Risk management

Risk management is an integrated part of BioPorto's operations. The Company identifies material risks that could affect revenues, development, production, future performance, or the interests of the shareholders with the purpose of running the Company in accordance with best practices in its industry.

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 2019, the Company partly finalized its work on securing alternative manufacturing capabilities by identifying and validating a manufacturer for antibodies according to the Company's Quality procedures.

The work of securing alternative manufacturing options to ensure a reliable supply of actionable biomarkers will continue in 2020.

In November 2019, the Company received feedback on the US application for regulatory clearance of The NGAL Test for pediatric risk assessment of AKI. Following a dialogue with the FDA, BioPorto decided to supplement its application with additional data and plans to submit a revised application in the second quarter of 2020.

In June 2019, the Company concluded a financing round and issued approximately 9.3 million new shares in a private placement. The gross proceeds from the financing amounted to DKK 36.7 million.

In 2019, the Company continued its work with data protection and implemented the GDPR framework.

The primary risks in 2019 related to: the enrollment of patients in the US NGAL adult study; the submissions and clearances of The NGAL Test for adults and children; the preparation and launch of the test in US following regulatory clearances; antibody sales; and the establishment of alternative manufacturing sources. In 2019, antibody sales were impacted by a ceased collaboration with a supplier.

In 2020, the primary risks will be related to the gathering of additional data and filing the submission for FDA clearance of The NGAL Test in pediatrics as well in securing continued growth in NGAL revenues.

The design and execution of the protocol for the additional pediatric data collection and submission of the application is the single most important task in 2020.

As announced earlier the Company is currently pursuing financing. It was the ambition to finalize the financing prior to the announcement of the Annual Report 2019. However, the increased volatility and negative reactions in the financial markets caused by the global outbreak of the COVID-19 virus has pushed the timeline. The Company expects the financing to be finalized by mid-April.

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:

- The Company's cash preparedness and ability to obtain funding necessary to fulfill the Company's strategy
- Submission and clearance of application by FDA in US for The NGAL Test in children
- Preparation and launch of The NGAL Test in the US market
- Preparation of submission of application to FDA in US for The NGAL Test in adults
- Securing an alternative manufacturing option for the Company's actionable biomarkers
- Cyber attacks
- Warning letter from FDA and/or failed inspections from various regulatory authorities

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

- Antibody sales
- Competing technologies adversely affecting the market roll-out of The NGAL Test
- Protection of patents and other intellectual property rights
- The ability to obtain the 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; most significantly CMOs and CROs
- Collaborative agreements, including distribution agreements

- Duration and outcome of review processes by various regulatory 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
- 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 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.