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, regulatory affairs, or the interests of the shareholders in order to run the Company effectively.

All departments in the Company participate in the identification and assessment of financial and 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.

Since 2020, the Company was – as was most of the world – affected by the COVID-19 pandemic whereby the Company took measures to safeguard its employees and 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 De Novo application to the FDA was delayed until November 2022.

In 2023, primary risks include obtaining FDA market authorization for NGAL tests in pediatrics in the US, securing market adoption and continued growth in NGAL revenues including in regions where CE Mark is accepted, and retaining qualified personnel in a competitive environment.

1 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 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, Adjusted EBITDA, or the profit/loss for the year. Key risks that are specific for the Company that, among others, could cause the Company's results, prospects, and financial performance to differ materially from those expressed forward-looking statements are:

- The Company's products and future 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 and market penetration may be lengthy and difficult.
- Timing of future clinical trials depends on many factors outside of the Company's control, including regulatory pathways and their conditions associated with submissions presently under review that will serve as predicates to other submissions, the impact of future potential pandemics, wars and other events, each of which may impair the Company's ability to complete clinical trials in a timely manner or at all.
- The Company's pending pediatric NGAL test submission may not be approved by the FDA, or its approval may be delayed by or conditioned by the FDA.

- A failure to obtain FDA approval of a NGAL test for risk assessment of AKI would have a material adverse effect on the Company's prospective future revenues, future growth prospects, future cash-flows and future results of operations.
- A failure to successfully commercialize NGAL tests for pediatric and later adult uses would have a material adverse effect on the Company's prospective future revenues, future growth prospects, future cash-flows and future results of operations.
- The product benefits of NGAL tests may not demonstrably provide a clinical and economic case to drive market adoption, including until the Company completes a direct health economics and outcomes study of such factors.
- 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 future success depends in part on its ability to attract and retain its management team and key employees.
- The Company's products and future products are complex to manufacture, and the Company may encounter difficulties in manufacturing that could have a material adverse effect on the Company's revenues, cash flow, results of operations and future growth prospects.
- 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.
- Several patents used by the Company will expire in the near term, which may lead to increased competition and materially adversely affect the Company's business, financial condition, results of operations and prospects.
- 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 on the Company.
- To realize its strategic objectives, the Company will require additional capital to fund its operations, which may not be available to the Company on acceptable terms or at all.
- The Company has incurred net losses and may continue to do so.

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 Contract Manufacturing Organizations and Contract Research Organizations.
- Clinical development and results from pipeline projects.

- Cyber-attacks.
- Risks relating to trade receivables and inventory.
- Changes in the USD exchange rate, capital markets, and the costs of financing, and their 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.

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. Based on its transaction volume, the Group has determined not to hedge its USD exposure. As the Danish kroner is pegged to the EUR, hedging of the Company's transactions in EUR is not necessary.

To the extent these risk factors are within the Company's control, the Company seeks to address them in the ordinary course of business.

2 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 that 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.

The annual audit and reporting process includes detailed planning of individual tasks and planning by finance based on an audit strategy approved by the Audit Committee.

At least annually, 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 not instituted an internal audit function at BioPorto, based on its assessment that the Company's size and complexity do not necessitate such a function.