Risk management

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

All units in the Company participate in the identification and assessment of operational risk factors in order to address them properly. Risk Management is part of the Rules of Procedures for the Audit Committee. The Board of Directors receives updates and recommendations on initiatives, which then form part of the Board's overall assessment and decision on the Company's activities and future.

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

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

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

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

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

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

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

Risk Factors

Expectations and assumptions in the annual report concerning BioPorto's business – the market for diagnostics in AKI and antibodies – and the Company's revenue, accounting results and expected market share are subject to substantial uncertainty. There is no guarantee that the Company in whole or in part will achieve its expectations for revenue or the profit/loss for the year. The most significant operational risks are:

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

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

- Securing new sites in U.S. using The NGAL Test™ for research use
- Competing technologies adversely affecting the market roll-out of The NGAL Test™
- Protection of patents and other intellectual property rights
- The ability to obtain Freedom to Operate in commercially relevant markets
- The ability to prevent competing companies from having Freedom to Operate in commercially relevant markets
- The ability to attract and retain key personnel
- Performance and dependence of the Company's subcontractors and most significantly CMOs and CROs
- Collaborative agreements, including distribution agreements
- Disputes concerning contractual relations where the company may risk losing the rights to products marketed by the company
- Duration and outcome of review processes by various authorities
- Clinical development and data from pipeline projects
- Risks relating to the Company's technologies, projects and products
- Risks relating to trade receivables and inventory
- Risks relating to a U.S. Government shutdown
- Changes in the USD exchange rate and its impact on the free liquidity, future revenue and net finances

- Tax risks
- Risks related to IT in general

The Company's risks further include the ability to enter into collaborations with partners for development, manufacturing, marketing and financial resources. There are additional risks related to sales contracts and the related production and logistics.

Currency risks include the risk arising from sales and production contracts being denominated in currencies other than Danish kroner. Contracts are primarily in USD and EUR, meaning that other currencies do not represent significant currency risks.

Revenues and contracts are still relatively modest and thus the Company is not hedging its USD exposure. However, the Company is monitoring its USD exposure and will be ready to use financial instruments to hedge this exposure if the need arises. As long as the DKK is linked to the EUR the Company's revenue and costs in EUR will not be hedged.

Internal controls

The Board of Directors and the Management of BioPorto are responsible for the Company's control and risk management in connection with the financial reporting process, including compliance with rules and regulations that are relevant in reporting.

The Board of Directors has established an Audit Committee which reviews and discusses the accounting and audit practices with the Company's auditors and the Management in accordance with the Rules of Procedures of the Audit Committee.

BioPorto's main focus in this area is to ensure that its financial statements are in compliance and give a correct and reliable view of the Company's operations and financial position.

The annual audit and reporting process include detailed planning of individual tasks and planning between investor relations, finance and the auditors. It is based on an audit strategy approved by the Audit Committee.

At least once a year the Audit Committee evaluates the risks connected with the financial reporting process, including the presence of internal controls and guidelines. The Audit Committee assesses the Company's organizational structure, including the risk of fraud and the measures to be taken to reduce and/or eliminate such risk.

In that regard, any incentive or motivation of the Management to manipulate earnings or perform any other fraudulent action is discussed.

The Company's internal controls and guidelines provide a reasonable but not an absolute certainty that unlawful use of assets, loss and/or significant errors or deficiencies in relation to the financial reporting process can be avoided.

The Board of Directors has decided not to institute an internal audit at BioPorto, based on its assessment that the Company's size and complexity does not necessitate such a function.