# BioPorto

Share offering with pre-emptive subscription rights March 2022



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### BioPorto Exists to Save Lives and Improve Quality of Life with Actionable Biomarkers

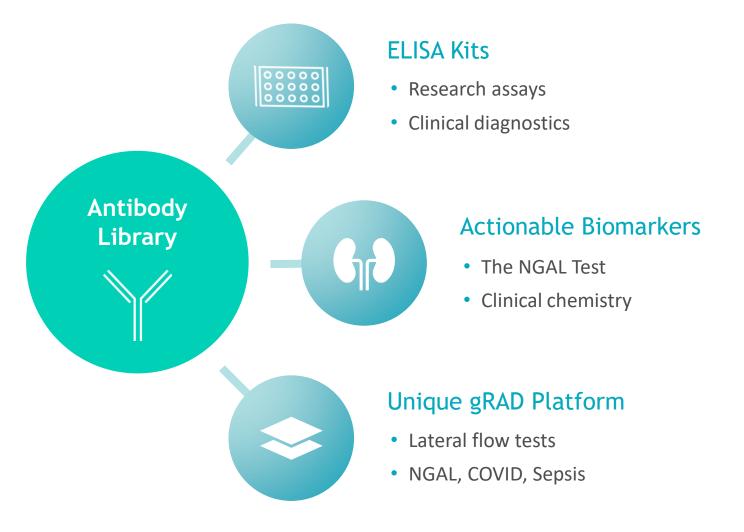




### **About BioPorto**

BioPorto is an in vitro diagnostics company that provides tests and antibodies to clinicians and researchers around the world. We use our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives.

BioPorto is headquartered in Hellerup, Denmark, with US headquarters near Boston, and is listed on the Nasdaq Copenhagen stock exchange [CPH:BIOPOR]. The company has 33 employees and LTM 2021-Q3 revenue of DKK 25 million.



### We Have a Strong Leadership Team in Place



Tony Pare CEO SINCE 2021

Over 25 years in senior leadership roles with public and private healthcare companies including Commercial, Business Development and General Manager positions at T2 Biosystems, Hemanext, and Haemonetics Inc.



Neil Goldman, CPA EVP & CFO SINCE 2021

Senior finance & corporate development leadership roles with diagnostics, global manufacturing and distribution companies including Chembio Diagnostics, Unwired Technology, and Delphi Corporation. Previously, an auditor and consultant with Ernst & Young.



Dr. Christopher Bird CMO SINCE 2019

Over 10 years as Head of North American Medical and Scientific Affairs at Roche Diagnostics Corporation, responsible for strategy and execution of all clinical education, study management and field support.



### **Offering Structure and Transaction Overview**

Transaction and terms	<ul> <li>Rights issue with offering of up to 66.9 new shares, gross proceeds of up to DKK 100.4 million and net proceeds of up to DKK 93.3 million</li> <li>Subscription price of DKK 1.50 per share with a subscription ratio of 4:1, implying that: <ul> <li>Existing shareholders in BioPorto receive one subscription right for each share held as of the record date</li> <li>Four (4) subscription rights entitles the holder to subscribe for one (1) new share in the rights issue</li> </ul> </li> </ul>
Subscription commitments & guarantees	<ul> <li>Approximately DKK 73,9 million has been pre-subscribed or guaranteed for by existing shareholders and external guarantors, subject to certain terms and conditions</li> <li>Existing shareholders and existing guarantors including Media-Invest Danmark A/S, Ejendomsselskabet Jano ApS, Aktieselskabet Arbejdernes Landsbank, Formue Nord Markedsneutral A/S and funds managed by Artha Capital and a number of other institutional and Qualified Investors</li> </ul>
Key dates	<ul> <li>Record day: 10 March 2022</li> <li>Rights trading period: 9 March 2022 to 22 March 2022</li> <li>Subscription period: 11 March 2022 to 24 March 2022</li> <li>Expected date of announcement of outcome 28 March 2022</li> </ul>
Use of proceeds	<ul> <li>Net proceeds from the Offering will be used for general corporate purposes, including to finance working capital, fund operating expenses in excess of those funded by margin from revenues, and undertake the committed and planned investments and activities, including capital expenses, to be taken towards the Company's strategic priorities, which include a clinical trial and application to the U.S. FDA for approval of the Company's Product, The NGAL Test, for assessment of AKI in children under the age of 22 (pediatrics) in the U.S. Following a potential approval by the FDA of The NGAL Test in pediatrics, strategic priorities include development of the Company's U.S. organization for a potential commercialization of The NGAL Test.</li> </ul>
Other	<ul> <li>The offering is a public offering in Denmark. The offering is a public offering in Denmark. Outside of Denmark, the offering will be made in compliance with U.S. Regulation S, with offers made only to non-U.S. persons who are either "qualified institutional buyers" or "accredited investors" (as defined in Rules 144A and 501(a), respectively, under the U.S. Securities Act of 1933). Please see the prospectus for further details</li> </ul>







Improve Quality of Life

with Actionable Biomarkers

# Launch an FDA Approved Product in the US

Strategic focus



Drive NGAL Test Market Adoption & Have a Pipeline of High Medical Value Products



- Complete clinical trials & submit The NGAL Test to FDA
- Grow rest-of-world revenues and NGAL awareness through focused distribution resources and tools
- Build US commercialization team to market the clinical value of the NGAL biomarker, and nurture key relationships at target accounts
- Leverage our antibody library and university relationships to costeffectively build the innovation pipeline

- Strengthen our key supplier relationships and implement scalable manufacturing processes
- Build robustness and ensure Quality Systems are FDA and IVDR audit-ready
- Prepare business processes for efficient and scalable growth



- Attract, Develop & Retain the Best and Brightest Employees Aligned with our Values
- Proactively recruit the most qualified talent to drive success
- Embrace flexible work environments enabling the ability to recruit from a larger pool of candidates
- Motivate and incentivize employees to stay & build shareholder value



#### US Regulatory Strategy: NGAL to Predict Acute Kidney Injury (AKI)

#### **Pediatric AKI**

FDA "Breakthrough Designation"

Predict AKI risk (stage 2/3) for ages 3 months to 22 years in the ICU

Roche c501 analyzer, then subsequent clearances for other Roche devices

#### Adult AKI

Adult AKI Risk

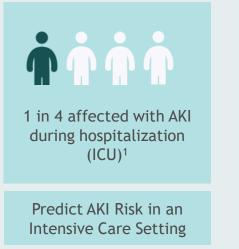
Study planning underway, 510(k) submission to FDA after pediatric clearance

#### **Expansion Areas**

Nephrotoxicity, Oncology, Cardiology, Diabetes, Transplant, Autoimmune, COVID-19 patient management Point-of-care applications Other analyzers

# Pediatric Trial Enrollment Expected to be Concluded in 👫 1H 2022, Quickly Followed by FDA Submission

#### Pediatric study



- Urine samples
- Predict Stage 2/3 AKI



- 15 hospital sites in US clinical trial for The NGAL Test in pediatrics
- Enrollment of patients affected by rise of COVID-19 pandemic which has slowed rate of patient enrollment and access to ICU's
- BioPorto expects to finalize pediatric trial enrollment in 1H 2022, followed by assembling the FDA submission package & De Novo application with Breakthrough Designation
- FDA targets up to 150 calendar days after submission to respond... excludes time for company to respond to FDA inquiries, which can include more data generation and "stops the clock"



#### TOTAL GLOBAL ADDRESSABLE MARKET: ~\$3 BILLION

### **Estimated Global NGAL Market Opportunity**

Based on estimates of NGAL use in these clinical settings:

- ICUs
- Emergency Departments
- Certain outpatient settings



### **Future Capital Market Intentions**



### An Approach to Access US Markets: Funding Onward Growth & Expansion

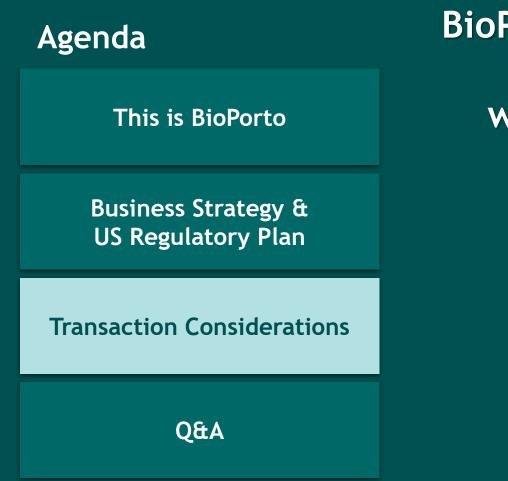
	2022-Q2		2022-Q3	2022-Q4		2023			
Financing					Cross-Bord Including the			U.S. Nasdaq Listing	
Pediatric NGAL	Finalize Clinical Trial Data Collection	Compile Results	FDA Review of De Novo Application (150 days + any inquiries) <sup>1</sup>				Commercialization		
Expand NGAL Population & Indications <sup>2</sup>			Develop Stu	dy Protocol, Sites & Co	ontracts	Prepare Pre-sub	FDA Reviews Pre-sub	Clinical Trial & Analytical Testing	

- Our objective includes building a dynamic presence in the US... the world's largest and leading IVD market
- To be Defined: capital structure, exchange listing(s), legal entities, etc.

• Timing and decision-making depend on a range of factors, including in particular the timing of the potential FDA De Novo application, pre-submissions and related reviews

<sup>1</sup>FDA targets up to 150 calendar days after submission to respond... excludes time for the company to respond to FDA inquiries, which can include more data generation and "stops the clock"

<sup>2</sup>Includes adult population, expanded claims, other NGAL indications, other lab instruments, etc.





### BioPorto Exists to Save Lives and Improve Quality of Life with Actionable Biomarkers



# **Key Elements of Pre-Emptive Rights Issue**



- Offering of 66,938,601 new shares at a subscription price of DKK 1.50 per share
- Holders of existing shares will receive one pre-emptive right for each share held
- Four (4) pre-emptive rights allow for subscription of one (1) new share against payment of subscription price







# Important Dates for the Rights Issue

7 Mar. 2022	Announcement of prospectus
8 Mar. 2022	Last day of trading in Existing Shares including Preemptive Rights
9 Mar. 2022	First day of trading in Existing Shares ex Pre-emptive Rights
9 Mar. 2022	First day of Rights Trading Period
10 Mar. 2022	Allocation Time of Pre-emptive Rights
11 Mar. 2022	First day of Subscription Period
22 Mar. 2022	Last day of Rights Trading Period
24 Mar. 2022	Last day of Subscription Period
28 Mar. 2022	Allocation of Remaining Shares
28 Mar. 2022	Expected date of publication of the results of the Offering
1 Apr. 2022	Expected registration of the New Shares with the Danish Business Authority
4 Apr. 2022	Expected date of admission of the New Shares to trading and official listing under the ISIN code of the Existing Shares
5 Apr. 2022	Expected merger of ISIN codes

# Summary of key risk factors

#### Risks related to the Company's business

- Timing of clinical trials depends on many factors outside of the Company's control, including the impact of COVID-19, which may impair the Company's ability to complete clinical trials in a timely manner or at all The results from the Company's ongoing clinical trial relating to pediatric use of The NGAL Test may not meet the primary outcomes previously committed to the FDA, which may prevent the Company from
- submitting the clinical trial's results to the FDA and/or ultimately obtaining FDA approval of The NGAL Test for risk assessment of AKI in pediatrics 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 and market penetration may be lengthy and difficult The Company may not be able to successfully implement its strategies
- The Company relies on third parties to conduct its clinical trials and perform data collection and analysis
- The Company faces current or potential 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 prior to or more successfully than the Company
- The Company is dependent on third-party partners to sell the Company's Products globally and the Company's ability to maintain and grow its business will be limited if it fails to maintain existing and develop new distribution channels
- 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 growth could suffer if the markets in which the Company sells its Products and intends to sell its Future (NGAL) Products decline or do not grow as anticipated
- Global or regional economic uncertainty and other global economic or political and regulatory developments could have a material adverse effect on the Company's business, results of operations, cash flows, financial condition, and/or prospects
- Serious adverse safety events involving the Company's Products and Future (NGAL) Products can negatively affect the Company's business. This could also adversely impact the Company's business, future financial position, results of operations and future growth prospects

#### Risks related to the Company's Products and Future (NGAL) Products

- A failure to obtain FDA approval of The 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 The NGAL Test for pediatric and later adult uses would have a material adverse effect on the Company's prospective future revenues, future growth prospects, future cashflows and future results of operations
- A failure to meet new regulatory requirements provided by the IVDR for current Products and Future (NGAL) Products would have a material adverse effect on the Company's future revenues, future cash flows, future results of operations and financial position
- Failure to successfully expand The NGAL Test's regulatory approval for adult AKI and successfully commercialize use for that population would have a material adverse effect on the Company's prospective future revenues, future cash-flows, future results of operations and growth prospects
- A failure to successfully design, evaluate the feasibility of, develop, obtain regulatory clearance for and commercialize Future Products could have a material adverse effect on the Company's prospective future revenues, future cash-flows, future results of operations and growth prospects
- A failure to successfully complete development, obtain regulatory clearance for in vitro diagnostics use of and commercialize Future NGAL Products on multiple clinical chemistry systems would have a material adverse effect on the Company's prospective future revenues, future cash-flows, future results of operations and growth prospects

#### Risks related to the Company's operations

- 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 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 Company's future success depends in part on its ability to attract and retain its management team and key employees
- The Company's Executive Management has been appointed recently, and may prove unsuccessful in managing the Company
- 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 revenues, cash flow, results of operations and future growth prospects
- The Company's ability to maintain inventory is limited and significant or unexpected increases in demand for the Company's Products could require the Company to expend considerable resources or harm its customer relationships if the Company is unable to meet that demand
- The Company is dependent on third-party vendors to provide certain products and services and its business and operations, including clinical trials, could be disrupted by any problems with its significant thirdparty vendors
- Any interruption in the operations of manufacturing facilities may impair the Company's ability to deliver products and maintain the Company's market positions
- A breakdown of or an attack on the Company's or its critical suppliers' or partners' IT systems including cyber security breaches may result in a material disruption of the Company's or its critical suppliers' or partners' manufacturing, control measures, commercialization, and delivery of the Company's Products and Future (NGAL) Products
- The Company may be exposed to risks associated with product liability, warranties or guarantees, recall demands or other lawsuits or claims
- The Company may not be able to obtain or maintain adequate protection against potential liabilities at acceptable cost by maintaining insurance coverage, and existing, or any future insurance policies or the Company's own resources may not adequately cover claims for damages that may be received in the future
- To manage its growth the Company must continually improve existing business, quality, and other reporting systems and procedures
- The Company's employees and collaborators may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm the Company's business
- The Company's operations involve hazardous materials, narcotic drug substances, GMOs, and ABPs and the Company and third parties with whom the Company contracts must comply with all relevant laws and regulations, which can be expensive and restrict how the Company does business
- The Company's international presence and reliance on third parties abroad exposes the Company's business to regulatory, cultural or other challenges

#### Risks related to the Company's Intellectual Property

- 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's ability to compete may decline if the Company does not adequately protect its proprietary rights and confidential information
- . The Company may be unable to protect or effectively enforce its intellectual property rights and such rights may be found invalid or unenforceable
- . The Company's ability to retain key licenses could affect its ability to manufacture and sell Products and Future (NGAL) Products
- . Third parties may assert ownership or commercial rights to inventions the Company develops
- Third parties may claim that the Company infringes their intellectual property rights
- . Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and the Company's patent protection could be reduced or eliminated for non-compliance with these requirements
- Third parties may assert that the Company's employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets

#### Risks related to legal and regulatory matters

- 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
- The Company's Products and Future (NGAL) Products, for which the Company has or obtains regulatory clearance, are subject to post-marketing requirements or withdrawal from the market and failure to comply thereof may make the Company subject to substantial penalties
- The Company's compliance with regulations governing public companies is complex and expensive.
- The Company's sale of its Products and Future (NGAL) Products depends on third-party payors coverage
- . The Company is and may in the future become involved in litigation, arbitration and governmental proceedings
- The Company faces risks related to data privacy concerns and failure to comply with privacy regulations and security requirements relating to data
- . The misuse or off-label use of the Company's Products and Future (NGAL) Products may harm the Company's reputation in the marketplace or result in costly investigations, fines or sanctions by regulatory bodies if the Company is deemed to have engaged in the promotion of these uses
- In the U.S., the Affordable Care Act or changes to the act may adversely affect the Company's business and results of operations

#### Risks related to the Company's financials

- There is a substantial doubt about the Company's ability to continue as a going concern and the Company will require additional capital to fund its operations, which capital may not be available to the Company on acceptable terms or at all
- The Company's business requires significant levels of capital investments, which the Company may be unable to fund
- . The Company's ability to utilize its net operating loss carryforwards and certain other tax attributes may be limited. .
- The Company faces risks related to sales and production contracts denominated in currencies other than DKK
- . Risks relating to trade receivables
- The Company bases its estimates or judgments relating to critical accounting policies on assumptions that can change or prove to be incorrect.
- Future financial results may significantly differ from the Company's estimates and guidance

#### Risks related to the Offering and the Shares

- The market price of the Company's Shares could continue to be highly volatile and Pre-emptive Rights may be highly volatile, and as such investors may not be able resell shares at or above the Subscription Price The Company expects to retain any available funds and future earnings to fund the development of its business and to ensure an adequate capital structure, and as such, a shareholder's ability to achieve a return on investment will depend on an appreciation in the price of the Shares
- Shareholders may not receive payments in the event of the Company's bankruptcy, winding-up or other similar event
- If the market price of the Shares declines significantly, the Pre-emptive Rights may lose their value and the market for the Pre-emptive Rights may offer only limited liquidity, and even if a market develops, the Pre-emptive Rights may not be effectively priced against the price of the Shares
- The Company's Shares has limited liquidity and present liquidity may not be maintained, and investors may not be able to sell as many Shares as they want at prevailing market prices or at all
- Shareholders in jurisdictions outside Denmark may be unable to exercise Pre-emptive Rights
- Shareholders outside Denmark are subject to exchange rate risk
- . Failure to exercise Pre-emptive Rights by the end of the Subscription Period (24 March 2022 at 5:00 p.m. CET) will result in the lapse of the holder's Pre-emptive Rights
- The sale of Pre-emptive Rights on behalf of shareholders who do not take up their Pre-emptive Rights may result in a decline in the market price of the Pre-emptive Rights and the Shares and increased volatility in the Shares
- If an Existing Shareholder does not exercise any or all of the Pre-emptive Rights, their ownership interest will become diluted, and such dilution may be material
- The Company is a public limited liability company registered under Danish law, which may make it difficult for shareholders and investors resident outside Denmark to exercise or enforce certain rights
- The Offering may not be completed and may be withdrawn, and Existing Shareholders and other investors having exercised and/or purchased Pre-emptive Rights or New Shares may incur a loss
- Following the Offering, certain Existing Shareholders may increase their shareholdings and may be able to influence important actions the Company takes
- The Subscription Commitments might not be honored
- . Any future issuances of shares in the Company could negatively affect the price of the Company's shares and the Company's ability to raise funds in new equity offerings
- · Sales of shares in the Company by members of Management or other Existing Shareholders could negatively affect the market price of such shares

#### The above is a summary of all risk factors listed in the prospectus. Please see the prospectus for a complete description of risk factors.





### BioPorto Exists to Save Lives and Improve Quality of Life with Actionable Biomarkers



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