

Risk situation and management

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

Commercial and developmental risks

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

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

The most significant short-term risks include the following:

- » That the company does not manage to establish the required number of routine users in the principal markets of the US, Europe and South Korea and that the roll-out of The NGAL Test™ does not take place at the speed wished for.
- » BioPorto does not obtain FDA approval of The NGAL Test™ in mid-2018 as planned.
- » That competing technologies adversely affect the market roll-out of NGAL.
- » That BioPorto does not retain exclusivity for sales of a number of antibodies, but can sell them non-exclusively instead.
- » BioPorto cannot obtain financing in the event of future financing needs.

Staff-related risks

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

Production risks and quality-related risks

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

Currency risks and other financial risks

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

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

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

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

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