock in the fiscal year nor in the base year.

Note 15

Deferred tax

| | 2012 | 2011 |
|------------------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Tax asset value | 32,178 | 29,676 |
| Write-down to assessed value | (32,178) | (29,676) |
| Book value | 0 | 0 |

A substantial deferred tax has been calculated. In the view of management and the board, however, the option of using the tax asset in the near future is not sufficiently plausible, taking the IFRS as the point of departure. For this reason, the management and the board have chosen not to recognize the calculated tax asset on the balance sheet, see note 2.

Deferred tax assets not recognized in the balance sheet:

| | 2012 | 2011 |
|--|---------------|---------------|
| | DKK thousand | DKK thousand |
| Intangible assets | 5,099 | 4,719 |
| Tangible assets | 689 | 692 |
| Shortterm assets | 238 | 184 |
| Tax losses allowed to be carried forward | 26,153 | 24,081 |
| Deferred tax, December 31, net | 32,178 | 29,676 |

Reconciliation of changes:

| | 2012 | 2011 |
|--|----------------|--------------|
| | DKK thousand | DKK thousand |
| Earnings before tax | (15,950) | (14,838) |
| Calculated (25%) tax | (3,988) | (3,709) |
| Adjustments, non-deductible expenses/income | 665 | 744 |
| Changes in tax assets not recognized as income | 2,072 | 2,965 |
| Total | (1,250) | 0 |
| Tax rate | 0% | 0% |

Note 16

Convertible bonds

In 2010 convertible loan were admitted totaling DKK 13,950 thousand, of which DKK450 thousand in 2011 were converted into shares. The loans bear interest at a fixed annual interest rate of 8%. Lender may choose to convert the bond within 4 weeks from the publication of the annual reports for 2011 and 2012 or for 4 weeks prior to the due date. Payment of interest cease on conversion- or maturity date. The conversion can be done at a rate of 6.97 per share. The full amount is due on September 20, 2013 at par.

| | 2012 | 2011 |
|---|---------------|---------------|
| | DKK thousand | DKK thousand |
| Nominal value of issued convertible bonds | 13,500 | 13,500 |
| Fair value of equity component | (2,158) | (2,158) |
| Fair value of the obligation at the time of issue | 11,342 | 11,342 |
| Calculated interest expense in the period | 1,818 | 1,729 |
| Interest liability Januar 1. | 1,146 | 568 |
| Paid interest during the year | (1,080) | (1,151) |
| Liability December 31, amortized cost | 13,226 | 12,488 |
| Breaks down as follows: | | |
| Convertible loans, long-term | 0 | 11,342 |
| Calculated interest expenses, long-term part | 0 | 844 |
| Long term liability, total | 0 | 12,186 |
| Convertible loans, short-term | 11,342 | 0 |
| Calculated interest expenses, short-term part | 1,884 | 302 |
| Liability December 31, amortized cost | 13,226 | 12,488 |
| Convertible bonds, equity share | | |
| Convertible bonds, fair value of equity component | 2,158 | 2,158 |
| Transaction costs | (121) | (121) |
| Book value | 2,037 | 2,037 |

Convertible loans are considered as a compound financial instrument classified as an equity component and a liability component. It includes an interest rate (effective rate) to the liability component of the bond so that the obligation in the balance at maturity reflects the total commitment. The effective rate for the convertible debt is calculated to 14,87 %. The fair value of convertible bonds amounted to DKK 12,597 thousand as of December 31, 2011. Fair value is calculated at the present value of future installments and interest payments using the assessed market rate of 14,1 % as the discount rate. The used market rate is equivalent to 14,87 % adjusted for changes in the risk free rate (10 year government bond) in the period since issuance.

Note 17

Financial risks and financial instruments

Categories of financial instruments

| | 2012 | 2011 |
|------------------------------------|---------------|---------------|
| | DKK thousand | DKK thousand |
| Receivables, sales | 2,638 | 1,576 |
| Other receivables | 1,243 | 1,341 |
| Cash resources | 8,349 | 14,105 |
| Loans and receivables | 12,230 | 17,022 |

| | 2012 | 2011 |
|---|---------------|---------------|
| | DKK thousand | DKK thousand |
| Convertible loan | 13,226 | 12,488 |
| Financial liabilities measured at amortized cost | 13,226 | 12,488 |
| Trade accounts payable | 2,608 | 1,757 |
| Other creditors | 1,741 | 1,398 |
| Financial liabilities measured at fair value | 4,349 | 3,155 |

Receivables, sales

In 2012, a small bad debt of DKK 29 thousand (2011: DKK 0) is identified. For receivables due within one year after the end of the fiscal year, the nominal value is deemed equivalent to the fair value.

| | 2012 | 2011 |
|---------------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Not overdue | 1,954 | 1,208 |
| Overdue 0-90 days | 697 | 418 |
| Overdue more than 90 days | 36 | 1 |

| | Currency | Yield | 2012 | 2011 |
|--|----------|-------|--------------|--------------|
| | | | DKK thousand | DKK thousand |
| Deposits with variable interest | DKK | 0.1% | 8,349 | 14,105 |
| Sensitivity at the time of variable interest fluctuation | | 1.0% | 83 | 141 |

Note 17

Financial risks and financial instruments, cont.

Financial liabilities

See note 16 for details on convertible bonds.

Convertible bonds are explained separately in note 16. Commitments under sales and other creditors are due within 1 year after the year end. For these liabilities the nominal value is considered equivalent to fair value.

Financial risks

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

The process comprises five sub-elements: identification, analysis, planning, action and follow-up. All heads of departments participate in efforts relating to the individual subsidiary activities where the individual risks are evaluated on the basis of probability and impact criteria. These efforts include both financial and non-financial risks. The board approves yearly targets for the risk-management efforts and a situation update is on the agenda of each board meeting.

Currency risk

As the Group exports its products to a number of different markets, it is vulnerable to changes in currency exchange rates. All foreign customers are invoiced in EUR, which reduces the direct risk. Indirectly, the fluctuations can influence BioPorto's competitiveness which is not recognized in the sensitivity analysis. Otherwise, the Group does not hedge exposure til currency fluctuations.

| | Currency | Exchange rate | 2012 DKK thousand | 2011 DKK thousand |
|----------------------------------|----------|---------------|----------------------|----------------------|
| Revenues settled in | EUR | 7.45 | 17,059 | 18,348 |
| Sensitivity | 0.15% | 0.01 | 191 | 205 |

Interest rate exposure

The Group's cash resources earn interest at a variable interest rate on market terms. The Group's risk is limited, according to the statement in this note under financial instruments. The convertible bond loan totaling DKK 13.5 million carries a fixed rate of 8% until the due date.

Credit risk

At present, the Group's credit risk is primarily related to the subsidiary's receivables. The customers' financial situation and ability to pay are known by the Group and the credit risk entailed by each receivable is assessed as modest. Prepayment of deliveries may be necessary for new customers. Otherwise, the Group does not hedge the credit risk in any other way.

Note 17

Financial risks and financial instruments, cont.

Liquidity risk

At the end of February, 2013, cash in the form of bank deposits totaled DKK 5.2 million, which is expected to finance BioPorto's activities until June 2013. The management estimates the funding needs by the end of May 2013 to be DKK 5-10 million and by third quarter at the latest an additional DKK 15-20 million in order to finance the activities of the group in 2013 and settle the convertible debt due in September 2013. Also, the management estimates a need for DKK 35-45 million to fund the activities planned for 2014 and 2015.

After considering the options available, management has decided to seek to carry out a rights issue to existing shareholders. The issue, planned for third quarter 2013, is expected to provide BioPorto with funds in the range of DKK 60-70 million, which is deemed sufficient to implement the planned activities over the next three years. Three of the major shareholders have given notice that they will participate in a rights issue and, if necessary, lend funds in the period leading up to the completion of the rights issue.

See note 2 for a detailed review

Maturities of financial liabilities are specified below by the temporal intervals used in the Group's cash management. The specified amount represents the amount due and payable including interest, etc.

| 2012 | Less than 1 year DKK thousand | Between 1 and 5 years DKK thousand | More than 5 years DKK thousand | Total DKK thousand |
|---|-------------------------------------|--|--------------------------------------|-----------------------|
| Convertible bonds | 13,500 | 0 | 0 | 13,500 |
| Interest liability on convertible bonds | 1,080 | 0 | 0 | 1,080 |
| Other liabilities | 4,349 | 0 | 0 | 4,349 |
| Financial liabilities | 18,929 | 0 | 0 | 18,929 |

| 2011 | Less than 1 year DKK thousand | Between 1 and 5 years DKK thousand | More than 5 years DKK thousand | Total DKK thousand |
|---|-------------------------------------|--|--------------------------------------|-----------------------|
| Convertible bonds | 0 | 13,500 | 0 | 13,500 |
| Interest liability on convertible bonds | 1,080 | 1,080 | 0 | 2,160 |
| Other liabilities | 3,155 | 0 | 0 | 3,155 |
| Financial liabilities | 4,235 | 14,580 | 0 | 18,815 |

Note 18

Operational lease commitments

Rent and lease:

A lease has been concluded for the lease of office, laboratory and production facilities. BioPorto and landlord has a notice period of 6 months. The lease includes fixed lease payments, which are annually index linked.

| | 2012 | 2011 |
|------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Less than 1 year | 502 | 494 |

BioPorto Diagnostics A/S' agreement for the use and storage of celle lines at the Statens Serum Institut runs until 2017. The minimum royalty agreed for the period is included in the overview. The agreement is non-terminal within the period, mentioned, after which the right of use continues without a fixed minimum royalty.

| | 2012 | 2011 |
|------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Less than 1 year | 414 | 621 |
| 1-5 years | 1,872 | 1,783 |
| Over 5 years | 0 | 503 |

Other research and licencing agreements: A fixed annual minimum royalty is included in the obligation. The agreement is non-terminable within the period mentioned and includes a renewal option.

| | 2012 | 2011 |
|------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Less than 1 year | 254 | 15 |
| 1-5 years | 60 | 60 |

Minimum payments recognized in the profit or loss for the year:

| | 2012 | 2011 |
|------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Less than 1 year | 1,626 | 1,527 |

Note 19

Change in working capital

| | 2012 | 2011 |
|-------------------------------|----------------|--------------|
| | DKK thousand | DKK thousand |
| Change in inventories | (570) | (225) |
| Change in receivables | (2,214) | (67) |
| Change in supplier debt | 851 | 146 |
| Change in other debt | 427 | (698) |
| | (1,506) | (844) |

Note 20

Contingent liabilities

In December 2006, BioPorto filed a patent invalidity case against Phadia's European patent DK/EP 0 756 708 in Denmark, particularly focusing on rendering invalid the patent's claim 1 which cites the use of HNL (another designation of NGAL) as a diagnostic marker of human illness. BioPorto's assertion that the patent's claims 1 and 2 are invalid in Denmark was upheld by the Maritime and Commercial Court in its ruling of June 2012. At the same time, the Court did not accept Phadia's claim for a ban against and damages in tort for BioPorto's sales of NGAL kits. Phadia appealed this decision to Denmark's Supreme Court in July 2012, and the court hearing will take place in June 2014. Phadia's patent expires on April 21, 2015.

The management does not expect that the patent appeal will lead to financial obligations for the group.

Note 21

Related parties and ownership

Related parties of the BioPorto Group:

Carsten Lønfeldt
Marianne Weile
Roar Bjørk Seeger (joined the board February 26, 2013)
Laura von Kobyletzki (joined the board February 26, 2013)
Thomas Magnussen (joined the board February 26, 2013)
Torben A. Nielsen (joined the board as deputy member February 26, 2013)
Claus Crone Fuglsang (joined the board as deputy member February 26, 2013)
Thea Olesen
Lars Otto Uttenthal, board member in BioPorto Diagnostics A/S
Peter Nordkild (resigned from the board February 26, 2013)
Niels Tækker Foged (resigned from the board February 26, 2013)

Group owned companies

BioPorto Diagnostics A/S

Transactions with related parties

The group has purchased consulting services from the following board members of BioPorto A/S or BioPorto Diagnostics A/S on market terms:

| | 2012 | 2011 |
|--|--------------|--------------|
| | DKK thousand | DKK thousand |
| Scientific supervision - Lars Otto Uttenthal | 963 | 954 |

In addition to remuneration cf. Note 4, during the year no transactions have been executed with Board of Directors, senior management, substantial shareholders, subsidiaries or related parties.

Income Statement

BioPorto A/S

January 1 – December 31, 2012

| Note | | 2012 | 2011 |
|------|---|----------------|----------------|
| | | DKK thousand | DKK thousand |
| 3 | Net revenues | 1,920 | 1,846 |
| | Gross income | 1,920 | 1,846 |
| | Gross margin | 100% | 100% |
| 4-5 | Administration expenses | (6,649) | (5,803) |
| | Earnings before interest (EBIT) | (4,730) | (3,957) |
| | EBIT margin | -246% | -214% |
| 6 | Financial income | 7,184 | 6,272 |
| 6 | Financial expenses | (1,352) | (1,355) |
| | Earnings before tax | 1,102 | 961 |
| 10 | Income taxes relating to net loss | 0 | 0 |
| | Net income/loss for the year | 1,102 | 961 |
| | Recommended appropriation of profit: | | |
| | Carried forward to the coming year | 1,102 | 961 |

Balance Sheet

BioPorto A/S

January 1 – December 31, 2012

| Note | 2012 Dec. 31 DKK thousand | 2011 Dec. 31 DKK thousand |
|--------------------------------------|---------------------------------|---------------------------------|
| Financial assets | | |
| 9 Receivables, subsidiary | 132,082 | 115,102 |
| 8 Investment in subsidiary | 48,000 | 48,000 |
| Deposits | 249 | 244 |
| Financial assets, total | 180,331 | 163,345 |
| Long-term assets, total | 180,331 | 163,345 |
| Current assets | | |
| 9 Other receivables | 391 | 538 |
| Receivables | 391 | 538 |
| Cash resources | 7,199 | 12,826 |
| Current assets, total | 7,590 | 13,364 |
| ASSETS, TOTAL | 187,921 | 176,709 |

Balance Sheet

BioPorto A/S

January 1 – December 31, 2012

| Note | 2012 Dec. 31 DKK thousand | 2011 Dec. 31 DKK thousand |
|--|---------------------------------|---------------------------------|
| Equity | | |
| Capital stock | 141,449 | 135,449 |
| Retained income | 30,681 | 25,969 |
| Equity, total | 172,130 | 161,418 |
| Liabilities | | |
| Long-term liabilities | | |
| 11 Convertible bond loans | 0 | 13,500 |
| Long-term liabilities, total | 0 | 13,500 |
| Short-term liabilities | | |
| 11 Convertible bonds | 13,802 | 302 |
| Supplier of goods and services | 582 | 126 |
| Other debt | 1,406 | 1,363 |
| Short-term liabilities, total | 15,791 | 1,791 |
| Liabilities, total | 15,791 | 15,291 |
| EQUITY AND LIABILITIES, TOTAL | 187,921 | 176,709 |

Statement of Changes in Equity

BioPorto A/S

January 1 – December 31, 2012

| | Capital stock DKK thousand | Premium DKK thousand | Retained income/loss DKK thousand | Total DKK thousand |
|--|-------------------------------|-------------------------|---|-----------------------|
| Equity, January 1, 2012 | 135,449 | 0 | 25,969 | 161,418 |
| Net income/loss for the year | 0 | 0 | 1,102 | 1,102 |
| Capital increase, directed issue | 6,000 | 4,200 | 0 | 10,200 |
| Issue costs | 0 | (589) | 0 | (589) |
| Transferred to "retained income" | 0 | (3,611) | 3,611 | 0 |
| Equity December 31, 2012 | 141,448 | 0 | 30,682 | 172,130 |

| | Capital stock DKK thousand | Premium DKK thousand | Retained income/loss DKK thousand | Total DKK thousand |
|--|-------------------------------|-------------------------|---|-----------------------|
| Equity, January 1, 2011 | 126,398 | 0 | 19,803 | 146,201 |
| Net income/loss for the year | 0 | 0 | 961 | 961 |
| Capital increase, directed issue | 8,100 | 5,400 | 0 | 13,500 |
| Exercised warrants and convertible bonds | 951 | 606 | 0 | 1,557 |
| Issue costs | 0 | (800) | 0 | (800) |
| Transferred to "retained income" | 0 | (5,206) | 5,206 | 0 |
| Equity December 31, 2011 | 135,449 | 0 | 25,969 | 161,418 |

Note Index

1. Accounting policies
2. Significant accounting estimates and assessments
3. Net revenues
4. Staff costs
5. Depreciation, amortization, write-downs and impairment
6. Financial income and expenses
7. Other plant, operating equipment and fixtures
8. Investment in subsidiaries
9. Receivables
10. Deferred tax
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Note 1

Accounting Policies

The Annual Report for the parent company, BioPorto A/S, was prepared in accordance with the provisions of the Danish Financial Statements Act for large companies in reporting class D.

The Annual Report is presented in Danish kroner (DKK), which is the functional currency of the company.

The accounting policies of the parent company are unchanged compared to last year.

Differences from the group's accounting policies

The company's accounting policies for recognition and measurement are in accordance with the consolidated accounting policies, with the following exceptions:

Income statement

The result of investments in subsidiaries

Dividend from subsidiaries is recognized in the parent company's income statement when the shareholders' right to receive dividend has been approved, after deduction of any write-downs on the investments.

Share-based remuneration

The value of share-based remuneration is not recognized in the income statement. The board and management's share-based remuneration is accounted for in the notes to the financial statements.

Balance sheet

Investment in subsidiaries

Investment in subsidiaries is measured at cost in the parent company's financial statements. If the cost exceeds the investment's recoverable amount, the investment is written down to this lower value.

The cost is also written down to the extent that the distributed profit exceeds the accumulated earnings after the date of acquisition.

Convertible bonds

Convertible bonds are treated solely as a debt instrument.

Cash flow statement

Pursuant to Section 86(4) of the Danish Financial Statements Act, no cash flow statement has been prepared, as this is included in the cash flow statement for the group.

Tax

The parent company is taxed jointly with the company's domestic (Danish) subsidiaries. The jointly taxed Danish companies are included in the Danish Tax Prepayment Scheme. The actual tax for the year for jointly taxed companies is recognized in the individual companies.

Note 2

Significant accounting Estimates and Assessments

By determining the carrying value of certain assets and liabilities, an estimate of how future events will affect the value of these assets and liabilities at the balance sheet date is required. Estimates that are material to the financial statements are made, including in determining the value of employment equity in the subsidiary claims of the subsidiary and deferred tax.

The estimates are based on assumptions that management considers reasonable, but which are inherently uncertain and unpredictable. Assumptions may be incomplete or inaccurate and unanticipated events or circumstances may occur. Furthermore, the company is subject to risks and uncertainties that could cause actual results to differ from estimates.

See note 2 under consolidated financial statements of accounting estimates and judgments that are shared with the group.

Investment and receivables BioPorto Diagnostics A/S

The management and board of directors have assessed the investment in the subsidiary BioPorto Diagnostics A/S and the parent company's receivable in the subsidiary with a view to possible impairment of the assets recognized. The two items comprise the following:

| | |
|--------------------------------|----------------------|
| Investment, December 31, 2012 | DKK 48,000 thousand |
| Receivables, December 31, 2012 | DKK 132,082 thousand |

The management and board of directors have assessed the following areas of the subsidiary:

Impairment test

Impairment test will only occur if events or circumstances indicate that the carrying amount may not be recoverable. Included in the factors taken into account when testing for impairment are as follows: Estimated market size and penetration, costs of developing, manufacturing, sales and marketing and the risk of related intellectual property and marketing authorizations cannot be maintained or achieved.

Financing

The company has a financial reserve of DKK 8,349 thousand as of December 31, 2012. See the part about capital resources for further detail.

Market value

The share holders' assessment of the group represents a market-related measurement for the group's combined activities and assets. As the majority of the group's activities and IP rights are placed in the subsidiary, the measurement (reduced for cash at bank and in hand) is also an approximate value for BioPorto Diagnostics A/S.

The conclusions are as follows:

- » The outlook for earnings potential of The NGAL Test TM makes it possible to achieve a positive cash flow within a few years and in the longer term ensure that the investment is recovered.
- » The management expects to obtain financing from existing investors, which is sufficient to implement the Company's activities in accordance with the planned strategy.
- » At the end of 2012, BioPorto A/S' market value was approx. DKK 208 million. Minus cash resources this results in a derived "market value" of approx. DKK 200 million. The market value has since fallen to approx. DKK 185 million and management believes that this is due to market uncertainty about future funding.

On the basis of this, the management and board of directors assess that there is no incentive for writing down the parent company's investment in BioPorto Diagnostics A/S or the parent company's receivable in the same company.

Note 3

Net revenues

| | 2012 | 2011 |
|---|--------------|--------------|
| | DKK thousand | DKK thousand |
| The geographical dispersion of the net revenues is as follows: | | |
| Denmark | 1,920 | 1,846 |
| Net revenues, total | 1,920 | 1,846 |

The sales of services in the parent company solely comprises intercompany sales.

Note 4

Staff costs

| | 2012 | 2011 |
|--------------------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Wages and salaries | 4,181 | 4,046 |
| Defined contribution, pensions | 562 | 518 |
| Other social security costs | 37 | 34 |
| Other staff costs | (59) | 13 |
| Staff costs | 4,722 | 4,612 |
| Average number of employees | 6 | 6 |

| | 2012 | 2011 |
|-------------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Administration expenses | 4,722 | 4,612 |

See also note 4-5 in the consolidated accounts for details on the remuneration of board of directors and management as well as share-based payment.

Note 5

Depreciation, Amortization, writedowns and impairment

There were no depreciations, amortizations, writedowns or impairments in 2012

Note 6

Financial Income and Expenses

| | 2012 | 2011 |
|--------------------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Interest income, subsidiaries | 7,184 | 6,251 |
| Interest income from bank | 0 | 22 |
| Other financial income | 0 | 0 |
| Financial income, total | 7,184 | 6,272 |

| | 2012 | 2011 |
|--|----------------|----------------|
| | DKK thousand | DKK thousand |
| Interest expenses, convertible bonds | (1,080) | (1,090) |
| Other financial expenses | (272) | (265) |
| Financial expenses, total | (1,352) | (1,354) |

Note 7

Other plant, Operating equipment and fixtures

| | 2012 | 2011 |
|---|--------------|--------------|
| | DKK thousand | DKK thousand |
| Cost, January 1 | 174 | 174 |
| Cost, December 31 | 174 | 174 |
| Depreciation and amortization, January 1 | (174) | (174) |
| Depreciation and amortization for the year | 0 | 0 |
| Depreciation and amortization, December 31 | (174) | (174) |
| Book value, December 31 | 0 | 0 |

Note 8

Investment in subsidiaries

| | 2012 | 2011 |
|--------------------------------------|---------------|---------------|
| | DKK thousand | DKK thousand |
| Cost, January 1 | 48,000 | 48,000 |
| Cost, December 31 | 48,000 | 48,000 |
| Book value, December 31 | 48,000 | 48,000 |

| | 2012 | 2011 |
|---|-------------------------------|-------------------------------|
| | Ownership and voting interest | Ownership and voting interest |
| BioPorto Diagnostics A/S Gentofte, Copenhagen | 100% | 100% |

Bioportio Diagnostics A/S is engaged in the development, production and sale of antibodies and diagnostic kits for analysis.

| Recent accounts for BioPorto Diagnostics A/S | 2011 |
|--|-----------------|
| | DKK thousand |
| Equity | (110,719) |
| Net loss | (13,915) |

Note 9

Receivables

| | 2012 | 2011 |
|---|----------------|----------------|
| | DKK thousand | DKK thousand |
| Intercompany receivables | 132,082 | 115,102 |
| Other receivables and prepayments | 391 | 538 |
| | 132,473 | 115,640 |

For receivables that fall due for payment within one year after the end of the fiscal year, the nominal value is deemed equivalent to the fair value. BioPorto A/S invests capital in the subsidiary BioPorto Diagnostics A/S on an ongoing basis to support the subsidiary's operating activities. The receivable amount carries an annual interest of 6 % which is charged once a year on December 31. The management of BioPorto A/S and BioPorto Diagnostics A/S coincide. As the subsidiary's activities constitute the majority of the Group's activities, see review by the management and board of directors, including the description of risks.

Note 10

Deferred tax

| | 2012 | 2011 |
|------------------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Tax asset value | 507 | 771 |
| Write-down to assessed value | (507) | (771) |
| Book value | 0 | 0 |

A substantial deferred tax has been calculated. In the view of management and the board, however, the option of using the tax asset in the near future is not sufficiently plausible. For this reason, the management and board have chosen not to recognize the calculated tax asset on the balance sheet, see Note 2

Deferred tax assets unrecognized on the balance sheet:

| | 2012 | 2011 |
|--|--------------|--------------|
| | DKK thousand | DKK thousand |
| Tangible assets | 59 | 59 |
| Short-term assets | (69) | (122) |
| Tax losses allowed to be carried forward | 517 | 834 |
| Deferred tax, December 31, net | 507 | 771 |

Note 11

Operational lease commitments

Rental and lease contracts

A lease is signed for the rental of laboratory and production facilities. BioPorto and the landlord have a notice period of 6 months. The contract has fixed lease payments and is indexed annually.

| | 2012 | 2011 |
|------------------------|--------------|--------------|
| | DKK thousand | DKK thousand |
| Less than 1 year | 502 | 494 |

| | 2012 | 2011 |
|--|--------------|--------------|
| | DKK thousand | DKK thousand |
| Tangible assets | 59 | 59 |
| Short-term assets | (69) | (122) |
| Tax losses allowed to be carried forward | 517 | 834 |
| Deferred tax, December 31, net | 507 | 771 |

Note 12

Convertible bonds

| | 2012 | 2011 |
|--|---------------|---------------|
| | DKK thousand | DKK thousand |
| Convertible loan, long-term part of debt | 0 | 13,500 |
| Convertible loan, interest due | 15,384 | 302 |
| Book value | 15,384 | 13,802 |
| Interest, convertible loans in 2011 | 1,080 | 1,090 |

See note 16 of the consolidated financial statements

Note 13

Fee for auditors elected by the general meeting

| | 2012 | 2011 |
|--|--------------|--------------|
| | DKK thousand | DKK thousand |
| Total fees, Deloitte State authorized partners. of public accountants | 195 | 204 |
| Itemized as follows: | | |
| Audit | 170 | 170 |
| Assurance engagements | 25 | 25 |
| Tax consultancy | 0 | 9 |
| Other services and regulation relating to previous years | 0 | 0 |
| Total fees for auditors elected by the general meeting | 195 | 204 |

Other notes

See note 13-14 of the consolidated financial statements for shares and treasury shares.

Refer to note 21 of the consolidated financial statements for matters relating to related parties, and the section on page 26 around the supervisory board directorships.

Glossary

| | | | |
|--|--|-------------------------------------|--|
| APC-PCI | The complex between activated protein C and the protein C inhibitor. Analyzing this complex in plasma will contribute to the diagnosis of thrombosis and related diseases and the complex also has other utilization possibilities for which BioPorto has patent applications pending. | MBL | <i>"Mannan-binding lectin"</i> , a blood protein that binds to foreign organisms and contributes to congenital (innate) immune response. |
| Biomarker/ diagnostic marker | 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. | 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. |
| 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. | NGAL | <i>"Neutrophil gelatinase-associated lipocalin"</i> , a biomarker that can indicate renal injury already at an early stage. |
| 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. | OEM | <i>"Original equipment manufacturer"</i> , used in the opposite sense of the word for distributors, for instance, who market products of other companies under their own name. |
| ELISA kit | <i>"Enzyme-linked immunosorbent assay"</i> kit, a laboratory assay format that can determine the content of a biomarker in body fluids such as blood or urine samples. | PCT application/ treatment | <i>"Patent Cooperation Treaty"</i> deals with international patent cooperation that makes it possible to apply for patents in a large number of countries in one application. |
| FDA approval | The <i>"Food and Drug Administration"</i> , is the US authority that authorizes the use of medicines, including diagnostic products. | Preclinical / clinical phase | Different stages of developing a new drug. The pre-clinical phase includes development and testing in laboratory animals and precedes the clinical phases I-IV, where the drug is tested in humans. |
| GLP-1 | <i>"Glucagon-like peptide-1"</i> , 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. | Routine diagnostics | Diagnostic analyses that are performed on a routine basis at the time of hospitalization. |
| Homogeneous/ heterogeneous 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. | Sandwich antibody pair | A pair of antibodies targeting the same biomarker which can be used in the sensitive and specific "sandwich" ELISA method whereby the biomarker is identified by two different antibodies. |
| IVD | <i>"In vitro diagnostic(s)"</i> , a diagnostic procedure that takes place outside the body, e.g. by analyzing blood and urine samples in a laboratory, as opposed to <i>"in vivo diagnostics"</i> , which are performed on the patient, such as a prick test in the skin or an X-ray. | 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. |
| Clinical acceptance | Recognition by the medical profession and the implementation of (a test) in the health system, eg the inclusion of a new diagnostic test. | Therapy/ Therapeutic products | Treatment of diseases and the products used for this, typically medicines. |
| | | Toxicology | Study of the toxicity of substances and the way in which they are capable of causing harmful effects in the body. Toxicological studies are an indispensable part of developing registerable 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 diagnostics 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.

We sell our products in more than 80 countries through diverse sales channels and partners.

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