# Risk management

Risk management is an integral part of BioPorto's operations. The Company identifies material risks that could affect revenues, development, production, future performance, or the interests of the shareholders in order to run 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 decisions on the Company's activities and future plans.

In 2020, the Company was – as was most of the world – affected by the COVID-19 pandemic. On March 13, 2020 when Denmark experienced the first lock down due to COVID-19 the Company took measures to safeguard its employees and at the same time modify facilities to enable the Company to continue operations.

While it is hard to measure the impact of the pandemic on revenues, our clinical studies have been broadly affected. Multiple waves of SARS-CoV-2 infections restricted BioPorto's access to hospitals and limited the healthcare system's ability to process and conduct studies according to the schedule the Company originally anticipated.

As a result, the NGAL pediatric trial has been delayed and the expected timeline for finalizing enrollment of patients has moved to summer 2021.

The pandemic also created new opportunities for the Company. In April 2020, the Company entered a collaboration with University of Southern Denmark to develop a rapid test to detect COVID-19 viral antigen.

In April 2020, the Company concluded a financing round and issued approximately 25 million new shares in a pre-emptive rights issue. The gross proceeds from the financing amounted to DKK 40 million.
In October 2020, the Company concluded a second financing round and issued approximately 66.6 million new shares in a pre-emptive rights issue. The gross proceeds from this financing amounted to DKK 106.6 million.

With the net proceeds from the financings in 2020 and revenues from current operations, the Company has funds through Q2 2022 including costs for two clinical trials for developing NGAL (adults) and the gRAD platform, as well as building its US organization to prepare for an FDA clearance and commercialization of The NGAL Test.

In 2021, the primary risks will be related to completing enrollment of patients and filing the submission for FDA clearance of The NGAL Test in pediatrics as well as in securing continued growth in NGAL revenues and building up the US organization for launch of The NGAL Test.

With regards to the Company's COVID-19 test, the collection of samples and the results of testing will be related risks. In the case of positive data, the Company expects to submit applications to various healthcare authorities, which also have attendant risks.

The speed with which the enrollment of patients for the NGAL pediatric trial and the sample collection for the COVID-19 testing occurs will very much depend on the COVID-19 pandemic, in particular in the US and Denmark.

## Risk Factors

Expectations and assumptions in the annual report concerning BioPorto's business – the market for diagnostics in AKI, antibodies and ELISA kits – 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:

- Public health epidemics, pandemics or outbreaks, such as COVID-19, could adversely impact the Company's business, future financial position, timeline, results of operations and future growth prospects

- The Company's capital structure may be insufficient to support its business operations and the Company may need to raise additional funding, which may not be available on acceptable terms, or at all, and failure to obtain such funding when needed may force the Company to delay, limit or terminate its product development efforts or other operations

- A failure to obtain FDA clearance of The NGAL Test for risk assessment of AKI would have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects

- The Company's future success depends in part on its ability to attract and retain its management team and key employees

- A failure to successfully commercialize The NGAL Test for pediatric and adult AKI uses would have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects

- The Company's Products and Future (NGAL) Products are complex to manufacture, and the Company may encounter difficulties in manufacturing that could have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects

- The Company's ability to compete may decline if the Company does not adequately protect its proprietary rights and confidential information

- The Company's Products and Future (NGAL) Products may fail to achieve the degree of market acceptance by physicians, laboratory management, healthcare payors and others in the medical community necessary for commercial success, making market penetration potentially lengthy and difficult

- The Company may face competition from companies with considerably more resources and experience and/or more novel technology than the Company, which may result in others discovering, developing, receiving clearance for or commercializing products before, or more successfully than, the Company

- The Company is dependent on third-party partners to sell the Company's Products globally

- The manufacture of the Company's Products is dependent on the supply of raw materials and key components from suppliers, some of which are single source suppliers for the Company

- The pricing of the Company's Products and Future (NGAL) Products will depend in part on the clinical value of the product and delivery technology used in such products

- The Company's ability to retain key licenses could affect its ability to manufacture and sell Products and Future (NGAL) Products

- The Company operates in a highly regulated industry, and changes in regulations or the implementation or enforcement of existing regulations could have a material adverse effect

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

- 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

- Performance and dependence of the Company's subcontractors; most significantly CMOs and CROs

- Clinical development and results from pipeline projects

- Cyber attacks

- 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 all of 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 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 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.