BioPorto A/S

(a public limited liability company incorporated in Denmark under company registration (CVR) no. 17 50 03 17)

Rights issue and admission to trading and official listing of up to 66,938,601 new shares at a subscription price of DKK 1.5 per new share with pre-emptive rights for the existing shareholders of BioPorto A/S at the ratio of 1:4.

This prospectus (the "**Prospectus**") has been prepared in connection with a capital increase comprising an offering (the "**Offering**") of up to 66,938,601 new shares (the "**New Shares**") in BioPorto A/S, CVR no. 17 50 03 17 (the "**Company**") with pre-emptive rights to subscribe for New Shares (the "**Pre-emptive Rights**") for the Existing Shareholders (as defined below) of the Company at the ratio of 1:4, meaning that each holder of shares in the Company who is registered as a shareholder of the Company (the "**Existing Shareholders**") with VP Securities A/S ("**Euronext Securities Copenhagen**") on 10 March 2022 at 5:59 p.m. CET (the "**Allocation Time**") will be allocated one (1) Pre-emptive Right for each Existing Share (as defined below). For four (4) Pre-emptive Rights, the holder is entitled to subscribe for one (1) New Share at a price of DKK 1.5 per New Share (the "**Subscription Price**"). The Offering is conditional upon at least 49,000,000 New Shares being subscribed for, corresponding to gross proceeds of DKK 73.5 million and net proceeds of approximately DKK 66.4 million.

The Offering is directed solely to Existing Shareholders and to Qualified Investors (as defined below). Immediately **prior** to the Offering, the Company has 267,754,404 shares issued (the "**Existing Shares**"). The Existing Shares are listed on Nasdaq Copenhagen A/S ("**Nasdaq Copenhagen**") under the ISIN code DK0011048619.

On 7 March 2022, the Company's board of directors (the "**Board of Directors**") resolved to issue up to 66,938,601 New Shares with Pre-emptive Rights for Existing Shareholders according to the authorization in sections 16a and 16c of the Company's Articles of Association by increasing the Company's share capital with between nominally DKK 49,000,000 and nominally DKK 66,938,601. The Pre-emptive Rights have been approved for trading and official listing on Nasdaq Copenhagen under the ISIN code DK0061685823.

The trading period for the Pre-emptive Rights commences on 9 March 2022 at 9:00 a.m. CET and closes on 22 March 2022 at 5:00 p.m. CET (the "**Rights Trading Period**"). The subscription period for the New Shares commences on 11 March 2022 at 9:00 a.m. CET and closes on 24 March 2022 at 5:00 p.m. CET (the "**Subscription Period**"). Once a holder of Pre-emptive Rights has exercised such rights and subscribed for New Shares, such subscription cannot be withdrawn or modified by such holder, except as set forth in this Prospectus. Any of the Pre-emptive Rights that are not exercised during the Subscription Period will lapse with no value, and the holder of such Pre-emptive Rights will not be entitled to any compensation. After payment of the Subscription Price, investors will be granted temporary share certificates to the investor's account in Euronext Securities Copenhagen under the temporary ISIN code DK0061685906. The temporary share certificates will not be admitted to trading and official listing on Nasdaq Copenhagen under the temporary ISIN code. The temporary ISIN code is, thus, registered in Euronext Securities Copenhagen solely for the subscription of New Shares. The New Shares will be registered with the Danish Business Authority after the completion of the Offering, expected on 1 April 2022. The New Shares will be admitted to trading and official listing on Nasdaq Copenhagen under the same ISIN code as the Existing Shares with the expected first day of trading and official listing being 4 April 2022.

New Shares which have not been subscribed for by holders of Pre-emptive Rights before the expiry of the Subscription Period (the "**Remaining Shares**") may, without compensation to the holders of unexercised Pre-emptive Rights, be subscribed for by Existing Shareholders or Qualified Investors, who have made binding undertakings to subscribe for the Remaining Shares according to the application form in Annex A before the expiry of the Subscription Period. In case of oversubscription of the Remaining Shares in connection with binding undertakings, such Remaining Shares will be allocated according to apportionment keys determined by the Company's Board of Directors.

Subject to satisfaction of certain conditions set out in and on the terms and conditions of separate advance subscription commitments and guarantee undertakings entered into between the Company and a number of Existing Shareholders and other investors, including Aktieselskabet Arbejdernes Landsbank, Formue Nord Markedsneutral A/S, investment entities administered by Artha Kapitalforvaltning, Media-Invest Danmark A/S, Ejendomsselskabet Jano ApS (the "**Guarantors**") prior to publication of this Prospectus (the "**Subscription Commitments**"), the Guarantors undertake to exercise Pre-emptive Rights and to subscribe for any Remaining Shares that have not been subscribed for by holders of the Pre-emptive Rights up to an aggregate amount of DKK 73.85 million. Investors should be aware that an investment in the Pre-emptive Rights and the New Shares involves a high degree of risk. See "*1. Risk factors*" for a description of factors that should be considered before investing in the Pre-emptive Rights and the New Shares.

The Offering is subject to Danish law and this Prospectus has been prepared in accordance with Danish legislation and regulations in compliance with the requirements set out in the Danish Consolidated Act no. 377 of 2 April 2020 on capital markets (the "Danish Capital Markets Act"), Regulation (EU) no. 2017/1129 of the European Parliament and of the Council of 14 June 2017 (the "Prospectus Regulation"), Commission Delegated Regulation (EU) no. 2019/980 of 14 March 2019 as well as Commission Delegated Regulation (EU) 2019/979 of 14 March 2019 (the "Delegated Prospectus Regulation"), and Nordic Main Market Rulebook for Issuers of Shares effective from 1 October 2021 ("Nasdaq Issuer Rules"). This Prospectus has been prepared in accordance with Article 14 (Simplified disclosure regime for secondary issuances) of the Prospectus Regulation, Annex 3 (Registration document for secondary issuances of equity securities) and Annex 12 (Securities note for secondary issuances of equity securities or of units issued by collective investment undertakings of the closed-end type) to the Commission Delegated Regulation (EU) no. 2019/980 of 14 March 2019. The Company has elected to apply the aforementioned Annexes, as the proportionate disclosure regime has been specifically implemented to be used in rights issues.

Neither this Prospectus nor any advertisement or any other offering material may be distributed, published or otherwise made available, the New Shares may not be offered, sold or subscribed for, directly or indirectly, and the Pre-emptive Rights may not be offered, sold, acquired or exercised, directly or indirectly, in any jurisdiction outside of Denmark, unless such distribution, offering, sale, acquisition, exercise or subscription is permitted under applicable legislation in the relevant jurisdiction, and the Company may require satisfactory documentation to that effect. Due to such restrictions under applicable legislation and regulations, the Company expects that some or all eligible Shareholders or other investors residing in the U.S., Canada, Australia, Japan and other jurisdictions outside Denmark may not have the Prospectus distributed to them and may not be entitled to exercise the Pre-emptive Rights or subscribe for the New Shares. No offer and no solicitation that may be unlawful are being made by the Company to any person in any jurisdiction under any circumstances. The Pre-emptive Rights and the New Shares have not been and will not be registered under the United States Securities Act 1933, as amended (the "U.S. Securities Act"), or any securities laws of any state or other jurisdiction of the U.S. and are only offered and sold (I) outside the U.S. to, or for the account or benefit of, non-U.S. persons (as defined in Regulation S under the U.S. Securities Act ("Regulation S")) in accordance with Regulation S, or (ii) to a limited number of investors that are qualified institutional buyers (as defined in Rule 144A under the U.S. Securities Act) ("QIBs") or accredited investors (as defined in Rule 501(a) ("Accredited Investors") under the U.S. Securities Act) in transactions otherwise exempt from, or not subject to, the registration requirements of the U.S. Securities Act. See "2.2. Certain information regarding the Prospectus and the Offering – Notice to Investors in the U.S." and "20.17. Terms and conditions of the offer of securities to the public – Transfer restrictions".

This Prospectus is dated 7 March 2022

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SUMMARY

Section A – Introduction and warnings

Introduction and Warnings	This summary should be read as an introduction to the Prospectus. Any decision to invest in the Pre-emptive Rights and the New Shares should be based on a consideration of the Prospectus as a whole by the investor. Shareholders and prospective investors in the Pre-emptive Rights and the New Shares could lose all or part of the invested capital. Where a claim relating to the information contained in the Prospectus is brought before a court, the plaintiff investor might, under national law, have to bear the costs of translating this Prospectus before the legal proceedings are initiated. Civil liability attaches only to those persons who have tabled the summary, including any translation thereof, but only where the summary is misleading, inaccurate or inconsistent, when read together with the other parts of the Prospectus, or where it does not provide, when read together with the other parts of the Prospectus, key information in order to aid investors when considering whether to invest in the Pre-emptive Rights and the New Shares.
Issuer information	The issuer of the Pre-emptive Rights and the New Shares is BioPorto A/S (the "Company"). The address and other contact details of the Company are Tuborg Havnevej 15, ground floor, DK-2900 Hellerup, Denmark, telephone: (+45) 45 29 00 00. The Company has the legal entity identifier (LEI) 5299004SWFL5JAN4W830 and has company registration (CVR) no. 17 50 03 17. The ISIN code for the Existing Shares is DK0011048619. The ISIN code for the Pre-emptive Rights is DK0061685823. The temporary ISIN code for the New Shares is DK0061685906, which will not be admitted to trading and official listing on the regulated market Nasdaq Copenhagen.
Competent authority	This Prospectus has been approved on 7 March 2022 by the Danish Financial Supervisory Authority as competent authority under the Prospectus Regulation. The address and other contact details of the Danish Financial Supervisory Authority are Århusgade 110, DK-2100 Copenhagen OE, Denmark, telephone number +45 33 55 82 82, email finanstilsynet@ftnet.dk and fax +45 33 55 82 00.

Section B – Key information on the issuer

Who is the issuer of the securities?

Domicile and legal form	The Company has its registered office at Tuborg Havnevej 15, ground floor, DK-2900 Hellerup, Denmark, in the municipality of Gentofte, Denmark and is incorporated in Denmark as a Danish public limited liability company under the laws of Denmark. The Company has the legal entity identifier (LEI) 5299004SWFL5JAN4W830 and has company registration (CVR) no. 17 50 03 17.
Principal activities	The Company is an in vitro diagnostic company focused on saving lives and improving the quality of life with actionable biomarkers – tools designed to help clinicians make changes in patient management. The Company uses its expertise in antibodies and assay development, as well as its platform for assay development, to create a pipeline of novel and compelling products that focus on conditions where there is significant unmet medical need, and where the Company's tests can help improve clinical and economic outcomes for patients, providers and the healthcare ecosystem. The Company's flagship product is The NGAL Test, which has been designed to aid in the risk assessment of Acute Kidney Injury ("**AKI**"), a common clinical syndrome that can have severe consequences, including significant morbidity and mortality if not identified and treated early. NGAL (Neutrophil Gelatinase-Associate Lipocalin) is a protein biomarker that is expressed by the kidney when it is injured. NGAL measurements are useful in the diagnosis of AKI which may lead to acute renal failure. With the aid of The NGAL Test, physicians can identify patients potentially at risk of AKI more rapidly, than is possible with current standard of care measurements, such as serum creatinine ("**sCr**") and urinary output ("**UOP**"), enabling earlier intervention and more tailored patient management strategies. AKI that is not identified and treated early can lead to chronic kidney disease or kidney failure. The Company believes that by helping to identify AKI risk before permanent kidney damage occurs, The NGAL Test will enable physicians to improve kidney health, reduce associated short term and long term morbidities, and reduce the economic burden AKI related treatments. In addition to developing its NGAL portfolio, the Company has an open platform technology, called gRAD, which enables rapid feasibility assessment of other clinically relevant biomarkers for a variety of disease states. Having tested the platform's ability to generate high quality results, including with NGAL, the Company is now engaged in feasibility activities that center around flexibility and rapid iteration to create simple assays.
Major Shareholders	At the Prospectus Date, the Company has received notifications of holdings of 5% or more of the share capital or voting rights from the shareholders below:

Shareholder	Ownership interest as per latest notification
Media-Invest Danmark A/S	10.38%
Ejendomsselskabet Jano ApS	>10%

The Company is not aware of being owned or controlled, directly or indirectly, by others, and the Company is not aware of any agreements that could later result in others taking over the control of the Company.

Managing directors

At the Prospectus Date, the Board of Directors consists of Christopher James Lindop (Chairman of the Board of Directors), John Patrick McDonough (Deputy Chairman of the Board of Directors), Michael Scott Singer, Donnie McCoy Hardison Jr., Jan Leth Christensen and Peter Mørch Eriksen. The Executive Management consists of Anthony Paul Pare and Neil Allan Goldman.

Statutory auditors

The statutory auditors of the Company is PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab.

The Company's financial statement for the financial year 1 January 2020 – 31 December 2020 were audited by Torben Jensen (mne18651) and Allan Knudsen (mne29465).

PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab is currently represented by State Authorized Public Accountants Mads Melgaard (mne34354) and Henrik Kyhnauv (mne40028).

What is the key financial information regarding the issuer?

Key financial information

The key financial information below has been derived from:

- The audited consolidated financial statements of the Company for the period 1 January 2020 – 31 December 2020 and 1 January 2019 – 31 December 2019 prepared in accordance with IFRS as adopted by the EU and additional requirements of the Danish Financial Statements Act.
- The unaudited consolidated financial statements of the Company for the period 1 January 2021 – 30 September 2021 prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the EU and additional requirements of the Danish Financial Statements Act.

Income statement ***1 January – 31 December***

DKK million	**2019**	**2020**
Total revenue	26.6	23.2
Operating profit (EBIT)	(74.3)	(63.6)
Net profit	(69.6)	(61.6)
Total comprehensive income	(70.0)	(59.8)

Statement of financial position ***1 January – 31 December***

DKK million	**2019**	**2020**
Total assets	42.7	140.3
Total equity	25.3	100.9
Total net financial debt	(13.3)	(96.6)

Statement of cash flow ***1 January – 31 December***

DKK million	**2019**	**2020**
Cash from operating activities	(60.2)	(35.6)
Cash from investing activities	(2.1)	(1.5)
Cash from financing activities	33.6	127.0

Income statement ***1 January – 30 September***

DKK million	**2020**	**2021**
Total revenue	15.7	17.4
Operating profit (EBIT)	(50.8)	(47.2)
Net profit	(48.1)	(40.4)
Total comprehensive income	(46.9)	(41.1)

Statement of financial position ***1 January – 30 September***

DKK million	**2020**	**2021**
Total assets	58.1	100.7
Total equity	19.0	62.8
Total net financial debt	(10.9)	(45.4)

Key financial information (continued)

Statement of cash flow		*1 January – 30 September*
DKK million	**2020**	**2021**
Cash from operating activities	(27.5)	(49.9)
Cash from investing activities	(1.1)	(0.4)
Cash from financing activities	35.0	1.8

What are the key risks that are specific to the issuer?

Key risks

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 (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.
- 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.
- 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 cash-flows and future results of 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 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 (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 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.
- 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 has incurred net losses and may continue to do so.

Forward-looking statements reflect the Company's current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, investors should not place undue reliance on these forward-looking statements. These risks are discussed in greater detail under the heading "1. Risk Factors" in this Prospectus and in the documents incorporated by reference herein. Also, these forward-looking statements represent the Company's estimates and assumptions only as of the date of the document containing the applicable statement.

Investors should read this Prospectus and the documents incorporated by reference herein completely and with the understanding that the Company's actual future results may be materially different from what the Company expects. The Company does not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Section C – Key information on the securities

What are the main features of the securities?

Type, class and ISIN

The Shares, including the New Shares, are not divided into multiple share classes.

The ISIN code for the Existing Shares is DK0011048619. The ISIN code for the Pre-emptive Rights is DK0061685823. The temporary ISIN code for the New Shares is DK0061685906, which will not be admitted to trading and official listing on the regulated market Nasdaq Copenhagen.

Subject to completion of the Offering, the New Shares will be admitted to trading and official listing on Nasdaq Copenhagen under the permanent ISIN code for the Existing Shares DK0011048619, which the Company expects to occur on 4 April 2022. The temporary ISIN code of the New Shares will be merged with the ISIN code of the Existing Shares, which the Company expects to occur on 5 April 2022.

The Existing Shares are denominated in DKK. At the Prospectus Date, the Company's registered share capital was DKK 267,754,404 divided into 267,754,404 shares (each with a nominal value of DKK 1). Upon completion of a fully-subscribed Offering, the Company's registered share capital will be 334,693,005 divided into 334,693,005 shares each with a nominal value of DKK 1.

Rights attached to the New Shares

The New Shares will have the same rights as the Existing Shares, including with respect to eligibility for any dividends. Any dividends will be paid in DKK to the shareholder's account with Euronext Securities Copenhagen. No restrictions on dividends or special procedures apply to holders of the New Shares who are not residing in Denmark.

All Shares in the Company will rank pari passu, including with respect to voting rights, eligibility to receive dividends and Pre-emptive rights. Upon completion of the Offering, all Shares will then carry 1 vote per nominal value of DKK 1.

In the event of the dissolution or winding-up of the Company, the New Shares will be entitled to a proportionate part of the Company's assets after full payment of the Company's creditors. The Articles of Association do not contain any provisions on redemption or exchange of the Shares.

Restrictions

The Shares, including the New Shares, are negotiable instruments, and there are no restrictions on the transferability of the Shares or the New Shares under the Company's Articles of Association or Danish law.

Dividend policy

The Company has not declared or made any dividend payments for the last financial year. Currently, the Company intends to use all available financial resources as well as the proceeds of its operations, if any, for purposes of the Company's current and future business, including the funding of operating losses, as it has done historically. As of the Prospectus Date, the Company does not expect to make dividend payments within the foreseeable future.

Where will the securities be traded?

Admission to trading and official listing

The New Shares are expected to be registered with the Danish Business Authority on 1 April 2022. The New Shares will not be admitted to trading and official listing on the regulated market Nasdaq Copenhagen under the temporary ISIN. The temporary ISIN code of the New Shares will be merged with the ISIN code of the Existing Shares, expectedly on 5 April 2022.

If so registered and issued, the New Shares will be admitted to trading and official listing on Nasdaq Copenhagen under the same ISIN code as the Existing Shares, DK0011048619 , with the expected first day of trading and official listing being on or around 4 April 2022.

What are the key risks that are specific to the securities?

Key risks

The key risks that are specific to the Offering are:

- 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 to 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.

Section D – Key information on the Offering and the admission

Under which conditions and timetable can I invest in this security?

Conditions and timetable

The Offering comprises up to 66,938,601 New Shares each of which will have a nominal value of DKK 1. The Offering is conditioned upon at least 49,000,000 New Shares being subscribed for, corresponding to gross proceeds of DKK 73.5 million and net proceeds of approximately DKK 66.4 million.

Shareholders registered with Euronext Securities Copenhagen on 10 March 2022 at 5:59 p.m. CET as shareholders of the Company will as Existing Shareholders be entitled to an allocation of Pre-emptive Rights. For four (4) Pre-emptive Rights, holders of Pre-emptive Rights will be entitled to subscribe for one (1) New Share subject to payment of the Subscription Price. Pre-emptive Rights will be allocated free of charge.

Shares traded after 8 March 2022 will be traded as ex Pre-emptive Rights provided that the Shares are traded at a customary two-day value.

The Pre-emptive Rights and the New Shares will be delivered in book-entry form through allocation to the Existing Shareholders' accounts held with Euronext Securities Copenhagen.

Publication of Prospectus:	7 March 2022
Last day of trading in Existing Shares including Pre-emptive Rights:	8 March 2022
First day of trading in Existing Shares ex Pre-emptive Rights:	9 March 2022
First day of Rights Trading Period:	9 March 2022
Allocation Time of Pre-emptive Rights:	10 March 2022

First day of Subscription Period:	11 March 2022
Last day of Rights Trading Period:	22 March 2022
Last day of Subscription Period:	24 March 2022
Allocation of Remaining Shares:	28 March 2022
Expected date of publication of the results of the Offering:	28 March 2022
Expected registration of the New Shares with the Danish Business Authority:	1 April 2022
Expected date of admission of the New Shares to trading and official listing under the ISIN code of the Existing Shares:	4 April 2022
Expected merger of ISIN codes:	5 April 2022

Admittance to trading

The Company's Existing Shares have been admitted to trading and official listing on the regulated market Nasdaq Copenhagen under the ISIN code DK0011048619.

In connection with the Offering, the Pre-emptive Rights have been approved for admission to trading and official listing on Nasdaq Copenhagen to the effect that they can be traded on Nasdaq Copenhagen during the period from 9 March 2022 at 9:00 a.m. CET to 22 March 2022 at 5:00 p.m. CET.

Dilution

If an Existing Shareholder decides not to exercise its Pre-emptive Rights, such shareholder's proportionate ownership interest will be diluted by up to 20%. If an Existing Shareholder exercises its Pre-emptive Rights in full, such Existing Shareholder will not be diluted by the Offering.

Estimated expenses

The estimated costs and expenses payable by the Company related to the Offering, assuming completion of the Offering, are approximately DKK 7.1 million.

The Company will pay Danish account holding institutions a subscription commission of 0.125% of the market value of the New Shares subscribed for through the relevant account holding institution, in connection with the Offering.

Why is this Prospectus being produced?

Use of proceeds

The purpose of the Offering is to strengthen the Company's capital resources and advance implementation of the Company's strategic priorities.

If the Offering is completed, the Offering will raise gross proceeds of at least approximately DKK 73.5 million. If fully subscribed, the Offering will raise gross proceeds of approximately DKK 100.4 million. The net proceeds to the Company from the issue of the New Shares in a completed Offering are expected to be at least approximately DKK 66.4 million, and the net proceeds to the Company from a fully subscribed Offering are expected to be approximately DKK 93.3 million, in each case after deduction of costs and expenses payable by the Company in relation to the Offering.

The Company will retain broad discretion over the use of the net proceeds from the Offering, but expects that the 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.

Subscription and guarantee commitments

The Company has entered into certain advance subscription commitments and guarantee undertakings dated on or about 7 March 2022 with the Guarantors comprising a number of Existing Shareholders, institutional investors and Qualified Investors. On the terms and conditions of the Subscription Commitments, the Guarantors have undertaken to exercise Pre-emptive Rights and/or to subscribe for any Remaining Shares for an amount of up to approximately DKK 73.85 million.

Material conflicts of interest

Certain members of the Board of Directors and the Executive Management are shareholders, directly or indirectly, in the Company. In addition, completion of the Offering and the use of proceeds may directly or indirectly be a precondition to the potential satisfaction of performance targets in the Company's short-term incentive programs for the Executive Management and certain employees. In addition, the Company has issued warrants to the Executive Management and certain employees of the Company. Therefore, these persons have an interest in the Offering.

Subject to the satisfaction of certain conditions in the Subscription Commitments, all New Shares that have not been subscribed for by the holders of the Pre-emptive Rights will be subscribed for by the Guarantors. Guarantors receive a fee for the portion of their commitments that do not relate to exercise of Pre-emptive Rights. Certain of the Guarantors are shareholders, directly or indirectly, in the Company and therefore have an interest in the Offering.

1. Risk factors

Investing in the New Shares and/or Pre-emptive Rights involves a high degree of financial risk. Shareholders and prospective investors should carefully consider each of the following risk factors and all of the other information provided in this Prospectus (including any information or material incorporated by reference), in considering whether to make or continue to hold an investment in the Company's Shares, in New Shares or Pre-emptive Rights. An investment in the Company's Shares, New Shares or Pre-emptive Rights involves a high degree of risk and should be considered only by persons that can afford the loss of their entire investment. This section addresses both general risks associated with the industry and market in which the Company operates, and specific risks associated with its business. If such risks were to materialize, the Company's business, results of operations, cash flows, financial condition, and/or prospects could be materially and adversely affected, resulting in a decline in the value of the Shares, including the New Shares and/or the Pre-emptive Right and a loss of part or all of the prospective investor's investment. Further, this section describes certain risks relating to the Offering, the Pre-emptive Rights, and the New Shares, which could also adversely impact the value of the Shares, including the New Shares, and/or the Pre-emptive Rights. With respect to forward-looking statements that involve risks and uncertainties (see "*2.9. Certain information regarding the Prospectus and the Offering – Forward-looking statements*").

The risks and uncertainties discussed below are those that the Company currently views as material, but these risks and uncertainties are not the only ones that it faces. Additional risks and uncertainties, including risks that are not known to the Company at present or that it currently deems immaterial may also arise or become material in the future and could, individually or in the aggregate, have a material adverse effect on the Company's business, results of operations, cash flows, financial condition, and/or prospects resulting in a decline in the value of the Shares, including the New Shares, and/or the Pre-emptive Rights, and a loss of part or all of Shareholders' and prospective investors' investment.

Within each of the categories 1.1 to 1.7 below, the risks are listed in order of materiality as currently assessed by the Company, taking into consideration the expected magnitude of their negative impact on the Company and the Company's business, results of operations, financial condition, and/or future prospects and the probability of their occurrence. This section should be read in conjunction with section "*18.3. Key information on persons involved in the Offering, capitalization and use of proceeds*", the Company's consolidated financial statements, the notes to those financial statements, the Management's statements related thereto, and the Company's announcements, each of which are incorporated into this Prospectus by reference. Except as implied by the order in which the risk factors are mentioned or as specifically set out in the respective descriptions of the risk factors, the Company has, due to the nature of the risks and the Company's business, considered that it is not reasonably possible for the Company to make specific and accurate assessments of the probability of occurrence of individual risk factors.

1.1. Risks related to the Company's business

1.1.1. 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 Company estimates for planning purposes the time for achieving various scientific, clinical, regulatory, and other product development objectives. These milestones may include the Company's expectations regarding the commencement or completion of scientific studies, clinical trials and the submission of regulatory filings or commercialization objectives. From time to time, the Company may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, regulatory clearance, or a commercial launch of a product.

The achievement of many of these milestones may be outside of the Company's control and may cause the timing to achieve the milestones, if at all, to vary considerably from the Company's estimates. Further, timing of milestones may be affected by strikes, natural disasters, labor disputes, disease outbreaks, pandemics, or other disruptions. If the Company fails to achieve milestones in the timeframes the Company expects, commercialization may be delayed, which would – *inter alia* - correspond to a delay in the potential FDA approval of The NGAL Test in the U.S. (see "*1.2.1. Risk factors – 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 revenues, future growth prospects, future cash-flows and future results of operations*"). In turn, this could materially adversely affect the Company's prospective revenues in the US (see "*5.6.1.1. Business – Markets – The NGAL Test – The U.S. Market Opportunity*") and the Company's future prospects. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors outside the Company's control, including the size and nature of the patient population, delays in recruitment due to unforeseen occurrences such as the COVID-19 pandemic, the patient mix within intensive care units ("**ICUs**") selected for clinical trials, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and the ability to get patient consent for the study when patients are very sick. As an example, in November 2021, the Company announced that it was unable to finalize enrollment of pediatric patients for the current U.S. pediatric trial within the previously announced timeline due to the global COVID-19 pandemic, which resulted in a delay in the clinical trial. There are risks for future delays if the pandemic worsens or if additional restrictions are imposed by governments – particularly where research coordinators are required on site to enroll patients.

1.1.2. 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

There can be no assurance that the Company's ongoing U.S. clinical trial relating to pediatric use of The NGAL Test, if successfully completed, will provide the result that meet the primary outcomes which the Company has previously committed to the FDA. The ongoing clinical trial consists of

three studies. The Company believes that the primary outcomes for the first two of the three studies are consistent with their primary objectives, with the outcomes of the third study still pending completion of enrollment and data analysis (see "*5.5.1.3. Business – Products and Product Pipeline – The NGAL Test – Regulatory Approval and Pathway of The NGAL Test*").

The Company has previously experienced that the FDA, in response to the Company's submissions thereto, has requested additional data (see *"1.2.1. Risk factors – 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 revenues, future growth prospects, future cash-flows and future results of operations"*). While the FDA's requests for additional information are customary, the nature, extent, and timing impact of the requests depends upon on matters particular to the situation, such as additional data, analyses, or root cause analysis for discordant results.. .

If the primary outcomes of the third study within the overall clinical trial are not met, the Company may chose not to submit the clinical trial results to the FDA or the FDA may, following a submission, request additional information or clinical studies, which could delay or preclude FDA's approval of The NGAL Test for risk assessment of AKI. This would, in turn, materially adversely affect the Company's prospective revenues in the U.S. (see *"5.6.1.1 – Markets – The U.S. Market Opportunity"*) and the Company's future prospects. Even if the primary outcomes of the trials are met, the FDA may request additional data instrument (see "*1.2.1. Risk factors – 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*"). .

1.1.3. 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's Products and Future (NGAL) Products, including the Company's flagship product, The NGAL Test, may fail to gain sufficient market acceptance by physicians, laboratory management, healthcare payors and others in the medical community. If an adequate level of acceptance is not achieved, the Company's commercial opportunity may be limited and/or revenues from sales of these products may be negatively impacted. The degree of market acceptance will depend on a number of factors, including the use of Medical Scientific Liaisons ("**MSL**") and Key Opinion Leaders ("**KOLs**") to educate the medical community on the value of these products, the availability of peer reviewed publications or studies to validate their clinical and/or economic benefit, price, ease of use in hospital labs or alternative sites, competitive advantages, labeling restrictions or warnings, changes in the regulatory environment, changes in physicians' diagnostic preferences, changes in the competitive landscape and changes in reimbursement policies (see "*5.6. Business – Markets*").

Changes to the standard of care for the targeted indications may also have an impact on market acceptance of such products. For example, the current standard for assessing kidney injury is the use of sCr (serum creatinine) and UOP (urinary output). Adding a new product, such as the Company's main product, The NGAL Test, requires substantial clinical evidence as well as successfully undertaking activities that result in the inclusion of NGAL (neutrophil gelatinase-associated lipocalin) in clinical guidance documents (see "*5.6. Business – Markets" and "5.12. Business – Regulatory environment*").

NGAL (the biomarker on which the Company's flagship product, The NGAL Test, is based) has been described extensively in published literature for its use in detecting AKI (acute kidney injury), yet physician knowledge of NGAL and its use varies – there is no consensus on how to use NGAL in clinical practice, if at all. This is due to a number of factors including; a) the initial NGAL product was delivered in a research format that did not allow for rapid turnaround of results, limiting its use to research studies; b) a belief that although the use of sCr (serum creatinine) and UOP (urinary output) was not ideal for the detection of early AKI, it was unclear what physicians could do differently if NGAL was used to detect injury earlier; and c) a late-adopter mindset of waiting to use NGAL until it was cleared by the U.S. Food and Drug Administration ("**FDA**") and/or recommended by clinical guidelines.

In order to achieve market penetration, the Company has developed a strategy that will include retaining KOLs for peer-to-peer education, hiring clinical sales representatives and MSLs to enhance communication with healthcare providers, selecting key distribution partners that will expand access to The NGAL Test and developing relationships with advocacy groups and kidney organizations to establish NGAL in clinical practice.

The Company may not be successful in all (or any) of these efforts. For example, it is often necessary for new tests to be adopted into clinical practice guidelines that are promulgated by societies, such as the global organization to develop and implement evidence-based clinical practice guidelines in kidney disease, KDIGO. This can be a very lengthy process with uncertain outcomes, as decisions require agreement across diverse groups of experts. In addition, other companies may develop and commercialize competing AKI diagnostic products and establish commercial partnerships with companies the Company is trying to engage with, resulting in a material adverse effect on the Company's prospective future worldwide revenues, and, in turn, the Company's results of operations, cash flow, and financial position (see "*1.1.6. Risk factors – Risks related to the Company's business – 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*").

1.1.4. The Company may not be able to successfully implement its strategies

The Company's future growth and success depends on the Company's ability to successfully implement its business strategies. These strategies include establishing a commercial team and commercial partners to drive growth; expanding the Company's product pipeline through development of new indications and new products, and strengthening the Company's operational, research & development, and production infrastructures to ensure quality and drive profitability. The Company's commercial team, commercial partner portfolio, and R&D organization are less developed relative to certain competitors in the life science industry, and there can be no assurance that the Company will be successful in developing these aspects of its business and otherwise implementing its strategies. In addition, the capital expenditures required to implement the Company's strategies may be greater than those required from certain competitors in the life sciences industry and may further be significantly greater than the Company currently anticipates. Any increase in capital expenditure would have a negative effect on the Company's cash flow and liquidity. Further, the Company cannot exclude that incumbents in any adjacent product or geographic markets may seek to bring legal action (or to encourage actions to be brought) against new entrants, including for alleged patent infringements. Even if such claims are found to be without merit, they may delay the Company's activities and/or require the Company to incur higher costs than anticipated, which may hinder or preclude the Company from implementing its business strategies. Any failure to implement the Company's business strategies in a timely and effective manner could have a material adverse effect on the Company's business, financial condition, results of operations or prospects.

1.1.5. The Company relies on third parties to conduct its clinical trials and perform data collection and analysis

The Company selectively relies on public and private research institutions, medical institutions, clinical investigators, contract research organizations, contract laboratories and collaborators to perform patient recruitment, testing, data collection and analysis for its clinical trials. As the Company's clinical trials are dependent on the participation of third parties, there could be scenarios where the trials are delayed, suspended, or terminated if such third parties do not successfully or timely carry out their responsibilities. Third-party performance failure may delay or preclude the Company's ability to obtain regulatory clearance and, in turn, delay or preclude the commercialization of the Company's Products and/or Future (NGAL) Products. The Company engages third parties through agreements that specify the obligations and deliverables for the clinical trial. If such parties cannot meet their obligations and need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised, the impact to the clinical trials could mean delays for the product submissions to regulatory authorities. Any of these circumstances would have a material adverse effect on the Company's prospective future revenues, and, in turn, its results of operations, and cash flows.

1.1.6. 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 diagnostic industry is highly competitive and subject to rapid technological advances. Numerous laboratories, companies, institutions, universities, and other research entities are actively involved in the discovery, research, development, and marketing of diagnostic tests. The Company has competitors in each of the verticals in which it competes, many of which have substantially greater name recognition, commercial infrastructure and financial, technical and personnel resources than the Company.

Some of the current biomarkers that are associated with kidney injury and loss of function include:

- NephroCheck, previously developed by Astute Medical and now owned by BioMerieux, is a product that predicts the risk of developing AKI by measuring two proteins that represent kidney stress. NephroCheck received FDA clearance in 2014 for use on a stand-alone meter, the Astute 140, and is CE marked.
- Cystatin C, another renal biomarker, cleared by the FDA, is commercially available on many automated systems (including those of Siemens, Abbott and Roche) and is complementary to NGAL, as it is a marker of glomerular function, and not of tubular injury.
- NephroClear CCL-14, another BioMerieux developed product, received a CE mark in 2021 and measures CCL-14 in urine using the stand-alone Astute 140 Meter. NephroClear CCL-14 is intended for use as an aid in the risk assessment of developing persistent severe AKI ("**PS-AKI"**). This product is expected to be commercialized by Baxter International.

In addition, Abbott Laboratories ("**Abbott**") licensed certain BioPorto NGAL Patents and applications for use with certain formats (see "*14. Material agreements*") and has a CE marked NGAL product for use on its Architect/Alinity instruments.

The NGAL Test could also be surpassed by products from other companies that develop and commercialize AKI diagnostic products that may have advantages over The NGAL Test. For example, the Company is aware of companies such as Renal Sense, Fize Medical and Olympus, that are developing products that provide real time monitoring of UOP to detect fluctuations that may indicate early AKI. Further, an FDA clearance of The NGAL Test may result in competitors seeking separate approvals of competing NGAL tests for the identification of AKI, (see "*1.4.2. Risk factors – Risks related to the Company's Intellectual Property – The Company's ability to compete may decline if the Company does not adequately protect its proprietary rights and confidential information"*). In order to be competitive, the Company's Products will have to remain competitive both in terms of performance and pricing, and the Company will have to be successful in its commercialization efforts, including by preparing information on why The NGAL Test is superior to new or similar products, and educating the clinical community on NGAL as a differentiated biomarker for assessing Stage 2 and 3 AKI. Any such, activities by the Company may be costly and time-consuming, and there is no guarantee that the Company will be successful in such attempts or that the Company's products will remain competitive.

1.1.7. 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 Company sells its Products, including The NGAL Test, antibodies, and other products through its own sales organization and through third-party distribution partners and depends to a considerable extent on such third parties for its global sales activities. The Company's strategy is to engage with third-party distributors that have experienced sales and marketing organizations with success in demand creation, market penetration, and medical education to supplement the Company's own sales efforts.

As a result, maintaining relationships with the third-party partners is critical to the Company's business, and the loss of any such partner or termination of such relationship may impair the Company's ability to provide its products and services to customers in a timely manner or cause the Company to lose out on business opportunities and, in turn, market share in a given market or markets. The Company may not be able to negotiate renewals of its current contracts with third-party partners on terms satisfactory to the Company, or at all. The Company has previously experienced third-party partners terminating their contract with the Company, as Siemens Healthcare Diagnostics Products GmbH terminated their supply and distribution agreement for expiry at the end of 2022 (see "*14.4- Material agreements - Supply and Distribution Agreement with Siemens Healthcare Diagnostics Products GmbH*").

The failure of third-party collaboration partners to perform and satisfy their contractual obligations or establish and comply with applicable laws and regulations may, among other things, require the Company to discontinue its business relationships with them. In addition, failure by such third-party collaboration partner to generate sales, for instance by prioritizing their efforts on other products (such as their own private label products that compete with the Company) versus the Company's, or developing their own NGAL test (in areas with no relevant patent coverage) or developing a kidney test that is competitive to The NGAL Test, or marketing a third-party product that is competitive to The NGAL Test, could all have adverse effects on the Company's current and prospective market shares and revenues which would, in turn, negatively impact the Company's results of operations, cash flows, and financial condition.

The Company plans to expand its business with distributors, however the Company may not be able to identify suitable distributors and/or negotiate distribution agreements with such distributors on terms satisfactory to the Company. Further, the Company's existing contractual obligations vis-à-vis its current distributors may prohibit or limit the Company with respect to entering into agreements with new distributors.

1.1.8. 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 pricing of the Company's Products and Future (NGAL) Products, including the Company's flagship product, The NGAL Test, will depend, in part, on the value that such products bring to patient management and/or hospital cost savings, and the technology used to deliver such products. The sCr test, which has been the standard of care diagnostic test for AKI for more than 50 years and routinely used for standard assessments of kidney function, is substantially less expensive than The NGAL Test. The Company will have to take this into consideration when pricing The NGAL Test, which may result in The NGAL Test being priced lower than currently expected. This would, in turn, negatively affect the Company's current and prospective revenues, cash flows and results of operations.

The technology used to deliver The NGAL Test may also affect its price. The NGAL Test is available for use on several automated central laboratory clinical chemistry instruments and other NGAL products such as NGALds would be provided through point-of-care or rapid device formats. The level of automation, user training, technician involvement, ease of use, or interpretation will also be included as an element in the considerations relating to the pricing of The NGAL Test and the Company's other Products.

Further, continued attention to and pressure on the cost diagnostic tests could also lead to regulatory reforms and legislative changes that limit Management when setting the price of the Products and Future (NGAL) Products.

1.1.9. 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

The Company's revenue and profit depend substantially on the volume and timing of customer orders, which are difficult to forecast with any degree of certainty. The markets may not be or develop to be as large as estimated by the Company. Any decline or lower than expected growth in the global healthcare market or important regional or local markets in which the Company is active could diminish demand for the Company's Products and Future (NGAL) Products. This could have a material adverse effect on the Company's business, financial condition and results of operations or prospects. In addition, demand for the Company's Products and Future (NGAL) Products also depends on customers' spending budgets and cycles as well as government funding policies. Matters of public policy and government budget dynamics as well as product and economic cycles can affect the spending decisions of these customers. Furthermore, demand for the Company's Products and Future (NGAL) Products is also sensitive to changes in customer order patterns, which may be affected by patients' access to healthcare generally, changes in healthcare providers' reimbursement levels and new product introductions, among other things.

1.1.10. 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

Growth in the life science market has become increasingly tied to global economic growth, and an economic downturn, for example as the result of armed conflicts or related politically imposed sanctions or COVID-19, may paralyze or hamper economic activities and/or reduce the amount of funding for the healthcare sector. As a result of the Company's flagship product, The NGAL Test not currently being accepted as the standard of care for its intended use – the risk assessment of AKI – it is reasonable to expect that the negative effects of any such developments would have a stronger negative effect on the Company relative to certain other competitors in the life science industry. Political conditions, sanctions, tension and uncertainty may also impact regulations applicable to the Company. The successful commercialization of the Company's Products and Future (NGAL) Products will depend in part on the extent to which governmental authorities and health insurers are willing and able to establish coverage and adequate reimbursement levels, as well as pricing policies. There is an expectation that many companies will see may experience a reduction in payments due to upcoming changes, but the actual results and how they affect each company are unknown.

As such, global or regional economic uncertainty and other global economic or political or regulatory developments may have material adverse effects on the Company's current and prospective revenues, and in turn its results of operations, cash flows, and financial condition (see further "*1.5.4. Risk factors – Risks related to legal and regulatory matters – The Company's sale of its Products and Future (NGAL) Products depends on third-party payors coverage"*).

1.1.11. 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

Serious adverse safety events involving the Company's Products and Future (NGAL) Products, which have received or may receive regulatory clearance in the future, may have a negative impact on the Company's commercialization efforts. Later discovery of safety issues with the Company's Products and Future (NGAL) Products that were not known at the time of their regulatory clearance could cause product liability litigation exposure, additional regulatory scrutiny, requirements for additional labeling, recall or withdrawal of products from the market, and the imposition of fines or criminal penalties on the Company. Any of these actions could result in material impairments of assets, material restructuring charges and other adverse impacts on the Company, which could have a materially adverse effect the Company's current and prospective future revenues, cash flows, results of operations, and financial condition. In addition, the reporting of adverse safety events involving the Company's Products or Future (NGAL) Products and public rumors about such events could lead to reputational damage and/or adverse market perception, which in turn may negatively affect the sales of the Company's Products and Future (NGAL) Products, resulting in a potential material adverse effect on the Company's prospective future revenues, cash flows, and results of operations. Further, any such reputational damage could cause the Company's share price to decline or experience periods of volatility. As a result of the Company's product portfolio being less extensive relative to certain other competitors in the life science industry, it is reasonable to expect that any of the aforementioned would be emphasized in relation to the Company.

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

1.2.1. 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

The Company's main product, The NGAL Test, was CE marked for measurement of NGAL based on an adult population in 2012 and has since then been available for in vitro diagnostic ("**IVD**") use in Europe and other jurisdictions through direct sales from the Company or certain distributors. Such sales have been limited by, among other things, funding available for investment in sales and marketing, distribution channels, and product adoption. The Company's business and future success is highly dependent on its ability to obtain clearance from the FDA of The NGAL Test for IVD use in order to successfully market and commercialize the product in the U.S. (see *"5.12. Business – Regulatory environment*").

Risks related to the ongoing pediatrics clinical trial and its respective submission to the FDA include the timeline for the clinical trial itself and the timeline for the FDA's review of the Company's submission thereto, assuming the Company is able to undertake such submission. The timeline for FDA approval, if at all, has been challenged by COVID-19, which has negatively impacted the pace of enrollment of patients in the Company's pediatrics clinical trial in the U.S. For example, the reduction or suspension in elective surgeries has reduced the number of patients that are potential candidates for trial enrollment. Additionally, clinical trial sites have, at times, decreased or suspended the operation of clinical trials due to staffing limitations, hospital site safety, or other reasons associated with the COVID-19 pandemic. See "*1.1.1. 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".*

Following the Company's anticipated submission of The NGAL Test to the FDA for review and potential approval for use for risk assessment of pediatric AKI on the Roche cobas c501 clinical chemistry instrument, the FDA may request additional information or clinical studies even if the primary outcomes of the ongoing pediatrics trial are met, which could also delay or preclude the approval. A De Novo submission's success (see *"5.12. Business – Regulatory environment*"), which is the type of FDA submission being pursued by the Company with regards to The NGAL Test, depends on several factors, such as recruiting sufficient numbers of participants for the clinical study, obtaining analytical and clinical data that

meets FDA requirements for the intended use, and managing requests for additional information or data during the FDA review with experienced medical/regulatory employees and consultants.

The Company has previously submitted applications for The NGAL Test to the FDA with unsuccessful results. The Company filed an application to the FDA for clearance of The NGAL Test for use in risk stratification of AKI in adults in June 2011. The FDA rejected the application in February 2012 citing that they required a more specific description of intended uses, and that analytic protocols did not meet their expectations. In September 2015, an application to the FDA for clearance of The NGAL Test for use in the risk stratification of AKI in adults in the U.S. was submitted again. Unfortunately, and contrary to the Company's expectations, the Company was notified in May 2016 that the FDA had rejected the application, primarily because the dataset contained mild cases of AKI that did not support the intended use. In 2016, the Company filed a pre-submission application, which was followed in 2017 by a multisite clinical trial of over 500 patients at medical centers in the U.S. In July 2018, the Company filed an application for the clearance of The NGAL Test for risk stratification to rule out AKI in adults within 48 hours of admission to the ICU (intensive care unit). In October 2018, the FDA responded that they required further data to support the application, citing that the company should not use a predicate, but rather pursue the de novo submission pathway.

In the meantime, the Company redirected its focus to prioritize its FDA efforts towards a pediatric population (defined as 3 months to <22 years in the Company's pediatric study), with the assistance of pediatric nephrologists and critical care intensivists in the U.S. In May 2019, the Company submitted an application to the FDA for clearance of The NGAL Test for risk assessment of AKI in children under the age of 22 and was granted Breakthrough Designation status (see *"5.12. Business – Regulatory environment")*. The submission was based on retrospective clinical samples from the AWARE study that was published in The New England Journal of Medicine ("**NEJM**"). In the Company's assessment, the study supported that NGAL as a biomarker could be successfully deployed to assess risk of pediatric AKI in the critical care setting. However, in July 2019, the FDA requested additional information due to a concern regarding possible bias in the intended use population. Thus, the submission was withdrawn, and the Company decided to conduct a prospective study to further support its planned pediatric application to the FDA. Following a scheduled pre-submission dialogue with the FDA in the first quarter of 2020, the Company designed and began to execute the protocol for the new pediatric study just as the COVID-19 pandemic began, which subsequently delayed clinical site and other contracting, budget review, Institutional Review Board approval for each site, and patient recruitment (see "*1.1.1. 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*"). In November 2021, the Company announced that in order to optimize the statistical power of the trial that patient enrollment would continue until the first half of 2022.

The timing of FDA approval, if at all, of The NGAL Test for risk assessment of AKI in children under the age of 22 using the Roche cobas c501analyzer, and potentially for use with other clinical instruments following separate submission with the FDA, depends on many factors, including recruiting sufficient numbers of participants for the clinical study, obtaining analytical and clinical data that meets FDA requirements for the intended use, and managing requests for additional information or data during the FDA review with experienced medical/regulatory employees and consultants, as well as the FDA's evaluation of the results of the clinical study itself. In addition, there is a risk that FDA approves The NGAL Test for a narrower use than applied for in the Company's submission, which could negatively affect market demand, and in turn, the Company's prospective future revenues, cash-flows and results of operations.

While pursuing FDA approval for The NGAL Test for risk assessment of AKI in children under the age of 22 using the Roche cobas c501 analyzer, the Company is evaluating the timeline whereby it may pursue FDA clearance of The NGAL Test in other patient populations, including adult AKI and using other clinical chemistry instruments, including such instruments manufactured by manufacturers other than Roche

A failure to obtain FDA approval of The NGAL Test for risk assessment of AKI for pediatric populations as well as clearance of adult populations or other intended uses and using additional clinical chemistry analyzers other than the Roche cobas c501 would have a material adverse effect on the Company's prospective future revenues, future growth prospects, future cash-flows and future results of operations, which effects may be further amplified by the potential reputational damage and/or adverse market perception that could result from such events (see "*1.2.4. Risk factors – Risks related to the Company's Products and Future (NGAL) Products – 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"* and "*1.2.6. Risk factors – Risks related to the Company's Products and Future (NGAL) Products – 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."*).

1.2.2. 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 cash-flows and future results of operations

In the event that an FDA approval is obtained for pediatric AKI use of The NGAL Test using the Roche cobas c501 analyzer instrument, the Company plans to focus on commercializing The NGAL Test in the U.S. and further expand into other countries by building a direct sales force and strategic distribution network (see "*5. Business"* for a more detailed description of the Company's plans for commercialization). Whether commercialization is successful will depend on several factors, including obtaining FDA clearance of The NGAL Test (for use with additional clinical chemistry analyzers), attracting and retaining experienced sales, marketing, KOLs (key opinion leaders) and MSLs (medical science liaisons) resources;

entering into key partnerships necessary to effectively expand market access for The NGAL Test, educating the clinical community and driving adoption of The NGAL Test. 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 cash-flows and future results of operations.

The Company's successful launch of its pediatric and adult products depends on its ability to achieve the following critical factors: (i) Leveraging KOLs to educate peers on the value of using NGAL in daily practice, through grand rounds or other speaker events and workshops. If the Company and its KOLs are not able to persuade physicians to use NGAL in daily practice, this will significantly reduce the demand for The NGAL Test and reduce revenues; (ii) retaining a team of clinically experienced sales representatives that can have detailed clinical discussions about the product with healthcare providers and lab directors, as well as provide resources to potential customers through the Company's KOL experts. If the Company cannot retain experienced sales representatives, who can communicate with medical personnel in a confident manner, this could diminish the interest of the clinical community, and therefore, reduce the number of potential customers; (iii) hiring MSLs who have a medical background and who can discuss the advantages of using The NGAL Test in the management of AKI patients. The MSLs may leverage their medical experience and credibility, versus a typical sales representative, when engaging with healthcare providers. They can also assist in identifying important areas for future clinical studies and liaise between healthcare providers and the Company's R&D team. If the Company cannot retain talented MSLs to communicate with potential customers, the healthcare community may not utilize The NGAL Test as quickly as they would with MSLs; (iv) partnering with key companies, especially diagnostic instrument manufacturers that make and sell the instruments that can run The NGAL Test, such as Roche Holding AG and its subsidiaries and affiliates (Roche), with who the Company has an existing distribution relationship. Although Roche has a significant market share, it would be beneficial to engage with additional major diagnostic companies such as Siemens, Abbott and Beckman Coulter Inc. to have the test available in as many hospital laboratories as possible. These companies have significant installed base of automated analyzers, and sales and marketing organizations with established relationships in all of the major medical centers and could significantly expand access to The NGAL Test. If Roche was to terminate its current distribution agreement or not use reasonable commercial efforts to sell The NGAL Test, the Company could expect to have lower than expected sales in the near term until expanded direct sales and new distributor solutions were created. In addition, news of terminated relationships with major diagnostic companies would make it very difficult to partner with other companies.

Continued spread of COVID-19 or other potential public health epidemics or outbreaks could impact the Company's ability to commercialize The NGAL Test, including by hindering the ability of the Company's sales representatives and MSLs to meet with prospective customers in person by visiting hospitals, which could result in slower than anticipated adoption of The NGAL Test as access to prospective customers could be more difficult by electronic means alone.

1.2.3. 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

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (IVDR) will apply from 26 May 2022 (see "*5.12. Business – Regulatory Environment*). Implementation of the IVDR significantly changes the regulatory requirements to which the Company must adhere, and the Company's ability to market and sell its current Products and Future (NGAL) Products in the EU, and thereby its future revenues, future cash flows and future results of operations, is highly dependent on its ability to meet the IVDR's new requirements. As the Company does not have the financial resources to maintain a roster of internal regulatory experts, the Company's challenges in relation to meeting the requirements introduced by the IVDR may be greater than those of certain other competitors in the life science industry. The Company may have to engage external regulatory consultants in this respect, which may result in the Company incurring greater costs to comply with the IVDR relative to its competitors in the IVDR industry.

Implementation of the IVDR means significant changes to the IVD industry and the Company's current and Future (NGAL) Products in the EU. The IVDR becoming applicable will require the Company to update its technical documentation, update its quality management system and add processes to safeguard proper use of ISO standards, additional clinical evidence, reporting and post market surveillance activities will also be required. The IVDR has additional requirements for clinical data to support performance and safety and will require that the selected Notified Body can perform the required technical assessment of design documentation for the products that are to be CE marked in accordance with the IVDR. The Company considers it likely that it will be required to make make investments in quality systems in preparation for the coming into effect of the IVDR during 2022 and 2023, and have budgeted for the estimated related capital expenditures (see *"7.3.6 - Consolidated Prospective Financial Information - Assumptions relating to EBIT – Preliminary Guidance for FY2022").*

Contracts with key suppliers and distributors must be reviewed to reflect the requirements provided by the IVDR. If the aforementioned items and measures are not successfully completed or implemented, the Company's current CE marked products have a limited lifetime under the current Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (IVDD), due to the requirement that no significant changes can be made to any CE products after May 26, 2022 without obtaining a full IVDR, CE approval.

If no changes are made to the Products, the Company must obtain a new CE mark prior to May 26, 2026, in order to continue marketing such Products in their current markets within the EU. This is a significant effort due to (i) IVDR will use a new device classification system that will place all of BioPorto' s CE marked products in a new category, and, thus, requiring significant work to obtain or maintain market approval, (ii) there is no grandfathering of any device and even the devices currently on the market, must conform to the new IVDR standards, (iii) increased requirements

for clinical data to support claims, and intended use population, (iv) increased requirements for documentation and test to verify performance and functionality, (v) increased requirements for involvement of Notified Bodies to obtain market clearance and (vi) increased reporting requirements for products put on the market.

Changes have been made to the Company's NGALds product, which is based on the gRAD platform, that requires the product to be re-validated and tested in accordance with the IVDR. The Company considers it to be unlikely that that the required tests will be completed and communicated to the Notified Body prior to 26 May 2022. Except for NGALds, the Company's Products, including The NGAL Test, have not undergone significant changes requiring them to be re-validated or tested in accordance with the IVDR, and the Company does not presently expect any such changes to be made before May 26, 2026.

The Company's success in marking its Products and Future (NGAL) Products according to IVDR will depend on several factors such as the Company having and/or obtaining sufficient data for the clinical studies, obtaining analytical and clinical data that meets IVDR requirements for the intended use, funding such studies and/or other data collection efforts and the internal work to evaluate them, and managing requests for additional information or data during the Notified Body review with experienced medical/regulatory employees and consultants. In addition, there is a risk that the Notified body will approve the Current and Future (NGAL) Products for a narrower use than applied for in the Company's submission. Clinical studies and data collection will be subject to the risks related to clinical studies set out above (see *"1.1.1. 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*").

1.2.4. 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

The Company's current clinical trial and planned FDA submission for The NGAL Test concerns risk assessment of AKI in children > 3 months and under the age of 22 using specifically the Roche cobas c501 clinical chemistry analyzer instrument (see "*1.2.1. Risk factors – 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*").

The Company believes that the pediatric market for AKI in the U.S. represents a relatively small portion of the U.S. market, and that the adult market for AKI in the U.S. represents the largest portion of the overall market for AKI in the U.S. Based on a range of alternative regulatory pathways in the U.S., the Company is evaluating the timeline whereby it may pursue FDA approval of The NGAL Test in patient populations related to adult AKI. Because of the Company's understanding of the relative size of the adult AKI population, if the Company does not pursue the appropriate regulatory pathway(s); is unsuccessful in completing the related clinical trials for such pathway(s); or, if successfully obtaining regulatory approval for The NGAL Test in adult populations, is unable to successfully commercialize The NGAL Test for such use; then, the Company would only be able to market The NGAL Test towards a part of the addressable market in the US, which would have a material adverse effect on the Company's prospective future revenues, future cash-flows, future results of operations and growth prospects. It is noted that obtaining approval for The NGAL Test for pediatrics using the Roche c501 analyzer is not expected to, in itself, allow the Company to reach profitability and that additional funding will be required (see "*1.6.1 - Risk factors- 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").*

1.2.5. 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

The Company's business and future success is dependent on its ability to successfully design, evaluate the feasibility of, develop, obtain regulatory clearance for and successfully commercialize Future Products, and a failure in these respects could have a material adverse effect on the Company's prospective future revenues, future cash-flows, future results of operations and growth prospects. Relative to certain other competitors in the life science industry, the Company maintains a slim R&D organization with the main focus of continued development of Future (NGAL) Products.

Successful clearance of Future Products in the U.S. depends on the Company's ability to clearly design clinical trials, execute agreements with clinical sites, recruit sufficient numbers of participants, obtain analytical and clinical data that meets regulatory requirements for the intended use; manage requests for additional information or data during the regulatory review and successfully manage the submission process with experienced medical/regulatory employees and consultants. Any such clinical trials and data collection will be subject to the risks related to clinical studies set out above (see *"1.1.1. 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"*).

New devices, including Future Products must be approved, and CE marked under the IVDR as it will become applicable on 26 May 2022. Accordingly, they cannot be submitted and CE marked under the IVDD.

See "*1.2.3. Risk factors – Risks related to the Company's Products and Future (NGAL) Products – 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.*"

Whether commercialization is successful will depend on factors such as the Company's ability to create demand for the Future (NGAL) Products, develop successful sales, marketing and Medical Science Liaison (MSL) organizations to support the launch and develop partnerships that enhance the availability of Future Products in the marketplace.

1.2.6. 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

The Company's business and future success are highly dependent on its strategy to deliver The NGAL Test on multiple clinical chemistry systems to support optimal market penetration. The Company's strategy is to obtain its initial FDA approval of The NGAL Test on the Roche cobas c501 analyzer instrument in the U.S., and thereafter expand The NGAL Test to other third-party clinical chemistry systems in subsequent filings. Undertaking these regulatory expansions will require capital to fund the related clinical and regulatory requirements.

The expansion of the CE marked The NGAL Test to other third-party chemistry systems is different in the EU and has until now been accomplished through self-certification. The IVDR, which will apply from 26 May 2022, will require approval from notified bodies for all CE marked products (see "*1.2.3. Risk factors – Risks related to the Company's Products and Future (NGAL) Products – 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*").

The ability to obtain U.S. regulatory clearance for Future NGAL Products on additional clinical chemistry systems will depend on several factors, including: obtaining access to the different systems for clinical and analytical studies, potentially requiring partnerships with the device manufacturers; managing any technical issues with the instruments when performing analytical and clinical studies; having sufficient clinical specimens and samples to use on the different systems; funding clinical and technical studies that may be required to meet FDA and other regulatory body submission requirements, and entering into agreements with third parties to conduct the studies, if necessary. Further, in the event that the Company is not able to reuse the samples collected in connection with the ongoing pediatrics trial for sample testing in connection with expanding a potential FDA clearance for additional instruments, additional clinical trials may be required. The Company is currently in the process of assessing the life-span of the samples.

Any delays or failures in obtaining clearance on additional instruments following the potential FDA approval of The NGAL Test for pediatrics use on the Roche cobas 501 will limit the Company' ability to sell The NGAL Test only to hospital laboratories that have the Roche cobas c501. In the event that The NGAL Test can only be used on one or a limited set of instrument platforms, this would materially adversely affect the Company's prospective future revenues, future cash-flows, future results of operations and growth prospects.

Although the Company believes there are clinical applications for The NGAL Test that could expand the market for the Company's Future NGAL Products, any such potential market expansions are subject to several activities occurring. For example, the Company expects to conduct clinical studies and FDA and other regulatory body submissions for uses in the U.S. and other countries that it believes are clinically relevant and commercially valuable, after the initial FDA approval is received. The ability to obtain regulatory clearance for new intended uses depends on the Company's ability to fund, initiate, and complete successful new clinical studies, if at all, that validate the new intended uses in a timely manner, each of which will be subject to the risks described elsewhere in this Prospectus. Failure to expand the applications for Future NGAL Products and achieve commercial success will have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects.

1.3. Risks related to the Company's operations

1.3.1. 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 current COVID-19 pandemic has impacted peoples' health and the financial development on a global scale and may continue to have such impact in the near future. The pandemic has also affected the Company and its partners, such as hospitals and other research institutions. Due to a variety of factors, including the Company's current strategic focus on completing its pediatric clinical trials for The NGAL Test in the U.S., the negative impact of COVID-19 on the Company has been amplified relative to other comparable companies. In November 2021, the Company announced that it was unable to finalize patient enrollment in 2021 in part due to the global COVID-19 pandemic, which deprioritized and delayed all non-critical clinical studies across the U.S. (see further "*1.1.1. 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*").

In response to the COVID-19 pandemic the Company has implemented plans to allow for continued production and sales efforts, e.g., by increasing sanitary and disinfecting activities, visitor protocol, as well as providing work from home options. The mitigative measures are assessed by the Company on an ongoing basis. The extent to which COVID-19 and other potential public health epidemics or outbreaks continue to impact the Company's operations, financial position, results of operations and growth prospects in the future will depend on future developments. These are highly uncertain and inherently unpredictable, including the duration and severity of the outbreak, and the actions and measures taken by governments, suppliers and partners to contain COVID-19 or other outbreaks or address its impact, among others.

In particular, the continued spread of COVID-19 and variants thereof or other potential public health epidemics or outbreaks could adversely impact the Company in a variety of ways including by causing further delays of the timing of the Company's clinical trials or by causing interruptions in the Company's supply chain. For example, if the Company's key suppliers in Japan and Norway that manufacture key components for The NGAL Test or other Products are adversely affected by COVID-19 variants, or other health epidemics/outbreaks, disruption of the supply chain may happen, and the Company's Products would not be able to be manufactured. In the midst of the current pandemic, and potentially also future epidemics or pandemics, surgeries and other procedures have and may continue to be delayed and the Company's Products may not be required. In addition, the Company's employees may be affected by COVID-19, causing several sick-leaves, which may adversely affect the Company's ability to continuously supply Products and provide support to ender users.

Accordingly, these and other factors may negatively affect the Company's prospective future revenues, cash flows, liquidity and results of operations. In addition to the financial implications, such an epidemic would also negatively impact patient recruitment and continuation of clinical trials for new indications, regulatory reviews, the ability to raise funding and other activities necessary for the Company's growth.

1.3.2. 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

There are a limited number of suppliers for raw materials and key components that the Company uses to manufacture Products. Some of the raw materials used to manufacture the Company's Products and Future (NGAL) Products are general-purpose materials used by other medical device manufacturers, while key components are manufactured specifically for use by the Company. As with any raw material, there is a risk that the quality of the material may not meet the Company's needs. Supplier failure may cause a delay in or cancellation of manufacturing which could have a material adverse effect on the Company's business and financial results. If such raw materials and key components are not available, recreating them would be expensive and time consuming which could result in delays in manufacturing the products, back orders, potential delays in clinical trials and regulatory submissions with a consequential loss of revenue.

One of the Company's suppliers manufactures key components, as well as buffer, calibrators and controls, which are all incorporated in The NGAL Test kit and related calibrator and control kits. The manufacturer is at present the Company's sole manufacturer for these components, meaning early termination of the Company's commercial relationship with that supplier or any disruption at the supplier's facility would adversely affect the Company's business and results of operations.

Further, the Company entered into an agreement with a supplier for the supply of the Company's NGAL antibodies, which are used in the production of NGAL products sold by the Company. The supplier is the Company's sole supplier for these antibodies, meaning early termination of the Company's commercial relationship with that supplier or any disruption at the supplier's facility would adversely affect the Company's business and results of operations. Further, some suppliers, including the Company's manufacturing partner for The NGAL Test, own intellectual property for the manufacture of components that could restrict the Company from entering into alternative supplier agreements, without first negotiating a license agreement with original supplier, if possible. Implementing components and antibodies manufactured by alternative suppliers into the Company's NGAL Products (including the NGAL Test kit and related calibrator and control kits), would require regulatory filings and approvals, which the Company may not be able to obtain in a timely manner, if at all. These factors limit both the Company's control over the process or timing of finalization of certain Products and its ability to prepare either a disaster recovery plan or an alternate supplier plan that mitigates these risks (see "*14. Material agreements*").

Moreover, some of these suppliers may experience financial difficulties that could prevent them from supplying the Company with components or subassemblies used in the design and manufacture of the Company's products. In addition, these suppliers may experience manufacturing delays or shutdowns due to circumstances beyond their control, such as complications related to armed conflicts related politically imposed sanctions, COVID-19, labor issues, political unrest or natural disasters.

Any supply chain deficiencies could materially and adversely affect the Company's ability to fulfill customer orders. The availability of critical components and materials from sole- or limited source suppliers could reduce the Company's control over pricing, quality and timely delivery, increase its costs, disrupt its ability to manufacture and sell, and preclude it from manufacturing and selling certain of its products into one or more markets. Any such event could have a material adverse effect on the Company's revenues, results of operations, and cash flow.

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

The Company has a relatively small organization and is highly dependent on its key employees in R&D, clinical, regulatory, operations, financial, marketing, sales and business development, along with the expertise of its senior management. As the Company has a limited number of key

employees and a lean management structure relative to other competitors in the life science industry, the loss of any one of these key employees or Management members may have an especially significant impact on the Company's development, commercialization and business strategy. Further, as the Company has limited financial resources, a large part of its compensation packages may be incentive-based. If the Company cannot get Products cleared for sale in the U.S. or elsewhere, successfully complete research and product development activities, or if the Company cannot achieve its sales goals, this will further emphasize the challenges facing the Company in relation to key employee retention. In addition, former employees may be hired to or carry out business which is in direct competition with the Company.

There are a limited number of individuals with the breadth of skills and experience required to successfully develop, gain regulatory clearance and commercialize diagnostic tests. Competition to hire from this limited pool is intense, and the Company may, for the reasons stated in the paragraph above, be unable to successfully attract, hire, train, retain or motivate the members of its management team or key employees on acceptable terms given the intense competition among numerous life science companies with greater financial resources for similar personnel.

Further, as the Company's Executive Management has been appointed recently, they have yet to prove that they will be successful in maintaining the level of employee engagement necessary to retain the Company's key personnel (see *"1.3.4 - Risk factors - Risks related to the Company's operationsThe Company's Executive Management has been appointed recently, and may prove unsuccessful in managing the Company"*).

In the event the Company is not able to attract and retain its key employees and management, including in the event of termination, death, disability, sickness or leaves, this could adversely affect the Company's business operations and financial forecasting. Such adverse effects could significantly affect the Company's operating results and financial position.

1.3.4. The Company's Executive Management has been appointed recently, and may prove unsuccessful in managing the Company

The members of the Company's Executive Management (CEO and CFO) were both appointed in November 2021 and have therefore only had limited time to gain knowledge of the Company's business, its culture and to fully define and implement their visions for the Company, which may differ from those held by previous members of the Executive Management. Given their limited time with the Company, the current Executive Management has yet to demonstrate that they are able to successfully manage the Company, including with respect to implementing the Company's strategic initiatives, and there can be no assurance that this will be the case. If the Executive Management are not able to successfully manage the Company, this may adversely affect the Company's results and prospects.

The Management, including the Executive Management, will have broad discretion as to the use of the net proceeds of the Offering and could, e.g. as a result of the above, fail to apply these funds in ways that achieve the Company's strategic objectives or improve the Company's financial results. Such failure to apply funds effectively could, accordingly, have a material adverse effect on the Company, including its ability to secure additional capital in the future.

1.3.5. 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 Products and Future (NGAL) Products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to ensure that it is reproducible. Slight deviations anywhere in the manufacturing process, such as changing materials, filling, labeling, packaging, storage and shipping conditions or changing quality control testing may result in batch failures, delay in the release of batches, product recalls or spoilage. If microbial, viral, or other contaminations are discovered in the Products and Future (NGAL) Products or in the manufacturing facilities in which these are made, the manufacturing facility may need to be closed for an extended period of time to investigate and remedy the contamination. Any of these failures could lead to increased costs due to duplicative or replacement manufacturing, delays in production, product recalls or a loss of reputation.

The Company's own facilities and the facilities used by the Company's contract manufacturers or suppliers to manufacture the Company's Products are subject to audit and inspections from regulatory authorities. Non–compliance may result in recall of the Company's products, which may cause the Company to lose its regulatory clearance.

Further, the Company's cleared Products must be manufactured in accordance with current good manufacturing practice ("**cGMP**") regulations. These regulations govern manufacturing processes and procedures, including record keeping and the implementation and operation of quality systems to control and assure the quality of products. The Company and its collaborators must supply all necessary documentation in support of a clearance or a submission or during an audit on a timely basis and must adhere to cGMP requirements enforced by the FDA and other regulatory agencies. The Company does not control the implementation of the manufacturing process of, and is completely dependent on, the Company's contract manufacturers or other third-party manufacturers for compliance with the cGMPs. If the Company or its collaborators fail to comply with cGMP, the Company could experience a disruption in the supply of the Company's Products or Future (NGAL) Products, a lock down of the factory which could delay or prevent regulatory clearance or commercial launch of such products, which could have a material adverse effect on the Company's prospective future revenues, cash flows, liquidity and results of operations.

In addition, the Company, its suppliers, or its contract manufacturers may not be able to successfully increase manufacturing capacity in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities or at other times. If the Company is unable to successfully scale up the manufacturing in sufficient quality and quantity, this could have a material adverse effect on the Company's, reputation with its customers or potential customers, its revenues, cash flow, liquidity, results of operations, and future prospects.

1.3.6. 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

To meet commercial commitments to deliver its Products, the Company may maintain inventory, however, from time to time such inventories may be insufficient to meet both planned and unplanned demand, in particular following delivery of larger orders. Given the Company's limited availability of working capital, its ability to store sufficient inventory, including raw material, work in process, and finished goods, is limited. In addition, certain raw materials and the production processes of the Company's Products have long lead times, which can impact the Company's ability to make timely deliveries. If back-up inventories are not sufficient, the Company may not be able to fulfill commercial commitments in case of batch failures, delay in the release of batches, product recalls or spoilage and as a result, the Company could incur liabilities and/or reputational damage.

Further, in case of a significant or unexpected increases in the demand for the Company's Products, the Company may not be able to meet that demand without expending additional capital resources. This would increase the Company's capital costs and operating costs, which could negatively affect the Company's earnings and liquidity in the short term. A substantial unexpected order for the Company's products could require material working capital, which, in light of the Company's current limited capital position, could require that the Company obtains additional funding sooner than presently expected, which may not be available to the Company at all or on terms acceptable to the Company and, if available, could dilute the ownership interests of Existing Shareholders or the value of their Shares, see *"1.6.1. Risk factors - 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"*.

New manufacturing equipment or facilities may require FDA and other regulatory approvals before they can be used to manufacture Products. To the extent the Company is unable to obtain or is delayed in obtaining such approvals, the Company's ability to meet the demand for its Products could be adversely affected. Furthermore, the Company's suppliers may be unable or unwilling to expend the necessary capital resources or otherwise expand their capacity, which could materially adversely affect the Company's business, including as a result of harm caused to the Company's relationship with its customers and impairments to the Company's reputation within the industry.

Further, the Company's business could be negatively affected if the Company and/or its suppliers are unable to develop necessary manufacturing capabilities in a timely manner. If the Company fails to increase production volumes in a cost-effective manner or if the Company experiences lower than anticipated yields or production problems as a result of changes that the Company or its suppliers make to manufacturing processes to meet increased demand, the Company could experience shipment delays or interruptions and increased manufacturing costs, which could also have a materially adverse effect on the Company's revenues and profitability.

If there are unexpected increases in demand for the Company's Products, the Company may further be required to obtain additional raw materials in order to manufacture products to meet the increase in demand. However, some raw materials require significant ordering lead times, and some are currently obtained from a sole supplier or a limited group of suppliers – see further "*1.3.2. Risk factors – Risks related to the Company's operations – 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*". There are also risks that one or more of the Company's suppliers may become unwilling or unable to deliver materials to the Company. Any shortfall in the Company's supply of raw materials and components, or the Company's inability to quickly and cost effectively obtain alternative sources for this supply, could have a material adverse effect on the Company's ability to meet increased demand for its products, and in turn negatively affect the Company's total revenues or cost of sales and related profits.

1.3.7. 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 third-party vendors

The Company engages a number of third-party suppliers and service providers to supply critical goods and services, such as key raw materials, contract research services, contract-manufacturing services, and IT services. Disruptions to the business, financial stability or operations of these suppliers and service providers, including strikes, natural disasters, labor disputes, authority closedown of supplier site or other disruptions to the workforce, could affect the Company's ability to develop and market its Products on a timely basis. If these suppliers and service providers were unable or unwilling to continue to provide their products or services in the manner expected, or at all, the Company could encounter difficulty finding alternative suppliers, if at all. Even if the Company can secure appropriate alternative suppliers in a timely manner, its costs could increase significantly, and delays in the lead times associated with new supply arrangements including qualification of manufacturing processes, validation of materials, and related activities could impact the Company's ability to meet its customer commitments. Any of these events could adversely affect the Company's revenues, cash flows, liquidity, results of operations, and future prospects.

The Company depends on agreements with external parties that carry out the clinical trials sponsored by the Company. The Company depends and contractually obligates such parties to adhere to relevant laws and regulations when conducting the clinical trials. Failure of such external parties

to establish and comply with required producers and regulations may lead to withdrawal of the Company's certificates required for market access in certain jurisdictions. If the external parties do not carry out their obligations under these agreements, or do not meet expected deadlines, if the parties need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised, ongoing and planned clinical trials may be extended, delayed or terminated which could have a material adverse effect on the Company's business, results of operations, cash flows, financial condition, and/or prospects.

1.3.8. Any interruption in the operations of manufacturing facilities may impair the Company's ability to deliver products and maintain the Company's market positions

The Company is dependent on its own and its suppliers' and distributors' operating networks, including the networks to develop, manufacture, assemble, supply and service the Company's products, services and systems. A work stoppage or other limitations of production or operation, including import or export restrictions and transportation issues such as the global supply chain crises, among others, could occur at the Company's or the Company's suppliers' facilities or otherwise affect the Company and its suppliers for any number of reasons, including as a result of labor or other legal disputes, regulatory enforcement actions, tight credit markets or other financial distress, production constraints or difficulties, unscheduled downtimes, natural disasters or other events and factors outside the Company's control.

The Company's critical components for The NGAL Test are manufactured by a manufacturing company located in Japan, a country that has a history of natural disasters such as earthquakes and tsunamis. If such an event occurs at this manufacturing site, the production of the components for The NGAL Test would be disrupted until an alternative supplier could be located. The Company has not entered into alternative supplier agreements for these components. Finding an alternative supplier can be a time-consuming and costly process in order to ensure the quality and consistency of the materials, components, services or expertise required, and, in some cases, such changes may not be possible. If the Company's sole supplier of key components to The NGAL Test kit cannot or will not meet its commitments and obligations, this could have a material adverse effect on the Company's revenues, results of operations, cash flows, liquidity, and/or prospects (see "*1.3.2. Risk factors – Risks related to the Company's operations – 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*")

Any event affecting any significant production or operating facility may result in a disruption to the Company's ability to supply customers, and standby capacity and critical components necessary for the reliable operation of the production or operating facility may not be available. The impact of any disruption would depend on the nature and extent of the damage caused to, or the duration of the interruption impacting such a facility. Such work stoppages, downtimes or other limitations on production at the Company's or the Company's suppliers' facilities could disrupt the Company's ability to supply products or provide services or solutions, in the short or long term, and thereby materially adversely affect the Company's reputation, brand perception and market positions. If any of these risks were to materialize, this could have a material adverse effect on the Company's revenues, cash flows, liquidity, and/or future prospects.

1.3.9. Business System Risks

1.3.9.1. 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's and its critical suppliers' or partners' business is dependent on the function of its IT system, which includes third-party systems. In addition, the Company's or its critical suppliers' or partners' internal computer systems (including cloud-based systems) and those of its current and any future collaboration partners and other contractors or consultants are vulnerable to damage from cyber security breaches, computer viruses, ransomware, corruption of data, unauthorized access or leaks, natural disasters, attacks, terrorism, war and telecommunication and electrical failures. The Company is reliant on a variety of third parties in relation to e.g. its manufacturing of its Products and the conducting of clinical trials, and the Company does not have control over the maintenance and security of such third parties' IT systems.

Further, the Company's future success is highly dependent on completing clinical trials and obtaining data required for submissions to the FDA (see e.g. "*1.2.1. Risk factors – 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*"") Any loss of clinical trial from the Company's completed or on-going clinical trials could significantly disrupt the analysis of and preparation of the submission of clinical trial data for regulatory clearance, thereby delaying commercialization and delivery of products and significant efforts and increased expenses would be needed to recover or reproduce data.

In 2020, the Company experienced two security breaches, in response to which the Company took appropriate mitigating actions. To the Company's knowledge, these breaches did not lead to loss of data, dissemination of trade secrets or other material adverse effects on the Company. Any other system failures, security breaches or cyber-attacks could result in a material disruption of operations, manufacturing of products, and its business operations, whether due to a loss of data in the systems, loss or dissemination of data, trade secrets or other proprietary information and the Company could incur liabilities, its competitive position could be harmed and the manufacturing and commercialization of the Company's cleared Products and Future (NGAL) Products could be delayed.

The Company's financial exposure from the items described above may not be fully covered through any insurance maintained by the Company, or at all, and could have a material adverse effect on the Company's prospective future revenue, cash flow, results of operations and liquidity. Additionally, actual, potential, or anticipated attacks may cause the Company to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants.

1.3.9.2. The Company may be exposed to risks associated with product liability, warranties or guarantees, recall demands or other lawsuits or claims

The Company operates within the IVD industry, in which product liability claims and warranty or guarantee claims, recall demands, lawsuits, and other claims are not rare. The NGAL Test has yet to be introduced to the US market for diagnostic use. As a result, clinicians and practitioners are still in the process of developing the experience and routines relating to the Company's Products, which may increase the risk of human and other errors or accidents during the operation of the Company's Products. Customers or their patients, among others, may bring product liability and warranty or guarantee claims in the event that the Company's Products fail, or allegedly fail, to perform as expected, show a failure rate that is higher than expected, or the use of Products or their results, result or alleged to result, in bodily injury, death or property damage. The Company may also be exposed to such claims or regulatory action if its Products do not conform to the applicable process, specification or design requirements. As a result, the Company may face substantial liability to patients, customers and others for damages resulting from the faulty, or allegedly faulty, design, manufacture, installation, servicing, support, testing or interoperability of the Company's Products, or their misuse or failure. Product and other liability claims and legislation are subject to significant uncertainty and may be expensive, time-consuming, and disrupt the Company's operations. For these and other reasons, the Company may choose to settle product liability claims and other liability, regardless of their actual merit. If a product liability action or other liability action or injunction were finally determined against the Company, it could result in the payment of significant damages and reputational harm, and the Company's liquidity, cash flows, revenue, and results of operations could be materially and adversely affected.

1.3.9.3. 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

The Company generally secures certain levels of insurance as a condition for any sale or use of its diagnostic tests and in the conduct of trials. However, due to the Company's prioritization of its historically limited financial resources, the Company has adopted a risk-based approach in relation to taking out insurance coverage, and there may be certain liability risks for which the Company does not have adequate insurance coverage. Further, the Company's insurance coverage is generally subject to commercially agreed terms and conditions, which includes from time to time various exemptions and limitations that serve to reduce the insurance coverage.

There can be no assurance that the Company's insurance is adequate to cover product liability, damages, and other material liability risks, as well as property casualty losses. Losses not covered by insurance could prevent or interfere with the Company's product development and commercialization efforts and could further have a material adverse effect on the Company's liquidity, cash flows and reputation.

1.3.9.4. To manage its growth the Company must continually improve existing business, quality, and other reporting systems and procedures

Relative to certain competitors in the life science industry, the Company has a very lean organization with few employees. As such, the Company's core business, internal processes, and reporting procedures are not as sophisticated as in more developed companies, including certain other life sciences companies. To manage its growth and improve its performance, the Company must maintain and improve its operational systems and processes, including its quality management, financial reporting, regulatory, commercial, customer management, and other related business and IT systems. Some of these improvements and areas of expansion may take time and require more funding or personnel resources than the Company has at its disposal. The Company considers it likely that it will seek additional funding before or around the date falling twelve months after the Prospectus Date, and that such funding may, among other things, be applied towards these areas of expansion (*see "1.6.1.- Risk factors - 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").* For example, the Company is planning to expand its sales organization and hire MSLs (medical science liaisons); however, the planning thereof is still at an early stage. The Company cannot assure that it will be able to implement, on a timely basis, projects, systems, procedures, and controls, or be able to hire on acceptable terms, if at all, personnel with the requisite experience or expertise required to support the growth of its business.

The Company will need to continually improve existing reporting systems and procedures and financial and management controls as well as implement new transaction processing, operational, regulatory, quality, customer management, financial, and other systems as the Company grows. The Company's ability to successfully commercialize its Products will depend on its ability to manage its expanding operations, including undertaking each of these activities successfully and in a timely manner.

1.3.9.5. 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 is exposed to the risk of employee fraud or other misconduct and the fraud and misconduct of its wide array of third party collaborators, such as suppliers and clinical trial partners. Due to the Company's historically limited financial resources, the Company internal compliance function is less extensive relative to certain other life science companies. Accordingly, while the Company has taken certain steps to

mitigate such risks, the Company does not regularly conduct internal or external compliance audits. Misconduct by the Company's employees or its collaborators could include non-intentional failures to comply with legal requirements or the requirements of government regulators, provide accurate information to applicable government authorities, comply with fraud and abuse and other healthcare laws and regulations in Denmark, the U.S. and elsewhere, report financial information or data accurately or disclose unauthorized activities to the Company. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee or collaborator misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to the Company's reputation. The Company has adopted a Code of Conduct, but it is not always possible to identify and detect employee misconduct, and the precautions the Company takes to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting the Company from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against the Company, and the Company is not successful in defending itself or asserting the Company's rights, those actions could have a significant impact on the Company's business, results of operations, financial condition, and/or future prospects including the imposition of significant fines or other sanctions.

1.3.9.6. 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 business activities involve the controlled use of hazardous materials, narcotic drug substances, Genetically Modified Organisms ("**GMOs**") and Animal Bi-Products ("**ABPs**") and therefore the Company is thus subject to a number of different environmental health and safety laws and regulations, including those governing the use of hazardous materials, drug substances, GMOs and ABPs. The cost of compliance with health and safety regulations is substantial. The Company's R&D and production activities involve the controlled storage, use and disposal of these materials, including the components of the Company's product candidates and other hazardous compounds. Manufacturers and suppliers with whom the Company may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. In some cases, these materials and various wastes resulting from their use are stored at the Company's and the Company's manufacturers' facilities pending their use and disposal. The Company cannot eliminate the risk of accidental contamination or injury from these materials, which could cause an interruption of the Company's commercialization efforts, R&D efforts and business operations, environmental damage resulting in costly clean up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

The Company cannot guarantee that the safety procedures utilized by third-party manufacturers and suppliers with whom the Company may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, the Company may be held liable for any resulting damages and such liability could exceed the Company's resources and European, U.S. federal and state or other applicable authorities may curtail the Company's use of certain materials and/or interrupt the Company's business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. The Company cannot predict the impact of such changes and cannot be certain of the Company's future compliance. The Company does not currently carry biological or hazardous waste insurance coverage. In the event of an accident or environmental discharge, the Company may be held liable for any consequential damage and any resulting claims for damages, which may exceed the Company's financial resources and may materially adversely affect the Company's liquidity, cash flows, results of operations and general future prospects.

1.3.9.7. The Company's international presence and reliance on third parties abroad exposes the Company's business to regulatory, cultural or other challenges

Economic, cultural and political conditions and foreign regulatory requirements may slow or prevent the manufacture of the Company's Products in countries other than Denmark. Interruption of the supply of the Company's, for example the Company's flagship product The NGAL Test could reduce revenues or cause us to incur significant additional expenses in finding an alternative source of supply. Foreign currency fluctuations and economic conditions in foreign countries could also increase the costs of manufacturing the Company's Products or conducting clinical trials in foreign countries Critical components for the Company's flagship product The NGAL Test are manufactured by a third party in Japan and further the Company has a key supplier located in Norway. Further, the Company relies on third parties to conduct its clinical pediatric trial in the U.S.

The Company will continue to try to increase revenue derived from international sales of the Company's products. There are several factors that may adversely affect the performance of the Company's business and/or cause the Company to incur substantially increased costs because of the Company's international presence and sales. These factors may be all emphasized in relation to the Company due to the Company's lean organizational structure and limited financial resources, and include: (i) uncertainty in the application of foreign laws and the interpretation of contracts with foreign parties; (ii) cultural and political differences that favor local competitors or make it difficult to effectively market, sell and gain acceptance of its products; (iii) exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on international distributors or representatives; (iv) trade protection measures, trade sanctions and import/export licensing requirements; (v) its inability to obtain or maintain regulatory approvals or registrations for its products; (vi) Economic conditions, political instability, the absence of available funding sources, terrorism, civil unrest, war and natural disasters in foreign countries; (vii) Reduced protection for, or enforcement of, its patents and other intellectual property rights in foreign countries; (viii) its inability to identify international distributors and negotiate acceptable terms for distribution agreements; and (ix) restrictions on its ability to repatriate investments and earnings from foreign operations.

1.4. Risks related to the Company's Intellectual Property

1.4.1. 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 five patent families comprising the Company's NGAL Patents (see *"5.9. Business – Proprietary Rights"*) will expire in the near term: 'Determination of Neutrophil Gelatinase-Associated Lipocalin (NGAL) as a Diagnostic Marker for Renal Disorders' will begin to expire in 2025; 'Diagnostic Test to Exclude Significant Renal Injury' will begin to expire in 2027; Diagnostic Use of Individual Molecular Forms of a Biomarker' will begin to expire in 2028; 'Diagnostic Test for Renal Injury' will begin to expire in 2028; and 'Methods for Rapid Assessment of Severity of a Trauma' will begin to expire in 2027.

The five patent families exclusively licensed by the Company from The Trustees of Columbia University (see *"5.9. Business – Proprietary Rights"*) will also expire in the near term: –'Method for the Early Detection of Renal Disease and Injury' will begin to expire in 2025; 'Method and Kit for Detecting the Early Onset of Renal Tubular Cell Injury' will begin to expire in 2024; 'Method for Diagnosing Acute Renal Failure or Chronic Renal Failure' will begin to expire in 2025; 'Diagnosis and Monitoring of Chronic Renal Disease Using NGAL' will begin to expire in 2026; and the Columbia NGAL Patent Family 5 - 'Method for Distinguishing Between Kidney Dysfunctions' will begin to expire in 2028. The gRAD patents licensed by the Company from Rapid Assays ApS (see *"5.9. Business – Proprietary Rights"*) will expire in 2028.

With the expiry of the abovementioned patents beginning in 2024, the Company (or The Trustees of Columbia University or Rapid Assays ApS, as applicable) will not be able to assert such expired patents rights against potential competitors, who may then be able to, subject to obtaining the necessary regulatory approvals and permits, manufacture and sell products in competition with the Company's Products, including The NGAL Test and Products utilizing gRAD, and Future (NGAL) Products. This may harm the Company's market share, and thereby the Company's revenue, cash flow, liquidity, results of operations, and future prospects.

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

The Company's commercial success depends, to a certain extent, on obtaining and maintaining proprietary technology and rights to its Products and Future (NGAL) Products and defending these rights against third-party challenges. The Company relies upon a combination of patents (including licenses to patents), trademarks, trade secret protection and confidentiality agreements to protect the intellectual property and know-how related to its Products and Future (NGAL) Products (see *"5.9. Business – Proprietary Rights"*).

The Company files patent applications and obtains patent protection for its proprietary technology where deemed commercially relevant and possible. The Company expects that any future patent applications are will be intended to cover, as applicable, compositions of matter, methods for making and using the Company's Products and Future (NGAL) Products. However, there can be no assurance that the scope of the Company's intellectual property is sufficient to effectively protect the Company from competition in relation to the Products and Future (NGAL) Products. The Company is only able to protect its Products and Future (NGAL) Product from use by third parties to the extent that valid and enforceable patents, or effectively protected know-how and trade secrets, are in place. The Company relies on trade secret laws and agreements with the Company's employees and other third parties to protect its proprietary rights. In addition, to assert in-licensed patent rights against third party infringers, the Company may need to rely on the cooperation of the licensing party; e.g., The Trustees of Columbia University without such cooperation, the Company may be unable to enforce the in-licensed patents.

The industry places considerable importance on obtaining patent and trademark protection and other intellectual property rights, for new technologies, products and processes, as well as maintaining confidentiality surrounding trade secrets and know-how. The Company's success depends, in part, on the Company's ability to develop and maintain a strong intellectual property portfolio or obtain licenses to patents and technologies, in the United States, the EU, and in other commercially relevant countries. If the Company cannot continue to develop, obtain and protect intellectual property rights, the Company's revenues and gross profits could be adversely affected. Moreover, the Company's current and future licenses or other rights to patents and other technologies may not be adequate for the operation of its business.

The Company's ability to obtain patent protection in applicable markets for Products and Future (NGAL) Products may be uncertain due to several factors, including, but not limited to: (i) the patent applications may not be sufficient to meet the statutory requirements for patentability or may not issue with commercially relevant claims; (ii) the Company or its licensees may not seek or obtain patent protection in countries that may eventually provide the Company with a significant business opportunity; (iii) issued patents may be too narrow and competitors may design around the issued claims and sell competing products; (iv) others may file oppositions or bring patent invalidity cases against the Company's or its licensees' patents to revoke or limit the patents; (v) the Company may have insufficient funds to pursue or defend new or existing patents and patent rights, or (vi) the Company may not be able to license third party patents to have freedom to operate in commercially relevant territories. In addition, since the U.S. Supreme Court's Prometheus v. Mayo decision in 2012, patents on diagnostic methods have been more difficult to achieve in the United States, and the decision has also resulted in uncertainty with respect to the validity of granted US patents on diagnostics and inventions relating to biomarkers and natural products. Accordingly, obtaining and maintaining patents on inventions relating to diagnostics in the U.S. may be challenging.

In addition, given the amount of time it takes to obtain a patent and the time it takes to develop and commercialize new products, the patent may expire or have a limited term that is inadequate to protect the Company's competitive position. The Company's own and in-licensed NGAL patent families expire in the period from 2025–2029, and the geographies covered may not fully protect the Company's current or future commercial objectives in those geographies *(see "1.4.1. Risk factors – 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 only way that the Company may extend patent term coverage is to submit new patent applications with claims that must be both novel and non-obvious over the prior art available at the filing date of the new application. Accordingly, these new claims may not be commercially relevant and therefore, the new patents may have little value. Obtaining and maintaining a patent portfolio entails significant expense and resources over the portfolio's lifetime. If the Company chooses not to pursue or maintain patent protection for particular inventions or fails to make certain payments or comply with certain requirements in the patent process, the Company could lose its competitive position by the absence or loss of this intellectual protection.

In addition to the protection afforded by patents, the Company relies on trade secrets and confidentiality agreements to protect proprietary know-how that is not patentable or difficult to enforce and other elements of its development processes that involve proprietary know-how, information or technology that is not covered by patents. The Company contractually requires its employees and – where commercially relevant and possible – consultants, advisors, and other commercial counterparties to assign inventions made during the course of their relationship with the Company. In addition, the Company's policies require that all employees, consultants, advisors and any third party who has access to the Company's proprietary know-how and information enter into confidentiality agreements that prevent the party from disclosing any confidential information developed by the party or made known to the party during the course of the party's relationship with the Company. The Company cannot provide any assurances that such agreements provide adequate protection and will not be breached, or that its trade secrets and confidential information will not otherwise be disclosed. If the Company is unable to prevent material disclosure of its confidential information and trade secrets then the Company may not be able to establish or maintain a competitive advantage in its market, which could materially adversely affect its business, results of operations and financial condition.

1.4.3. The Company may be unable to protect or effectively enforce its intellectual property rights and such rights may be found invalid or unenforceable

Filing, prosecuting, and defending patents in all countries and jurisdictions throughout the world would be prohibitively expensive, and the Company's intellectual property rights in some countries outside Europe could be less extensive than those in Europe. Competitors may use the Company's technologies in jurisdictions where the Company does not pursue and obtain patent protection to develop their own products and, further, may export otherwise infringing products to territories where the Company has patent protection, but where enforcement is more difficult than in Europe. These products may compete with the Company's Products and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The Company may also need to resort to litigation to enforce a patent issued to the Company, to protect its trade secrets, or to determine the scope and validity of third-party proprietary rights. Such legal actions can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and may be met by counterclaims alleging invalidity and unenforceability. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness (lack of inventive step) or non-enablement. Third parties may also raise similar claims before administrative bodies in Europe and the U.S. or in other countries, even outside the context of litigation. Such mechanisms include re-examination, post-grant review and/or inter parties review and equivalent proceedings, and opposition proceedings. Such proceedings could result in revocation or limitation of the Company's patents in such a way that they no longer cover the Company's current products, product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, the Company cannot be certain that there is no invalidating prior art, of which the Company or the patent examiner were unaware during prosecution. Further, the Company cannot be certain that all of the potentially relevant art relating to its patents and patent applications has been cited in every patent office. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, the Company would lose at least part, and perhaps all, of the patent protection on its product candidates.

The Company's patent in South Korea related to EP 2128625B1 is currently undergoing litigation proceedings in South Korea regarding its validity. The Company has appealed a decision by a lower court to invalidate the patent and has an on-going appeal at the South Korean Supreme Court. Possible outcomes include that the patent will be upheld; upheld in part; or that the patent will be revoked in South Korea.

The Company may or may not choose to pursue litigation or other actions against those that have infringed its patents, or used them without authorization, due to associated expense and time commitment of monitoring these activities. The Company may wish to undertake such steps but may not have the capital to fund them. Further, there can be no assurance that the Company will discover any infringement of its intellectual property rights (including patents) by third parties. If the Company fails or is unable to protect or to enforce its intellectual property rights successfully, its competitive position could suffer, which could materially adversely affect the Company's revenues, cash flow, liquidity results of operations, and future prospects

The Company's registered trademarks may further be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. Under those circumstances, the Company may not be able to protect its rights to these trademarks and trade names. Over the long term, if the Company is unable to establish name recognition based on its trademarks and trade names, the Company may not be able to compete effectively, which could materially adversely affect its revenues, cash flow, liquidity, results of operations and future prospects.

There is significant litigation in the life science industry regarding patent and other intellectual property rights. The Company may be exposed to future litigation by third parties based on claims that its Products and/or Future (NGAL) Products, technologies or activities infringe the intellectual property rights of others. If the Company's activities are found to infringe any such patents, the Company may have to pay significant damages or seek licenses to such patents. A patentee could prevent the Company from commercializing the Products or Future (NGAL) Products.

The NGAL Test and other Products or Future (NGAL) Products are or may be designed to operate on laboratory analyzer instruments. The manufacturers of those instruments have substantially greater resources than the Company, and therefore they may be in a position to develop competing tests that run on their instruments, and the Company may not have the commercial or financial resources to combat such actions, which could potentially adversely affect the Company's market shares and thereby its revenues, cash flow, results of operations and general future prospects.

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

The Company has entered into patent license agreements to support a strategic position for certain of its Products and Future (NGAL) Products. Specifically, in relation to NGAL, the Company has entered into a license agreement with The Trustees of Columbia University for key NGAL Patents Further, in relation to its generic rapid assay device (gRAD), the Company has entered into a license agreement with another third party, Rapid Assays ApS (see "*14. Material agreements*"). If the Company fails to comply with the terms of a license agreement, the Company may lose access to critical in-licensed patents, which could result in the Company's inability to sell products containing the relevant in-licensed technology, which would adversely affect its revenues, cash flows, liquidity and results of operations.

The Company is responsible for obtaining and maintaining patents under these agreements. The Company's ability to obtain patent protection for Products and Future (NGAL) Products may be uncertain due to several factors, including, but not limited to the factors set out in section 1.4.2(i) – (vi).

Obtaining and maintaining a patent portfolio entails significant expense and resources over the portfolio's lifetime. If the Company chooses not to pursue or maintain patent protection for particular inventions or fails to make certain payments or comply with certain requirements in the patent process, the Company could lose its competitive position by the absence or loss of this intellectual protection.

1.4.5. Third parties may assert ownership or commercial rights to inventions the Company develops

Third parties may in the future make claims challenging the inventorship or ownership of the Company's intellectual property. The Company has written agreements with collaborators that provide for the ownership of intellectual property arising from its collaborations. These agreements provide that the Company must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by its collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from collaboration. If the Company cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from its use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, the Company may be limited in its ability to capitalize on the market potential of these inventions.

In addition, the Company may face claims by third parties that its agreements with employees, contractors or consultants obligating them to assign intellectual property to the Company are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property that the Company has developed or will develop and interferes with its ability to capture the commercial value of such inventions.

Litigation may be necessary to resolve an ownership dispute and the Company may not have the commercial or financial resources to combat such actions. If the Company is not successful, the Company may be precluded from using certain intellectual property or may lose its exclusive rights in that intellectual property. Either outcome could have an adverse impact on the Company's revenues, cash flow, liquidity results of operations, and future prospects. Even if successful, the Company is likely to have to expend significant financial resources in connection with such ownership disputes, which would negatively affect the Company's cash flow, liquidity and results of operations.

1.4.6. Third parties may claim that the Company infringes their intellectual property rights

The Company operates in an industry characterized by a focus scientific discovery and rapid technological development. As a result, a wide array of protected intellectual property rights exist and are continuously developed. Third parties may claim that the Company is infringing their intellectual property rights. The Company may not be routinely monitoring potentially conflicting intellectual property rights and may therefore not be aware of infringing intellectual property rights of others that relate to the Company's products, services, solutions or technologies. When performing freedom to operate searches, the Company's outside patent counsel may also fail to identify relevant third party patent rights.

The Company's competitors continually review other companies' activities for possible conflicts with their own intellectual property rights. In addition, non-practicing entities may review the Company's activities for conflicts with intellectual property rights they hold. Determining whether

a product infringes a third party's intellectual property rights involves complex legal and factual issues, and the outcome of this type of litigation is often uncertain and inconsistent, particularly across various jurisdictions.

The Company may receive notices from third parties asserting infringement and be subject to lawsuits alleging infringement of third-party intellectual property rights, and the Company has previously been involved in oppositions against the Company's own patents and third party patents at the European Patent Office (EPO). Currently, the Company is involved in an opposition in South Korea regarding one of the Company's patents (see "*1.4.3. Risk factors – Risks related to the Company's Intellectual Property - The Company may be unable to protect or effectively enforce its intellectual property rights and such rights may be found invalid or unenforceable*"). Further, the Company has previously been involved in a court case where the Company claimed invalidity and non-infringement of a third party's patent which has since expired. If claims regarding potential infringement of third-party intellectual property rights are asserted against the Company, the Company may seek to obtain a license under the third party's intellectual property rights. The Company cannot provide any assurance that the Company will be able to obtain any or all of the necessary licenses on satisfactory terms, if at all. In the event that the Company cannot obtain a license, these parties may file lawsuits against the Company seeking damages or an injunction against the import, marketing, sale or operation of the Company's products, systems and services that incorporate allegedly infringed intellectual property rights or against the operation of the Company's business as presently conducted. Such lawsuits could result in an increase in the costs of selling certain of the Company's products, systems and services, the need to partially or completely redesign them or stop the sale or operation of some or all of them and may result in damage to the Company's reputation as well as the termination of agreements by the Company's customers, suppliers or distributors. Any dispute or litigation could require significant financial and management resources regardless of the merits or outcome, and the Company cannot assure that it would prevail. The Company does not maintain insurance for intellectual property infringement, so costs of defense, whether or not the Company is successful in defending an infringement claim, may be borne by the Company and could be significant. If the Company is unsuccessful in defending or appealing an infringement claim, the Company may be subject to significant damages and the Company's financial position, results of operations or cash flows could be materially adversely affected, particularly if actual liabilities significantly exceed the Company's estimates regarding potential liabilities. The award of damages, including material royalty payments, or the entry of an injunction against the import, marketing, sale or operation of some or all of the Company's products, or the Company's entry into some other agreement could affect the Company's ability to compete and have a material adverse effect on the Company's business, financial condition and results of operations, reputation or prospects.

1.4.7. 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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the various governmental patent agencies, including the United States Patent and Trademark Office in several stages over the lifetime of the patents and applications. Governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. The Company may become involved in intellectual property litigation, which may cause the Company to incur significant costs and impair the Company's ability to sell certain products.

1.4.8. Third parties may assert that the Company's employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets

The Company employs individuals, including members of the Executive Board who were previously, and in some cases until recently, employed at universities or other life science companies, including its competitors or potential competitors. Further, as the Company maintains a limited number of employees, the Company routinely relies on assistance from third party consultants or independent contracts who act for other life science companies. Although the Company tries to ensure that its employees and consultants do not use the proprietary information or know-how of others in their work for the Company, and no such claims against the Company are currently pending, the Company may be subject to claims that the Company or its employees, consultants or independent contractors have used or disclosed intellectual property, trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims, which may require the Company to expend substantial resources.

If the Company fails in defending any such claims, in addition to paying monetary damages, the Company may lose valuable intellectual property rights or personnel, which could preclude the Company from selling its Products and/or expose the Company to liability in the form of royalty payments, penalties, reimbursement of litigation costs and legal fees, special and punitive damages, or future royalty payments, any of which could significantly affect the Company's future earnings. Further, the Company may under certain contracts be obliged to indemnify the contractual counterparty for any losses incurred by such party as a result of the Company's infringement of third-party intellectual property rights.

Even if the Company is successful in defending against such claims, litigation could result in the consumption of a substantial portion of managerial and financial resources. Further, the pendency of any litigation may in and of itself cause the Company's distributors and customers to reduce or cease purchases of the Company's products.

1.5. Risks related to legal and regulatory matters

1.5.1. 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 life science industry is subject to a number of regulatory requirements including laboratory safety, product information, environmental and other regulatory compliance procedures within the markets where the Company operates. In particular, these laws govern the protection of the health and safety of patients and users of the Company's medical devices as well as, among other things, the following activities in which the Company may be involved: product development, product testing (including clinical evaluations or clinical investigations), product manufacturing, product labeling, product safety, product storage, product marketing clearance and approval, product advertising and promotion, product import and export, product sales and distribution, and product performance/effectiveness. Accordingly, the Company's business may be affected by changes in any such laws and regulations (see "*5.12. Business – Regulatory environment*"). Especially in the U.S., the Company faces a high degree of regulatory compliance, which is both costly and time-consuming to adhere to. Further, the Company's business may also become further affected by new laws and regulations (see "*5.12. Business – Regulatory environment*").

The Company is also subject to various Danish and foreign taxes, including direct and indirect taxes, imposed on its global activities, and the Company's effective tax rate is impacted by the composition of the Company's taxable income in the countries in which the Company has activities. Due to the complexity of international tax rules, including transfer pricing rules, the provisions for direct and indirect taxes in the Company's accounts are subject to a certain degree of judgement, and there are many transactions and calculations where the ultimate direct and indirect tax determination is uncertain. Governmental authorities could question the Company's tax policies and judgements and seek to impose additional or increased taxes or penalties on the Company, and the final determination of tax audits and any related litigation could be materially different from the Company's historical direct and indirect tax provisions and accruals. Local tax rules and interpretations of tax rules in different jurisdictions change from time to time, and any changes may be implemented with retroactive effect. A change in tax rules or interpretation of tax rules in one or more jurisdictions could increase the Company's tax liabilities.

Regulatory scrutiny and regulation of the Company's products, systems and services, including combined offerings of equipment and services, may increase in the future and could require the Company to change the way the Company operates. These laws and regulations are complex, change frequently, are often subject to public review and comment and have tended to become more stringent over time. The need to comply with regulations is a substantial controlling, operational and reputational risk. Further, any new legislation and regulation may impose significant and costly new obligations on the Company, which may negatively affect the Company's cost of sales. Given all of the foregoing, future costs and liabilities relating to compliance with applicable laws and regulations could have a material adverse effect on the Company's business, financial condition and results of operations or prospects.

If any of the Company's practices or operational activities were found to be in violation of any of the laws or any other governmental regulations that may apply to the Company, the Company may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from government funded healthcare programs, such as the U.S. Medicare and Medicaid programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of the Company's operations, any of which could substantially disrupt the Company's operations. If the physicians or other providers or entities with whom the Company expects to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

1.5.2. 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 Products or any of the Company's Future (NGAL) Products for which the Company has or obtains regulatory clearance, as well as the manufacturing processes, labeling, advertising and promotional activities for such products, among other things, are subject to extensive regulatory requirements. These requirements include post-marketing surveillance, registration and listing requirements, and quality control assurances. Even if regulatory clearance of a product candidate is given, the product will be subject to limitations on the indicated uses for which the product may be marketed, or to the conditions of clearance documented in the regulation, special controls or clearance letters.

The U.S. Food and Drug Administration (FDA) and other agencies, including the U.S. Department of Justice, closely regulate and monitor the promotion of products to ensure that the products are manufactured, marketed and distributed only for the cleared indications and in accordance with the provisions of the cleared labeling. The FDA and other agencies impose stringent restrictions on manufacturers' communications regarding off-label use and if the Company markets any of its product outside of the approved clearances, the Company may be subject to warnings or enforcement action for off-label marketing. Violation of the U.S. Federal Food Drug and Cosmetic Act, and other statutes, including the U.S. False Claims Act, relating to the promotion and advertising of diagnostic tests may lead to investigations or allegations of violations of U.S. federal and state health care fraud and abuse laws and state consumer protection laws.

If the Company is subject to post-marketing requirements or needs to withdraw from the market and/or must pay penalties, this would damage the commercialization process, which would adversely impact the Company's business, future financial position, results of operations and future growth prospects.

1.5.3. The Company's compliance with regulations governing public companies is complex and expensive.

As the Company's shares are admitted to trading and official listing on Nasdaq Copenhagen, the Company is subject to various rules, laws and regulations applicable to publicly traded companies, including the Nasdaq Issuer Rules and the Market Abuse Regulation. Due to the Company's lean organizational structure and historically limited financial resources, the Company has not established a function dedicated to compliance with such rules, laws and regulation. Accordingly, the compliance with and implementation of certain aspects of these rules, laws and regulations has required and will continue to require from the Company substantial management time and oversight and has and may continue to require the Company to incur significant additional accounting and legal costs. Failure to comply with these rules could result in the Company's shares being excluded from trading and official listing on Nasdaq Copenhagen and/or the imposition of administrative, civil or criminal penalties, including fines which may be issued by Nasdaq Copenhagen, each of which may adversely affect the Company's operating results and cash flow.

1.5.4. The Company's sale of its Products and Future (NGAL) Products depends on third-party payors coverage

Sales of certain of the Company's Products and Future (NGAL) Products, if and when regulatory clearance is achieved, will depend, in part, on the extent to which they will be covered by third-party payors, e.g. as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for diagnostic tests and services. Because coverage and reimbursement determinations are made on a payor-by-payor basis, obtaining coverage and adequate reimbursement from one payor does not guarantee that a product obtain similar coverage or reimbursement from another payor. In addition, government and other authorities have continued implementing cost containment programs, including price controls, and restrictions on coverage and reimbursement. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit the Company's net revenue and results. Decreases in third-party reimbursement for the Company's Products and Future (NGAL) Products or a decision by a third-party payor not to cover the Company's Products or Future (NGAL) Products or provide only limited reimbursement for the Company's Products and Future (NGAL) Products could reduce usage, once cleared, and have a material adverse effect on the Company's sales, results of operations and financial condition.

Further, the adoption and implementation of any future governmental cost containment or other healthcare reform initiative may result in additional downward pressure on the price that the Company may receive for any cleared product.

In the U.S., or other principal markets in which the Company may sell its Products and Future (NGAL) Products, there is a continued economic, regulatory and political pressure to promote changes in healthcare systems to reduce healthcare costs, which may negatively impact the sale of such products.

Legislation that has been enacted in the U.S. at both the federal and state levels, has introduced cost-reduction measures and other provisions that could decrease the coverage and compensation that the Company may receive for its Products and Future (NGAL) Products. In the U.S., Medicare and Medicaid reimbursement for laboratory tests fall under Diagnosis Related Group ("**DRG**") codes for inpatients and Current Procedural Terminology ("**CPT**") codes for outpatients. Since The NGAL Test is primarily focused on critical care inpatients, it will be covered under DRG codes, that cover all costs associated with treatment of a defined disease state on a capitated basis. There is uncertainty about how recent changes to reimbursement structures and rates may affect the Company's Products and Future (NGAL) Products, but the Company may experience a reduction in payments due to upcoming changes, which could have a material adverse effect on the Company's sales, results of operations and financial condition.

In the EU, changes to healthcare systems, including the establishment and operation of health services and the pricing and reimbursement of diagnostic products, are mostly a matter a domestic policy in the member states. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of diagnostics, and such measures are expected to continue. This could affect the Company's ability to commercialize any product candidate for which it obtains regulatory clearance and, in turn, have a material adverse effect on the Company's sales, results of operations and financial condition.

1.5.5. The Company is and may in the future become involved in litigation, arbitration and governmental proceedings

From time to time, the Company may be involved in, or threatened with, legal, arbitration and governmental proceedings in the ordinary course of the Company's business, including disputes with employees, competitors, customers, suppliers, competition authorities, regulators and other authorities, purported whistle-blowers, or regulatory agencies concerning, among other things, breaches of contract, product liability, product defects, intellectual property infringement, logistics or manufacturing related topics, quality regulations, environmental or employment issues, termination of business relationship, and/or alleged or suspected violations of applicable laws in various jurisdictions. The outcome of pending or potential future legal, arbitration and governmental proceedings is, as a general matter, difficult to predict. If such proceedings are determined against the Company, the Company may be subject to the imposition of fines, required to change the Company's business practices or the Company may incur liabilities or monetary losses, some of which may not be covered by the Company's existing insurance policies and may be significantly disruptive to the operation of the Company's business. In addition, the costs and penalties related to litigation, arbitration and governmental proceedings may be significant. Exposure to litigation, whether directed at the Company, its customers, suppliers or distributors or the Company's or their respective business partners, could also result in the distraction of management resources and materially adversely affect the Company's reputation or the reputation of Company's products, which could have a material adverse effect on Company's business, financial condition and results of operations or prospects.

1.5.6. The Company faces risks related to data privacy concerns and failure to comply with privacy regulations and security requirements relating to data

The Company processes personal data as part of its daily business operations and clinical trials and is thus subject to data protection laws, privacy requirements and other regulatory restrictions, including the General Data Protection Regulation (EU) 2016/679) ("**GDPR**"), in the various jurisdictions in which the Company operates.

Failure to keep apprised of, and comply with, privacy, data use and security laws, standards and regulations, including, for instance, (i) inadequate disclosure and invalid consent for processing of personal data or (ii) unauthorized disclosure of or access to personal data, could result in the suspension or revocation of the Company's clearances or registrations, the limitation, suspension or termination of services or the imposition of administrative, civil or criminal penalties, including fines which may be issued under the GDPR, of up to EUR 20 million or 4% of the annual worldwide turnover of an undertaking for serious infringements. In addition, such failure or non-compliance may: (a) cause existing or potential partners, including hospitals, physicians and patients to cease interacting with the Company; (b) damage the Company's reputation and brand; (c) lead to breach of contract claims by partners whose data the Company possesses; or (d) lead to civil claims under the GDPR. Also, to the extent more restrictive laws, rules, industry standards, security requirements, contractual commitments or other obligations relating to business and personal data are adopted in the future in the various jurisdictions in which the Company operates, such changes could have an adverse impact on the Company's business, results of operations, financial condition, and/or future prospects by increasing its costs or imposing restrictions on its business processes.

The Company's financial exposure from the items referenced above may either not be insured against or not fully covered through any insurance maintained by the Company and could have a material adverse effect on the Company's business, financial condition or results of operations.

1.5.7. 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

Regulatory authorities, including FDA, strictly regulate the indications for use and associated promotional safety and effectiveness claims that may be made about prescription products. In particular, a medical device may not be promoted for uses that are not consistent with the product's approved or cleared labeling. Any labeling approved or cleared by regulatory agencies for the Company's Products and Future (NGAL) Products may include restrictions on use, warnings, precautions, and contraindications. If the Company receives marketing approval or clearance for any products it develops, physicians may nevertheless lawfully choose to use such products on their patients in a manner that is inconsistent with the approved or cleared label. For example, following the potential FDA approval of The NGAL Test for risk assessment of AKI in pediatric population using the Roche cobas c501 analyzer, physicians may elect use The NGAL Test with other clinical chemistry analyzers or in other manners which are not consistent with the FDA approval. However, if regulatory authorities determine that the Company's promotional materials or physician training, constitutes promotion of an off-label use, such authorities could request that the Company modify its training or promotional materials or subject the Company to enforcement action, including warning letters, untitled letters, fines, penalties, or seizures. If the Company is found to have promoted such off-label uses, it may become subject to significant liability. The U.S. government, for example, has levied large civil and criminal fines and/or other penalties against companies for alleged improper promotion and has investigated, prosecuted, and/or enjoined several companies from engaging in off-label promotion. Regulatory authorities may also request that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed, curtailed or prohibited. If the Company cannot successfully manage the promotion of and training for its products and product candidates, it could become subject to significant liability and restrictions, which could materially adversely affect the Company's business, financial condition and results of operations or prospects.

1.5.8. In the U.S., the Affordable Care Act or changes to the act may adversely affect the Company's business and results of operations

The Affordable Care Act ("**ACA**") was enacted in 2010 and had three primary goals: i) make affordable healthcare available to more people; ii) expand the Medicaid program to cover all adults with income below 138% of the federal poverty level; and iii) support innovative medical care methods to lower overall healthcare costs. The law originally included an excise tax on diagnostic products, such as the Company's Products, but the tax was repealed at the end of 2019. In an attempt to lower overall health costs there has been discussion about bundling reimbursement for patient care. If a healthcare provider receives a lump sum amount for the management of a patient with a specific condition, all the expenses and services for treating that patient have to be paid from that amount and any additional care or testing beyond that amount results in a loss to the healthcare provider. Bundled reimbursement and other elements of the ACA, including comparative effectiveness research, an independent payment advisory board, and payment system reforms could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of the Company's business, results of operations, financial condition, and/or future prospects, including the demand for and availability of the Company's Products and Future (NGAL) Products, the reimbursement available from governmental and third-party payors, and medical procedure volumes. Various healthcare reform proposals have also emerged in the U.S. at the state level, and the Company is unable to predict which, if any, of these proposals will be enacted. The Company is also unable to predict what effect ongoing uncertainty surrounding U.S. federal and state health reform proposals will have on its customer's purchasing decisions. However, an expansion in government's role in the U.S. healthcare industry may adversely affect the Company's business, possibly materially. In addition, it is possible that changes in administration and policy, including the potential repeal of all or parts of the ACA could result in additional proposals and/or changes to health care

system legislation which could have a material adverse effect on the Company's business. The full effect that a full or partial repeal of the ACA would have on the Company's business may not be predicted at this time.

1.6. Risks related to the Company's financials

1.6.1. 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 is currently advancing its internal product candidates through clinical development and is conducting studies with respect to other programs either alone or within partnerships. Developing diagnostic test candidates is expensive, lengthy and associated with high risks. As of 31 December 2021, the Company's cash and cash equivalents were approximately DKK 45.5 million. The Company is of the opinion that, as at the Prospectus Date, and without taking into account any net proceeds the Company may raise through the Offering and potential other equity offerings in the period, its present working capital, including its current cash position and other sources of funds, is not sufficient to meet the Company's present requirements considering a twelve months' period after the Prospectus Date, being 7 March 2022. See "*18.3. Key information on persons involved in the Offering, capitalization and use of proceeds – Working capital statement".*

The Company intends to continue to expend substantial financial resources for the foreseeable future in connection with its efforts to realize its strategic priorities and the continued development and commercialization of its Products and potential Future (NGAL) Products, to the extent such financial resources are available to the Company, which is expected to require that the Company seeks additional funding in addition to the present Offering. Such expenditures are expected to comprise mainly costs associated with research and development activity, corporate administration, business development, debt service, marketing and selling of Products.

Based on the assessment and further assumptions detailed in "*18.3. Key information on persons involved in the Offering, capitalization and use of proceeds – Working capital statement",* the Company expects that if the Offering is completed with gross proceeds of at least DKK 80 million, the Company's cash position will be sufficient to meet the Company's present and future requirements for a twelve months' period after the Prospectus Date. However, the Company's operating plans and the Company's financial estimates and guidance, including the prospective financial information set out in section 7of this Prospectus, may change as a result of a variety of factors, and the Company may need to seek additional funds sooner than planned through public or private equity offerings, debt financings or corporate collaboration, licensing and/or distribution agreements (see "*5.3.4. Business – Strategic Priorities – Preparation of future financing and expanding access to capital*"). Further, the Company may seek additional capital if market conditions are favorable or if the Company has specific strategic considerations or capital requirements. Accordingly, the Company considers it likely that it will seek additional funding before or around the date falling twelve months after the Prospectus Date.

There can be no assurance that the Company will be successful in raising the necessary capital or that capital will be available on terms acceptable to the Company, or at all. If the Company is unable to raise any sufficient additional capital on acceptable terms, it could have a materially adverse effect on the Company's business, including as a result of the Company being forced to significantly delay, scale back or discontinue the development or commercialization of one or more Products or Future (NGAL) Products or one or more of its other research and development initiatives. Further, if any such capital raise is completed, it may be dilutive to the shareholding and/or economic value of Existing Shareholders' ownership stake in the Company.

The outbreak of the COVID-19 pandemic has significantly disrupted world financial markets, delayed the Company's clinical trials in the U.S. for The NGAL Test, and negatively impacted U.S. market conditions, and it may reduce opportunities for the Company to obtain the required additional funding. A decline in the market price of the Company's Shares, could make it more difficult for the Company to offer equity or equity-related securities in the future at such times as deemed appropriate by the Company. These reasons also contributed to the Company's determination that there is substantial doubt about the Company's ability to continue as a going concern.

Doubt about the Company's ability to continue as a going concern may adversely affect the Company's relationships with current and future employees, suppliers, vendors, customers, regulators and investors, who may become concerned about the Company's ability to meet its ongoing financial obligations. There is risk that, among other things: (i) third parties lose confidence in the Company's ability to continue to operate in the ordinary course, which could impact the Company's ability to execute on its business strategy; (ii) it may become more difficult for the Company to attract, retain or replace employees; (iii) the Company's employees may become be distracted from performance of their duties; (iv) the Company could lose some or a significant portion of its liquidity, either due to stricter credit terms from vendors, or, in the event the Company commences bankruptcy, restructuring or similar proceedings; and the Company's suppliers, vendors and service providers could seek to renegotiate the terms of their arrangements with the Company, terminate the relationships with Company or require financial assurances from the Company.

The Company is providing the preliminary estimates of certain operating results for the twelve months ended December 31, 2021 set forth under ("*7.Consolidated Prospective Financial Information*") below on a going concern basis, which assumes that the Company will be able to meet its commitments, realize its assets and discharge its liabilities in the ordinary course of business. Those preliminary estimates do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

1.6.2. The Company has incurred net losses and may continue to do so

The Company recognized net losses of DKK 57 in 2021 (unaudited estimate), DKK 61.6 in 2020 and DKK 69.6 million in 2019. The Company considers that its ability to generate revenue and reach profitability primarily depends on obtaining the regulatory clearance of The NGAL Test in the U.S. for both the pediatric and adult populations, the pricing of The NGAL Test, and the successful commercialization of The NGAL Test through the Company's own sales force as well as through its distribution partners. Obtaining approval for The NGAL Test for pediatrics using the Roche c501 analyzer is not expected to, in itself, allow the Company to reach profitability and that, accordingly, additional funding will be required (see "*1.6.1 - Risk factors - 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").*

See "*1.1.8. Risk factors – Risks related to the Company's business – 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", "1.2.1. Risk factors – 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 in would have a material adverse effect on the Company's prospective future revenues, future growth prospects, future cash-flows and future results of operations", " 1.2.2. Risk factors – Risks related to the Company's Products and Future (NGAL) Products - A failure to successfully commercialize The NGAL Test for pediatric and later adult uses would have a material adverse effect on the Company's future revenues, future growth prospects, future cash-flows and future results of operations", and "1.2.4. Risk factors – Risks related to the Company's Products and Future (NGAL) Products – 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."*

If the uptake of The NGAL Test is not significant, the intended use approved by regulatory authorities has a narrower scope than anticipated, if the Company is not able to price The NGAL Test at satisfactory levels, or if the adoption of The NGAL Test is reduced because of competing products, physician/hospital preferences or lack of clinical guidelines, this will negatively impact the revenue generated by this product and have an adverse effect on the Company's prospective future revenues, cash flow, liquidity and results of operations.

1.6.3. The Company's business requires significant levels of capital investments, which the Company may be unable to fund

The Company's business regularly requires significant levels of capital investments, including for product design and development, clinical trials, patent portfolio maintenance, manufacturing and maintenance and expansionary expenditures, as well as significant spending on R&D, in addition to having a relatively high fixed cost base.

As examples, following the potential FDA approval of The NGAL Test for risk assessment of AKI in pediatric patients using the Roche cobas c501 laboratory instrument analyzer, further investment, including potentially in relation to additional clinical trials if the Company is not able to reuse the samples collected during the ongoing pediatrics trial, will be required in order to potentially expand such FDA approval to comprise other patient populations (see *"1.2.4. Risk factors – Risks related to the Company's Products and Future (NGAL) Products – 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")* and for use with additional clinical chemistry analyzers (see "*1.2.6. Risk factors – Risks related to the Company's Product and Future (NGAL) Products – A failure to successfully complete development, obtain regulatory clearance for in vitro diagnostics (IVD) use of and commercialize Future NGAL Products would have a material adverse effect on the Company's prospective future revenues, future cash-flows, future results of operations and growth prospects*").

The Company considers it likely that it will be required to make investments in quality systems in preparation for the coming into effect of the IVDR during 2022 and 2023, and have budgeted for the estimated related capital expenditures (see *"7.3.6 - Consolidated Prospective Financial Information - Assumptions relating to EBIT – Preliminary Guidance for FY2022")*.Further, to the extent that new regulatory burdens are imposed, the Company may be required to make capital expenditures, even though the Company may not have available resources at such time.The Company is susceptible to such regulatory changes as it does not have an extensive in-house compliance function in place (see "*1.5.3. Risk factors – Risks related to legal and regulatory matters – The Company's compliance with regulations governing public companies is complex and expensive*"). If the Company is unable to meet its capital expenditure requirements, the Company may not be able to maintain its product development and commercialization, and this may adversely harm the Company's prospective future revenue, cash flow and result of operations.

1.6.4. The Company's ability to utilize its net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2020, the Company had consolidated, unrealized and unrecognized deferred taxes of DKK 64.7 million, which is equal to approximately 9.9% of the total market value of the Company's shares as at 31 January 2021. The Company's ability to utilize its net operating loss and tax credit carryforwards may be limited under Danish tax law and the tax jurisdictions where such losses reside, including in Denmark and the U.S. If the Company's ability to use its net operating loss carryforwards and/or other tax attributed to offset its taxable income is limited, the Company's future cash flows could be adversely affected. Further, there can be no assurance that the unrealized and unrecognized deferred taxes have not affected the market price of the Company's Shares, and that any factors limiting the Company's ability to carry forward such losses may negatively affect the price of the Shares.

Danish tax law provides for a limitation of offset where more than 50 percentage in ownership interest or voting rights on equity changes in an income year. However, these limitations generally do not apply where shares in the relevant company are listed in the loss generating year and in the year with the transfer of majority ownership or voting rights. Furthermore, Danish law generally limits the Company to use tax carryforwards derived from losses to reduce the taxable income with 60% (after a reduction of the taxable income with DKK 7.5 million). For net operating losses residing in the U.S., Sections 382 and 383 of the U.S. Internal Revenue Code of 1986 provide for limitations to carryforward net losses in case the Company experiences an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the ownership of the Company's equity by certain stockholders over a rolling three-year period.

1.6.5. The Company faces risks related to sales and production contracts denominated in currencies other than DKK

Currency risks include the risk arising from sales and production contracts being denominated in currencies other than DKK. The Company's contracts are primarily made in USD and EUR, and the Company does not engage in hedging activities in the ordinary course of business.

Changes in the value of the DKK against other currencies will affect the Company's reported operating revenue and expenses and the value of balance sheet items originally denominated in other currencies, and the Company considers it likely that fluctuations in exchange rates between DKK and USD will continue. This can affect the Company's margins, as its operating revenue in any one currency is not matched by expenses in the same currency. The Company's financial results could be materially adversely affected by currency exchange rate fluctuations, and there is no assurance that efforts by the Company, if at all, to engage in currency hedging will be effective.

1.6.6. Risks relating to trade receivables

The Company's customers are primarily hospitals, universities, companies in the pharmaceutical industry and laboratories, and as such, the Company's credit risk is widely spread. In 2021, the Company's largest customer amounted to more than 10% of total revenue (unaudited).

The Company monitors its credit risk through a simplified credit loss model. Based upon this model, the Company recognizes its bad debt provision. The Company's bad debt provision was DKK 0.4 million, DKK 0.4 million, DKK 0.3 million as of September 30, 2021, and December 31, 2020 and 2019, respectively.

There can be no assurance that the Company will not suffer losses from trade receivables in the future. To the extent that the Company is unable to collect its outstanding accounts receivable, this could have a material adverse effect on the Company's business, results of operations, cash flows, financial position and prospects.

There may be circumstances and timing that require the Company to accept payment terms, including delayed payment terms, from distributors or customers, which, if not satisfied, could cause financial losses. The Company generally accepts payment terms that require us to ship product before the contract price has been paid fully, and there also are circumstances pursuant to which the Company may accept further delayed payment terms pursuant to which it may continue to deliver product. To the extent that these circumstances result in significant accounts receivables and those accounts receivables are not paid on a timely basis, or are not paid at all, especially if concentrated in one or two customers, the Company could suffer financial losses.

1.6.7. The Company bases its estimates or judgments relating to critical accounting policies on assumptions that can change or prove to be incorrect.

The Company's financial statements have been prepared in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act ("**IFRS**"), and the Company's management reviews and financial reviews are based on such statements.

The preparation of financial statements requires Management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company continuously evaluates significant estimates used in preparing its financial statements, including those related to (i) revenue recognition, including uncertainties related to variable consideration and milestones; (ii) stock-based compensation; (iii) allowance for uncollectible accounts receivable; (iv) inventory reserves and obsolescence; (v) customer sales returns and allowances; (vi) contingencies; and (vii) income taxes, (viii) intangibles, and (ix) research and development costs.

The Company's estimates are based on historical experience and various other assumptions that the Company believe to be reasonable, as set forth in its discussion and analysis of financial condition and results of operations, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these and other estimates if the Company's assumptions change or if actual circumstances differ from those in its assumptions. If the Company's operating results fall below the expectations of securities analysts and investors, the price of the Shares may decline.

1.6.8. Future financial results may significantly differ from the Company's estimates and guidance

The forward-looking statements contained in this Prospectus, including the Prospective Financial Information in its section 7, are based on a number of assumptions and estimates and are conditional on a number of factors, including the assumptions set out in section 7.

The forward-looking statements involve known and unknown risks and uncertainties, many of which are based on Management's current beliefs and expectations about future events. No assurance can be given that such future results will be achieved. Actual events or results may differ materially as a result of risks and uncertainties to which the Company is subject, which could cause actual results to vary materially from the future results indicated, expressed, or implied in forward-looking statements.

If the Company fails to achieve the future results indicated in its forward-looking statements, the price of the Shares may decline.

1.7. Risks related to the Offering and the Shares

1.7.1. 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 market price of the Company's Shares has been, and may in the future continue to be, highly volatile, subject to significant fluctuations in response to various factors, many of which are beyond the Company's control and which may be unrelated to the Company's business, operations or prospects. Recent outbreaks of armed conflicts have negatively affected the price of shares of publicly traded companies worldwide and it is impossible for the Company to predict with any degree of certainties how such conflicts will evolve and how global stock markets will be affected.

The price of the Pre-emptive Rights and the New Shares may be highly volatile during the Rights Trading Period and the Subscription Period, respectively. Until the merger of the ISIN codes has been completed, the liquidity and market price of the New Shares under the interim ISIN code may be substantially different from the liquidity and market price of the Existing Shares under the existing ISIN code. Matters that could affect the price of the Shares include actual or anticipated variations in operating results, including announcements by the Company or other parties relating to regulatory approvals or rejections, results of clinical studies, of technological innovations by the Company, of new partnerships or terminations, etc. Future (NGAL) Products introduced by the Company, other products announced by the Company's competitors, conditions, trends or changes in the life science industry, changes in the market valuations of similar companies, additions or departures of members of Corporate Management or other key employees and further sales of Shares by the Company or the Company's Management or Major Shareholders may also affect the price of the Company's Shares, including New Shares, and Pre-emptive Rights.

In addition, the equity market in general, and the market for technology and diagnostic companies, has experienced significant price and volume fluctuations that may be unrelated or disproportionate to the operating performance of individual companies. No assurances can be given that equity market fluctuations, even if otherwise unrelated to the Company's activities, will not have a material adverse effect on the market price of the Shares, including New Shares. Accordingly, investors may not be able to resell New Shares at or above the Subscription Price.

Further, over the past year, listed shares of companies similar to the Company, which have relatively volatile stock prices, higher daily trading volumes and lower share price per units, have increasingly experienced significant and extreme volatility in stock price due to short sellers of shares, known as a "short squeeze." Such short squeezes have caused extreme volatility in those companies and in the market and have led to the price per share of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Sharp rises in a company's stock price may force traders in a short position to buy the stock to avoid even greater losses. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. There can be no assurance that the Company will not, in the future, be a target of a short squeeze. Shareholders who purchase shares in the Company at a rate that is significantly disconnected from the Company's underlying value may lose a significant portion or all their investment.

1.7.2. 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

The Company does not expect to distribute any cash dividends in the foreseeable future as future earnings will be re-invested in the Company. During this period, investors must rely on sales of their Shares as the only way to realize any future gains on their investments. Any future determination on the Company's dividend policy and the declaration of any dividends will be made at the discretion of the Board of Directors. Any future dividend payments will depend on a number of factors, including the Company's results of operation, financial position, future prospects, potential general meeting approval, contractual restrictions, restrictions imposed by applicable law and other factors the Board of Directors deems relevant.

1.7.3. Shareholders may not receive payments in the event of the Company's bankruptcy, winding-up or other similar event

In case of the dissolution or winding-up of the Company, including as a result of the Company's bankruptcy, the Shares will be entitled to a proportionate part of the Company's assets after payment of the Company's creditors, including fees to the trustee of the bankruptcy estate or liquidator, There can be no assurance that the value of the Company's assets will exceed the liabilities towards the Company's creditors in the event of bankruptcy or other dissolution or winding up proceedings, and accordingly, the holders of Shares may not receive any payment in such event.

1.7.4. 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 market price of the Pre-emptive Rights depends on the price of the Shares. A decline in the price of the Shares could have an adverse effect on the value and market price of the Pre-emptive Rights.

The Rights Trading Period during which the Pre-emptive Rights can be traded on Nasdaq Copenhagen commences on 9 March 2022 at 9:00 a.m. CET and closes on 22 March 2022 at 5:00 p.m. CET. There can be no assurance that a market for the Pre-emptive Rights will develop when they are initially traded on Nasdaq Copenhagen, and if such a market develops, the Pre-emptive Rights may not be effectively priced against the price of the Shares.

1.7.5. 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

The liquidity of the Company's Shares depends on several factors and may be reduced as a result of, among other things, the Company's financial results, overall market conditions, and the Company's shareholder structure, including any further consolidation of share ownership which may result from the Offering, or in the event that Existing Shareholders or other investors do not exercise the Pre-emptive Rights (see "*18. Key information on persons involved in the Offering, capitalization and use of proceeds").* Accordingly, it is not possible to predict whether the current level of liquidity will continue, be sustained, or decrease. Decreased trading volume of the Company's Shares would make it more difficult for investors to sell their Shares in larger portions or at all, and may further have an adverse effect on the price of the Company's Shares.

1.7.6. Shareholders in jurisdictions outside Denmark may be unable to exercise Pre-emptive Rights

Holders of Shares in jurisdictions outside Denmark, such as the U.S., may be unable to exercise any Pre-emptive Rights, unless such exercise occurs in accordance with relevant local laws and/or pursuant to an exemption from applicable registration requirements. The Company is under no obligation and does not intend to file a registration statement in any jurisdiction outside Denmark with respect to the Pre-emptive Rights or the New Shares, and makes no representation as to the availability of any exemption from any registration requirements under the laws of any jurisdiction other than Denmark with respect to any such rights or the Shares, including the New Shares, in the future.

1.7.7. Shareholders outside Denmark are subject to exchange rate risk

The Pre-emptive Rights and the New Shares are priced in DKK. Accordingly, the value of the Pre-emptive Rights and the New Shares is likely to fluctuate with respect to any fluctuation of the exchange rate between the local currency of the country in which an investor outside Denmark is based and DKK. If the value of DKK depreciates against the local currency of the country in which an investor outside Denmark is based, the value of the Pre-emptive Rights and the New Shares will decrease when expressed in such local currency.

1.7.8. 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

If Pre-emptive Rights are not exercised by the end of the Subscription Period, such holders' Pre-emptive Rights to subscribe for New Shares will lapse with no value and the holder will not be entitled to compensation. Accordingly, Existing Shareholders and other holders of Pre-emptive Rights must ensure that all required exercise instructions are received by such Existing Shareholder's or other holder's bank before the deadline. If an Existing Shareholder or other holder fails to provide all required exercise instructions or otherwise fails to follow the procedure applicable to exercising the Pre-emptive Rights prior to 24 March 2022 at 5:00 p.m. CET, the Pre-emptive Rights will lapse with no value.

1.7.9. 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

Certain Existing Shareholders may be unable to take up and exercise their Pre-emptive Rights as a matter of applicable law. The Pre-emptive Rights of such Existing Shareholders, with the exception of Pre-emptive Rights held through financial intermediaries, may be sold by the Existing Shareholders' own custodian banks, but no assurance can be given as to whether such sales may actually take place. Other Existing Shareholders may also choose not to exercise their Pre-emptive Rights and therefore sell them in the market. The sale of Pre-emptive Rights by or on behalf of Existing Shareholders could cause significant downward pressure on, and may result in a substantial decline in, the price of the Pre-emptive Rights and the Shares.

1.7.10. 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 issue of the New Shares will cause Existing Shareholders who have not exercised their Pre-emptive Rights to experience a substantial dilution of their ownership interest and voting rights. As the rights issue is completed at a discount to market price, the economic value of the Existing Shareholder's ownership stake will in such case also be diluted. Even if the Existing Shareholder decides to sell its Pre-emptive Rights, the payment it receives may not be sufficient to offset the dilution (see "*24. Dilution*").

1.7.11. 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 Company is a public limited liability company incorporated in Denmark, and a majority of the Company's assets and operations are held and conducted in Denmark. As such, it may be difficult for shareholders and investors outside of Denmark to exercise or enforce certain rights. The rights of holders of Shares and Pre-emptive Rights are governed by Danish law and by the Company's Articles of Association. These shareholder rights may differ from the typical rights of shareholders in the U.S. and other jurisdictions. As a result, it may not be possible for investors to effect service of process upon the Company outside Denmark or to enforce judgments obtained in courts outside Denmark based on applicable laws in jurisdictions outside Denmark. In addition, shareholders outside of Denmark may not be able to exercise their shareholder rights, such as voting rights.

1.7.12. 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

The Offering may not be completed or may be withdrawn during the period leading up to registration with the Danish Business Authority of the capital increase pertaining to the New Shares, e.g. due to the minimum of 49,000,000 New Shares not being subscribed for. If the Offering is not completed or is withdrawn, the exercise of Pre-emptive Rights that has already taken place will be cancelled automatically. The subscription amount for the New Shares will be refunded (less any transaction costs), all Pre-emptive Rights will lapse, and no New Shares will be issued. However, trades of Pre-emptive Rights executed during the Rights Trading Period will not be affected. As a result, shareholders and investors who purchase Pre-emptive Rights will incur a loss corresponding to the purchase price of the Pre-emptive Rights and any transaction costs. Similarly, if the Offering is not completed, the New Shares will not be issued. However, trades in New Shares will not be affected, and shareholders and investors who have purchased New Shares will receive a refund of the subscription amount for the New Shares (less any transaction costs).

Existing Shareholders and other investors who have purchased New Shares will consequently incur a loss corresponding to the difference between the purchase price and the Subscription Price of the New Shares plus any transaction fees, unless they succeed in recovering the purchase price from the seller of the New Shares.

1.7.13. Following the Offering, certain Existing Shareholders may increase their shareholdings and may be able to influence important actions the Company takes

As of the date of this Prospectus, the two largest Existing Shareholders, Media-Invest Danmark A/S and Ejendomsselskabet Jano ApS, hold 10.38% and >10%, respectively, of the Company's share capital. Following completion of the Offering, Media-Invest Danmark A/S and Ejendomsselskabet Jano ApS may increase their relative ownership of the Company's share capital.

As a result of these Existing Shareholder's share ownership, Media-Invest Danmark A/S and Ejendomsselskabet Jano ApS are able to exercise significant influence over the Company's Executive Management and day-to-day operations and over the Company's general meetings, such as in relation to potential mergers, consolidations, acquisitions or other forms of combinations, the issuance of equity or other securities and the appointment of the majority of members of the Board of Directors. This influence may be enhanced following the potential increase in concentration of share ownership following the Offering. The interests of Media-Invest Danmark A/S and Ejendomsselskabet Jano ApS may not be aligned with the interests of minority shareholders or new shareholders with respect to such voting decisions.

1.7.14. The Subscription Commitments might not be honored

A number of Guarantors have, subject to the satisfaction of certain terms and conditions in the Subscription Commitments, made binding undertakings to subscribe for New Shares that have not been subscribed for by holders of the Pre-emptive Rights. The undertakings are non-terminable for the Guarantors; however, each Guarantor may not honor its individual commitment. As the Offering is conditioned upon at least 49,000,000 New Shares being subscribed for, if any Subscription Commitment is not honored, this may cause the termination of the Offering, which may materially adversely impact the Company's cash flow, liquidity (see "*1.6.1. Risk factors – 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*").

1.7.15. 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

The Company may need to seek additional funds within 12 months after the Prospectus Date (see "*1.6.1. Risk factors – 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*"). Any future issuance of a substantial number of shares in the Company or other equity-based securities, or the perception that such issuances may occur, could adversely affect the price of the shares in the Company, and could impair the Company's ability to raise capital through future public or private offerings of equity or equity-based securities.

1.7.16. Sales of shares in the Company by members of Management or other Existing Shareholders could negatively affect the market price of such shares

A significant part of the compensation packages for the Executive Management and key employees is incentive based *(see "1.3.3. Risk factors – Risks related to the Company's operations - The Company's future success depends in part on its ability and retain its management team and key employees")*. If the Company's Existing shareholders and/or members of Management sell their shares in the Company in the public market, or if there is a perception that such sales may occur, it could negatively affect the price of the Company's shares. The Company is not able to estimate the number of its shares that may actually be resold in the public market since this will depend on the market price of such shares, the individual circumstances of the sellers and other factors.

Institutional shareholders own significant amounts of the Company's Existing shares. If one or more of these shareholders sell large portions of their holdings in a relatively short time, the prevailing price of the Company's shares could be negatively affected. In addition, it is possible that one or more members of Management could sell shares in the Company during an open trading window. These transactions and the perceived reasons for these transactions could have a negative effect on the prevailing market price the Company's shares.

2. Certain information regarding the Prospectus and the Offering

2.1. Introduction

This Prospectus has been prepared for the Offering and for admission to trading and official listing of the Pre-emptive Rights and the New Shares on Nasdaq Copenhagen in compliance with Danish legislation and regulations, including the Danish Capital Markets Act, the Prospectus Regulation, Commission Delegated Regulation (EU) no. 2019/980 of 14 March 2019 as well as Commission Delegated Regulation (EU) 2019/979 of 14 March 2019. This Prospectus has been prepared in accordance with the Prospectus Regulation and Annex 3 and Annex 12 to the Commission Delegated Regulation (EU) no. 2019/980 of 14 March 2019.

This Prospectus has been prepared for the public Offering in Denmark and the private placement of securities in certain jurisdictions outside of Denmark, and not for any jurisdiction in which an offering or sale would be unlawful under the applicable legislation of such jurisdiction.

The distribution of this Prospectus and the Offering is restricted by law in certain jurisdictions, and this Prospectus may not be used for the purpose of, or in connection with, any offer or solicitation to anyone in any jurisdiction in which such offer or solicitation is not authorized, or to any person to whom it is unlawful to make such offer or solicitation. This Prospectus does not constitute an offer of, or an invitation to, acquire any Pre-emptive Rights or to subscribe for New Shares in any jurisdiction in which such offer or invitation would be unlawful. Persons into whose possession this Prospectus may come must inform themselves of and observe all such restrictions. The Company does not accept any legal responsibility for any violation of any such restrictions by any person, whether or not such person is a prospective purchaser of Pre-emptive Rights or a subscriber and acquirer of the New Shares. For a more detailed description of certain restrictions in connection with the Offering (see "*20.17. Terms and conditions of the offer of securities to the public – Transfer restrictions*").

This Prospectus may not be distributed or otherwise be made available, the New Shares may not be offered or sold, directly or indirectly, and the Pre-emptive Rights may not be exercised or otherwise offered or sold, directly or indirectly, in the U.S., Canada, Australia or Japan or in any other jurisdiction outside Denmark, unless such distribution, offering, sale or exercise is permitted under applicable legislation in the relevant jurisdiction, and the Company receives satisfactory documentation to that effect.

Due to restrictions under applicable legislation, the Company expects that some or all investors residing in the U.S., Canada, Australia, Japan and other jurisdictions outside Denmark may not have the Prospectus distributed to them and may not be entitled to exercise the Pre-emptive Rights and subscribe for the New Shares. The Company makes no offer or solicitation to any person under any circumstances that may be unlawful.

2.2. Notice to Investors in the U.S.

The Pre-emptive Rights and the New Shares have not been approved, disapproved or recommended by the U.S. Securities and Exchange Commission, any state securities commission in the U.S. or any other U.S. regulatory authority, nor have any of such regulatory authorities passed upon or endorsed the merits of the Offering or the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offence in the U.S.

Neither the Pre-emptive Rights nor the New Shares have been, or will be, registered under the U.S. Securities Act or any securities laws of any state or other jurisdiction of the U.S. and are only offered and sold (i) outside the U.S. or to, or for the account or benefit of, non-U.S. persons (as defined in Regulation S) in offshore transactions in accordance with Regulation S or (ii) to a limited number of investors that are QIBs or Accredited Investors in transactions otherwise exempt from, or not subject to, the registration requirements of the U.S. Securities Act. The Offering is subject to Danish legislation and requirements and, therefore, any information contained in this Prospectus may not be comparable to information contained in prospectuses of U.S. companies or of companies offering securities registered under the U.S. Securities Act. See "*20.17.2. Terms and conditions of the offer of securities to the public – Transfer restrictions – Selling Restrictions in the U.S.*"

2.3. Notice to Investors in the European Economic Area

In relation to each member state of the European Economic Area where the Prospectus Regulation applies (each a "**Relevant Member State**"), no offering of Pre-emptive Rights or New Shares will be made to the public in any Relevant Member State prior to the publication of a prospectus concerning the Pre-emptive Rights and the New Shares which has been approved by the competent authority in such Relevant Member State or, where relevant, approved in another Relevant Member State and notified to the competent authority in such Relevant Member State, all pursuant to the Prospectus Regulation, except that an offering of Pre-emptive Rights and New Shares may be made to the public at any time in such Relevant Member State pursuant to the following exemptions from the Prospectus Regulation:

a) to any legal entity which is a qualified investor as defined in the Prospectus Regulation ("**Qualified Investor**");

b) to fewer than 150 natural or legal persons other than Qualified Investors, subject to obtaining the prior written consent of the Company; or

c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation.

In any Relevant Member State other than Denmark, the Prospectus is only addressed to, and is only directed at, investors in such Relevant Member State that fulfil the criteria for exemption from the obligation to publish a prospectus, including Qualified Investors.

For the purposes of the above, the expression an "offer of Pre-emptive Rights and New Shares to the public" in relation to Pre-emptive Rights and New Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the Offering, the Pre-emptive Rights and the New Shares so as to enable an investor to decide whether to acquire the Pre-emptive Rights and acquire or subscribe for the New Shares.

2.4. Notice to Investors in the United Kingdom

This Prospectus is only being distributed to, and is only directed at, (i) persons outside the United Kingdom (the "**UK**") or (ii) "investment professionals" falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "**Financial Promotion Order**") or (iii) "high net worth companies" and other persons to whom it may lawfully be communicated, falling within the meaning of Article 49(2)(a) to (d) of the Financial Promotion Order (all such persons being "**Relevant Persons**"). Pre-emptive Rights and New Shares are only available to Relevant Persons and any invitation, offer or agreement to subscribe for, purchase or otherwise acquire such Pre-emptive Rights or New Shares will be engaged in only with Relevant Persons. Any person who is not a Relevant Person should not act on or rely upon this Prospectus or any of its contents.

2.5. Notice to Investors in Canada, Australia and Japan

The Pre-emptive Rights and the New Shares have not been approved, disapproved or recommended by any foreign regulatory authorities, nor have any of such authorities passed upon or endorsed the merits of the Offering or the accuracy or adequacy of this Prospectus.

This Prospectus may not be distributed or otherwise made available, the New Shares may not be offered, sold or subscribed for, directly or indirectly, and the Pre-emptive Rights may not be offered, sold, acquired or exercised, directly or indirectly, in Canada, Australia or Japan, unless such distribution, offering, sale, acquisition, exercise or subscription is permitted under applicable legislation in the relevant jurisdiction, and the Company receives satisfactory documentation to that effect.

2.6. Information to Distributors

Solely for the purposes of the product governance requirements contained within: (a) Directive 2014/65/EU on markets in financial instruments, as amended ("**MiFID II**"); (b) Articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II; and (c) local implementing measures (together, the "**MiFID II Product Governance Requirements**"), and disclaiming all and any liability, whether arising in tort, contract or otherwise, which any "manufacturer" (for the purposes of the MiFID II Product Governance Requirements) may otherwise have with respect thereto, the securities that are the subject of the Offering have been subject to a product approval process, which has determined that the Pre-emptive Rights and the New Shares are: (i) compatible with an end target market of retail investors and investors who meet the criteria of professional clients and eligible counterparties, each as defined in MiFID II; and (ii) eligible for distribution through all distribution channels as are permitted by MiFID II (the "**Target Market Assessment**").

Notwithstanding the Target Market Assessment, distributors should note that: the price of the Pre-emptive Rights and the shares of the Company may decline and shareholders and investors could lose all or part of their investment; the Pre-emptive Rights and the shares of the Company offer no guaranteed income and no capital protection; and an investment in the Pre-emptive Rights and the shares of the Company is compatible only with shareholders and investors who do not need a guaranteed income or capital protection, who (either alone or in conjunction with an appropriate financial or other adviser) are capable of evaluating the merits and risks of such an investment and who have sufficient resources to be able to bear any losses that may result therefrom. The Target Market Assessment is without prejudice to the requirements of any contractual, legal or regulatory selling restrictions in relation to the Offering.

For the avoidance of doubt, the Target Market Assessment does not constitute: (a) an assessment of suitability or appropriateness for the purposes of MiFID II; or (b) a recommendation to any investor or shareholder in the Company or group of investors or shareholders in the Company to invest in, or purchase, or take any other action whatsoever with respect to, the Pre-emptive Rights and the New Shares.

Each distributor is responsible for undertaking its own Target Market Assessment in respect of the Pre-emptive Rights and the New Shares and determining appropriate distribution channels.

2.7. General information about the Prospectus

This Prospectus has been prepared in accordance with Danish legislations and regulations in compliance with the requirements set out in the Danish Capital Markets Act, the Prospectus Regulation, Commission Delegated Regulation (EU) no. 2019/980 of 14 March 2019 as well as Commission Delegated Regulation (EU) 2019/979 of 14 March 2019 and Nasdaq Issuer Rules. This Prospectus is governed by Danish law.

References in this Prospectus to the "Company" are references to BioPorto A/S, CVR no. 17 50 03 17, or BioPorto A/S and its consolidated subsidiaries, respectively, considering the context in which it is used. See "*26. Glossary*" for a list of terms and definitions frequently used in this Prospectus.

This Prospectus is not intended to provide the basis of any credit or any other evaluation and should not be considered as a recommendation or invitation by the Company that any recipient of this Prospectus should acquire or exercise any Pre-emptive Rights or subscribe for any New Shares. Each prospective investor should determine for itself the relevance of the information contained in this Prospectus, and any acquisition or exercise of the Pre-emptive Rights or subscription of the New Shares should be based upon such information as it deems necessary.

Investors are authorized to use this Prospectus for the purpose of considering the acquisition or exercise of the Pre-emptive Rights and subscription of the New Shares described in this Prospectus. The information contained in this Prospectus has been provided by the Company and by other sources identified herein.

Neither the delivery of this Prospectus nor the exercise of Pre-emptive Rights or the subscription or acquisition of the New Shares will create any implication that the information contained herein is correct as at any time subsequent to the Prospectus Date. Any material changes in connection with the information in this Prospectus which may affect the evaluation of the Pre-emptive Rights, the New Shares or the Existing Shares, which occur or are ascertained between the time of approval of this Prospectus and the final completion of the Offering or the commencement of trading on Nasdaq Copenhagen, will be published as a supplement pursuant to applicable rules and legislation in Denmark. Investors who have accepted to exercise Pre-emptive Rights prior to publication of the supplement will be entitled to withdraw their acceptance for three (3) business days after the publication of such supplement.

Further, investors acknowledge that they have relied only on the information contained in this Prospectus, and that no person has been authorized to give any information or to make any representation concerning the Company or the Shares other than contained in this Prospectus, and, if given or made, any such information or representation should not be relied upon as having been authorized by the Company.

Prospective purchasers of Pre-emptive Rights and/or subscribers of New Shares should make an independent assessment as to whether the information in this Prospectus is relevant, and any purchase of Pre-emptive Rights and/or subscription of New Shares should be based on the examinations that the prospective purchasers and/or subscribers may deem necessary.

The Prospectus may not be forwarded, reproduced or otherwise redistributed, in whole or in part, by anyone but the Company. Investors may not reproduce or distribute this Prospectus, in whole or in part, and investors may not disclose any of the contents of this Prospectus or use any information herein for any purpose other than for considering the purchase of Pre-emptive Rights and/or the subscription of New Shares described in this Prospectus. Investors agree to the foregoing by accepting delivery of this Prospectus.

The Offering will be subject to Danish law, and the Company has not taken nor will take any action in any jurisdiction, with the exception of Denmark, which may result in a public offering of Pre-emptive Rights and/or New Shares. Further, the Company and any of its representatives, will not make any representation to any offeree or purchaser of the Pre-emptive Rights or the New Shares regarding the lawfulness of an investment in the Pre-emptive Rights or the New Shares by such offeree or purchaser under the legislation applicable to such offeree or purchaser. All prospective subscribers and purchasers should individually examine the legal basis and consequences of the Offering, including any tax issues and currency restrictions that may be relevant in connection with the Offering. Further, all investors should individually examine the legal basis, including tax consequences of an investment in Pre-emptive Rights and the New Shares or the trading in Pre-emptive Rights, through their own advisers. This Prospectus does not constitute an offer of or an invitation to purchase any Pre-emptive Rights or purchase or subscribe for any New Shares in any jurisdiction in which such offer or invitation would be unlawful.

Furthermore, the Pre-emptive Rights and the New Shares are subject to transfer and selling restrictions in certain jurisdictions (see "*20.17. Terms and conditions of the offer of securities to the public – Transfer restrictions*"). Prospective purchasers of Pre-emptive Rights and/or subscribers of the New Shares must comply with all applicable rules and legislation in countries or territories in which they acquire, subscribe for, offer or sell Pre-emptive Rights and/or New Shares or possess or distribute this Prospectus and must obtain consent, approval or permission, as required, for the acquisition of the Pre-emptive Rights or the New Shares. Any person into whose possession this Prospectus may come are required by the Company to inform themselves about such restrictions and to observe such restrictions. Neither the Company nor the Company's auditors accept liability for any violation of these restrictions by any person, irrespective of whether such person is an Existing Shareholder or a potential purchaser of Pre-emptive Rights and/or subscriber of the New Shares.

2.8. Enforceability of judgments

The Company is a public limited liability company organized under Danish law. Some of the members of Management are residents of Denmark, and all or a substantial share of assets of the Company and such persons are located in Denmark. As a result, it may not be possible for investors to effect service of process upon such persons or the Company outside Denmark or to enforce judgments obtained in courts outside Denmark based on applicable legislation in jurisdictions outside Denmark against such persons or the Company.

2.9. Forward-looking statements

Certain statements in this Prospectus, including, but not limited to, certain statements in "*Summary*", "*1. Risk factors*", "*5. Business*", "*7. Consolidated Prospective Financial Information*", "*11.1. Information on assets and liabilities, financial position, results and dividends – Financial statements*", and "*11.6. Information on assets and liabilities, financial position, results and dividends – Dividend policy*", are based on views of Management, as well as on assumptions made by and information currently available to Management, and such statements are forward-looking statements within the meaning of securities laws of certain jurisdictions. Such forward-looking statements (other than statements of historical fact) regarding the Company's future results of operations, financial position, cash flows, business strategy, plans and objectives of Management for future operations are generally identified by terminology such as "aim", "believe", "may", "anticipate", "continue" , "contemplate", "could", "estimate", "expect", "forecasts", "intend", "objective", "outlook", "plan", "potential", "project", "seek", "should", "strategy", "target", will", "would" or similar expressions or the negative forms thereof. All statements addressing future operating performance, and statements addressing events and developments that the Company expects or anticipates will occur in the future, are forward-looking statements. Other forward-looking statements can be identified in the context in which the statements are made.

Such forward-looking statements are subject to known and unknown risks, uncertainties related to investments in the Company and other factors because they relate to events and depend on circumstances that may or may not occur in the future. The Company's actual results may differ significantly from the results discussed or implied in the forward-looking statements. Factors that may cause such difference include, but are not limited to, those discussed in "*Summary*", "*1. Risk factors*", "*5. Business*" and "*7. Consolidated Prospective Financial Information*" herein. The forward-looking statements are made as at the Prospectus Date and, except as required by law or rules and regulations (including, but not limited to the rules of Nasdaq Copenhagen), the Company undertakes no obligation to publicly update or publicly revise any forward-looking statements, whether as a result of new information, future events or otherwise. Investors should carefully consider the risk factors described in this Prospectus before making any investments decision. If one or more of these risks materialize, it may have an adverse effect on the Company's business, position, and results of operations or objectives. In addition, other risks that have not yet been identified or which the Company has not considered to be material may have an adverse effect, and investors may lose all or part of their investments. See "*1. Risk factors*". In addition, even if its result of operations, financial position and cash flows, and the development of the industry in which it operates, are consistent with the forward-looking statements contained in this Prospectus, those results or developments may not be indicative of results or developments in subsequent periods.

All subsequent written or oral forward-looking statements attributable to the Company or to persons acting on the Company's behalf are expressly qualified in their entirety by the cautionary statements referred to above and contained in this Prospectus, including but not limited to those set forth under "*1. Risk factors*".

2.10. Presentation of financial statements and other information

Certain accounting and statistical figures in this Prospectus have been subject to rounding adjustments. Accordingly, the sum of these figures is not necessarily equivalent to the total amounts stated. In addition, certain percentage figures reflect calculations based on the underlying information prior to rounding up and, accordingly, the percentage figures may not necessarily be exactly equivalent to the figures that would be derived if the relevant calculations were based upon the rounded numbers.

References to "DKK" are references to Danish kroner. References to "GBP" are references to pound sterling. References to "EUR" are references to the common European currency, and references to "USD" are references to United States Dollar, the lawful currency of the U.S.

The audited consolidated financial statements of the Company for the period 1 January 2019 – 31 December 2019 ("**FY2019 Financial Statements**"), the audited consolidated financial statements of the Company for the period 1 January 2020 – 31 December 2020 ("**FY2020 Financial Statements**"), the unaudited consolidated financial statements for the period 1 January 2021 – 30 June 2021 (the "**Half Year 2021 Financial Statements**") and the unaudited consolidated financial statements for the period 1 January 2021 – 30 September 2021 (the **"3rd Quarter 2021 Financial Statements"**) are included in the Prospectus by reference. FY2019 Financial Statements and FY2020 Financial Statements have been prepared in accordance with IFRS as adopted by the EU and additional Danish disclosure requirements for annual reports for listed companies. The Half Year 2021 Financial Statements and the 3rd Quarter 2021 Financial Statements have been prepared in accordance with IAS 34 'Interim Financial Reporting' as issued by the International Accounting Standards Board (IASB) and adopted by the EU and additional Danish disclosure requirements for listed companies. The Company publishes its consolidated financial statements in DKK.

2.11. Third party information

This Prospectus contains statistics, data and other information relating to markets, market sizes, market shares, market positions and other industry data pertaining to the Company's business and markets. Unless otherwise indicated, such information is based on the Company's analysis of multiple sources, including clinical studies, scientific publications, articles and reports and other third-party sources as referenced throughout the Prospectus.

While the Company can confirm that information from external sources has been accurately reproduced, the Company has not independently verified and cannot give any assurances as to the accuracy of market data as presented in this Prospectus that was extracted or derived from these external sources, or whether such information has been updated by such external source or has changed through the passage of time. As far as the Company is aware and able to ascertain from this information, no facts have been omitted which would render the information provided inaccurate or misleading.

Industry publications or reports generally state that the information they contain has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. Market data and statistics are inherently predictive and subject to uncertainty and not necessarily reflective of actual market conditions. Such statistics are based on clinical studies, scientific publications, articles and reports and other third-party sources as well as Company estimates. Such clinical studies, scientific publications, articles and reports and other third-party sources are based on sampling and subjective judgements by both the researchers and the respondents.

The Company does not make any representations as to the accuracy of such information that was extracted or derived from these external sources. Thus, any development in the Company's activities may deviate from the market developments stated in the Prospectus. The Company does not assume any obligation to update such information. If information has been obtained from third parties, the Company confirms that such information has been accurately reproduced and that, to the best of the Company's knowledge and belief and in so far as can be ascertained from the information published by such third party, no facts have been omitted which would render the information reproduced inaccurate or misleading.

As a result, prospective investors should be aware that statistics, data, statements and other information relating to markets, market sizes, market shares, market positions and other industry data in this Prospectus (and projections, assumptions and estimates based on such information) may not be reliable indicators of the Company's future performance and the future performance of the industry in which it operates. Such indicators are necessarily subject to a high degree of uncertainty and risk due to the limitations described above and to a variety of other factors, including those described under "*1. Risk factors*" included elsewhere in this Prospectus.

3. Responsibility Statement and Persons Responsible

3.1. The Company's Responsibility

The Company is responsible for this Prospectus in accordance with Danish law.

3.2. The Company's Statement

We hereby declare that we, as the persons responsible for this Prospectus on behalf of the Company in our capacity as members of the Board of Directors and the Executive Management, have taken all reasonable care to ensure that, to the best of our knowledge and belief, the information contained in this Prospectus is in accordance with the facts and does not omit anything likely to affect the import of its contents.

We furthermore declare that this Prospectus has been approved by the Danish Financial Supervisory Authority as competent authority under the Prospectus Regulation. The Danish Financial Supervisory Authority only approves this Prospectus as meeting the standards of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. Such approval should not be considered as an endorsement of the Company that is the subject of this Prospectus. The Prospectus has been drawn up as part of a simplified prospectus in accordance with Article 14 of the Prospectus Regulation.

Copenhagen, 7 March 2022

BioPorto A/S

Board of Directors

Christopher James Lindop
Chairman

John Patrick McDonough
Vice Chairman

Michael Scott Singer
Board member

Donnie McCoy Hardison Jr
Board member

Jan Leth Christensen
Board member

Peter Mørch Eriksen
Board member

Christopher James Lindop: Professional Board member
John Patrick McDonough: Professional Board member
Michael Scott Singer: Vice President and Chief Scientific Officer of Cartesian Therapeutics, Inc.
Donnie McCoy Hardison Jr: Professional Board member
Jan Leth Christensen: Attorney-at-law, Board member and partner at Lønberg & Leth Christensen Advokataktieselskab.
Peter Mørch Eriksen: Chairman of the Board of Directors of FluoGuide A/S and member of Lund University Advisory Board and the Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Medical Center in Ohio, US.

Executive Management

Anthony Paul Pare
CEO

Neil A. Goldman
Executive Vice President and CFO

4. Company information

4.1. Persons responsible, third party information, experts' report and competent authority approval

4.1.1. Persons responsible and approval from competent authorities

See "*3. Responsibility Statement and Persons Responsible*".

4.1.2. Experts report and third party statements

See "*2.11. Certain information regarding the Prospectus and the Offering – Third party information.*"

4.2. Auditors

The Company's independent auditors are:

PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab,
Company registration (CVR) no. 33 77 12 31
Strandvejen 44
DK-2900 Hellerup
Denmark

PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab is represented by Mads Melgaard (mne34354), State Authorized Public Accountant and Henrik Kyhnauv (mne40028), State Authorized Public Accountant.

The independent auditor's report included in the Company's published annual report for the financial year 1 January 2019 – 31 December 2019 and the annual report for the financial year 1 January 2020 – 31 December 2020 were signed by State Authorized Public Accountants Torben Jensen (mne18651) and Allan Knudsen (mne29465) of PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab.

The auditors in charge are members of FSR – Danish Auditors, the Danish association for state authorized public accountants, (FSR – Danske Revisorer).

4.3. Risk factors

See "*1. Risk factors*".

4.4. Company information

4.4.1. Name and registered office

BioPorto A/S
Company registration (CVR) no. 17 50 03 17
Tuborg Havnevej 15, ground floor
DK-2900 Hellerup
Denmark
Legal Entity Identifier (LEI): 5299004SWFL5JAN4W830

Telephone: (+45) 45 29 00 00
E-mail: info@bioporto.com
Website: www.bioporto.com

The information on the website does not form part of the Prospectus unless that information is incorporated by reference into the Prospectus.

4.4.2. Country of incorporation and governing law

The Company is a limited liability company incorporated in Denmark and is subject to Danish law.

5. Business

5.1. Principal Activities and Business Overview

The Company was established in 2000 and is located in Hellerup, Gentofte Municipality, Denmark and currently has three subsidiaries, BioPorto Diagnostics A/S, Veterinary Diagnostics A/S and BioPorto Inc. The group further comprises of BioPorto Inc.'s wholly owned subsidiary BioPorto Diagnostics Inc. The Company was listed on Nasdaq Copenhagen in 2004. The Company's initial strategy was to develop and commercialize antibodies from a biobank sourced from select scientific institutions. Over time, and particularly as data on the Company's NGAL products began to demonstrate the biomarker's potential, the Company's focus evolved to include the development of novel diagnostics.

Since 2011, the Company has transitioned into an IVD (in vitro medical devices) company focused on developing actionable biomarkers – tools designed to help clinicians make changes in patient management. The Company uses its expertise in antibody and assay development, as well as its platform for assay development, to create a pipeline of novel and compelling products that focus on conditions where there is significant unmet medical need, and where the Company's tests may help improve clinical and economic outcomes for patients, providers and the healthcare ecosystem.

The global IVD market in which the Company operates includes a wide variety of diagnostic testing, including laboratory-based, hospital-based and home-use product sales for a broad array of clinical conditions. The market exceeds USD 117 billion (2021), with expected growth to USD 128 billion in 2026. [1] The recent global outbreak of COVID-19 has drawn further attention to the importance of diagnostics, including the significance of providing accurate testing that can be widely available and produce timely results.

The Company's flagship product is called The NGAL Test. The test is designed to aid in the risk assessment and diagnosis of AKI (acute kidney injury), a common clinical syndrome that can have severe consequences, including significant morbidity and mortality.[2] With the aid of The NGAL Test, physicians can identify patients at risk of AKI more rapidly, potentially allowing earlier intervention and more tailored management strategies than is possible with current standard of care measurements, such as sCr (serum creatinine) and UOP (urinary output). The Company believes that by helping to identify AKI risk before permanent kidney damage occurs, The NGAL Test will enable physicians to improve kidney health, minimize long term effects, and reduce the economic burden of AKI.

The NGAL Test, which will address a potential global market estimated at or above USD 3 billion annually (including projections for the Product's subsequent potential FDA approval and with expanded indications) is currently CE marked for sale in Europe and several other geographies. The CE mark claim for The NGAL Test is for the measurement of NGAL in adult populations. In addition, the Company is in the process of continuing pediatric patient recruitment into the first half of 2022, after which data from the study will be compiled and reviewed to determine when to prepare a De Novo submission for FDA review (see "*5.12. Business – Regulatory environment*"). This is an important step for the Company, as the U.S. is the largest market for IVD tests in the world and is considered a "first mover" in the adoption of IVD innovation. Gaining access to the U.S. market (which is estimated to be the largest geographic market representing 40% of the estimated global market) and continued access to the EU market is conditioned upon a variety of factors detailed elsewhere in this Prospectus, including in particular with respect to obtaining FDA approval, successful commercialization of The NGAL Test, and accomplishing IVDR compliance ahead of the relevant deadline.

In addition to developing its NGAL portfolio, the Company has exclusively in-licensed a new platform technology, called gRAD, that enables rapid development of lateral flow assays through the identification of the analyte(s) of interest. Having tested the platform's ability to achieve this objective, including with NGAL, the Company is and has been engaged in a number of investigations that center around flexibility and rapid iteration to create simple assays.

The Company, together with its subsidiaries, has a small, dedicated team of 33 employees.

The Company's facility in Denmark houses corporate functions, R&D, manufacturing, customer service, quality assurance and regulatory, while the U.S. organization includes management positions, clinical/regulatory/medical affairs and business development personnel.

5.2. Key Strengths

The Company believes it possesses several key strengths in relation to developing, sourcing and commercializing tests in the healthcare market.

- **Rapid of Analytical and Clinical Development**: With the benefit of an experienced and seasoned leadership team, many of which with 20+ years of experience in their related fields, the Company is nimble and agile in its decision-making and execution.
- **Team with History of Successful Product Submissions**: Over the past 1-2 years, the Board has recruited a management team with a track record of successful clinical trials, product launch, and product commercialization.
- **Deep Clinical Relationships and Reputational Leadership**: The Company has longstanding collaborations with key opinion leaders and the target clinical audience in nephrology, critical care, cardiology, and other leading disciplines related to The NGAL Test. These

[1] Kalorama Information, The In Vitro Diagnostics Market, https://kaloramainformation.com/the-in-vitro-diagnostics-market/
[2] Hoste EA., et al. (2015) 'Epidemiology of acute kidney injury in critically ill patients: the multinational AKI-EPI study', Intensive Care Med. 2015;41(8):1411-1423. doi:10.1007/s00134-015-3934-7

relationships well-position the Company and its reputation for the high quality of The NGAL Test in advance of the planned commercialization process in the U.S.

- **Rapid Antibody-based Assay Development**: With the proprietary gRAD platform, the Company can quickly evaluate the efficacy of antibodies to accelerate the launch of research studies.

5.3. Strategic Priorities

The Company helps healthcare providers improve patient management and outcomes with products that provide early and specific insights into significant clinical conditions. By 2025, the Company aspires to become one of the world's leading companies in diagnostics that improve kidney health. This vision is supported by three strategic pillars.

5.3.1. Drive Market Adoption of The NGAL Test & have a Pipeline of Products that Deliver High Medical Value

Through the Company's own commercial team, as well as through partnerships, the Company seeks to drive market adoption of the use of NGAL to assess kidney health in early stages of AKI. It intends to accomplish this by communicating and marketing the clinical and economic value of NGAL Products and Future (NGAL) Products in a clear, efficient and compelling manner. Further, the Company will continue to evaluate opportunities to develop and commercialize other high value, actionable biomarkers.

5.3.2. Strengthen the Company to Scale & Execute

The Company will work towards readying itself for a US product launch of The NGAL Test by building the required commercial and clinical organization, scaling production capacity, improving the robustness of its quality systems, working towards ensuring that it continues to comply with regulatory requirements applicable from time to time, and by expanding its intellectual property portfolio, and ensuring it has the financing to support operations.

5.3.3. Attract, Develop & Retain the Best and Brightest Employees aligned with our Values and with Clear Roles and Responsibilities

The Company will employ proactive efforts to recruit the most qualified people to drive success and embrace the Company's core values. The Company will motivate employees to stay and contribute by employing consistent, long term incentive programs and flexible work arrangements that are aligned with personal and company needs, providing frequent feedback and clarity in their contribution to Company success, and celebrating successes.

5.3.4. Preparation of future financing and expanding access to capital

The Company has historically sought financing through equity offering on a reasonably frequent basis and applied the proceeds towards implementation of its strategic priorities. To be able to realize its strategic priorities, the Company will need to seek additional financing in addition to the Offering. The Company has a long term ambition of gaining access to the U.S. capital markets with the ultimate goal of a potential U.S listing. As a step towards this, the Company may explore opportunities in relation to a targeted cross-border offering, including potentially in the U.S.

5.4. Technical Foundation

The Company's technical foundation is based on antibody expertise, leveraging a robust library of monoclonal antibodies to develop assays for both research and clinical diagnostics. Product formats range from enzyme-linked immunosorbent assay (ELISA) kits, IVD automated assays, to gRAD, a novel platform for the rapid development of lateral flow tests through the identification of the analyte(s) of interest.

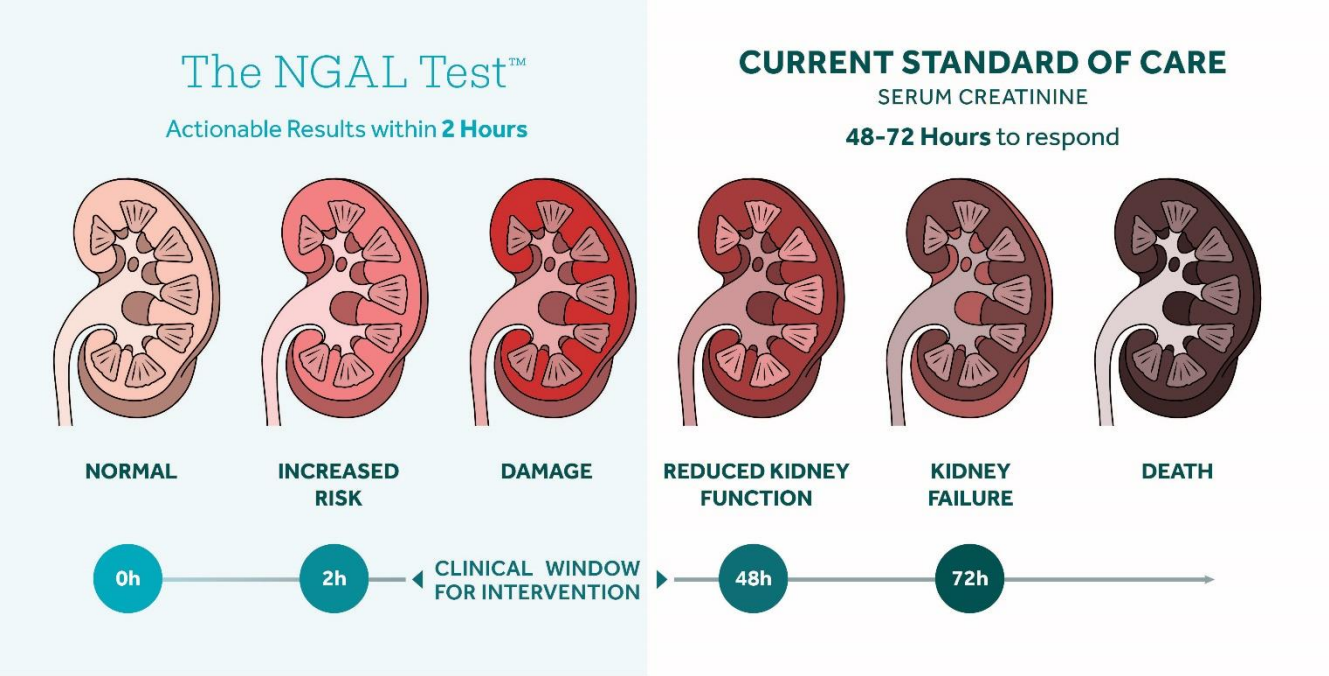
Within the portfolio of clinically actionable biomarkers, the biomarker NGAL has been developed across each of these product formats. NGAL is a protein expressed in a variety of human tissues, including the lung, liver and kidney. It has been implicated in multiple biological processes, including attenuation of apoptosis and differentiation of renal tubule epithelial cells and nephrons. [3] The Company expects that the development of NGAL can create significant commercial opportunities based on its potential for broad clinical application.

5.5. Products and Product Pipeline

5.5.1. The NGAL Test

The NGAL Test is designed to help clinicians identify levels of urinary or plasma NGAL, a biomarker that rises rapidly in response to kidney injury, preceding changes in creatinine by as much as two to three days.[10] By identifying patients at risk of AKI as quickly as two hours after an insult to the kidney, an NGAL result may help clinicians take a more focused approach to patient management. The NGAL Test is a particle-enhanced immunoassay for the quantitative determination of NGAL in human specimens. It uses an analytical method that can be run on most clinical chemistry systems that are used routinely in hospital laboratories. This facilitates laboratory adoption of the test and eventual market penetration.

[3] Haase-Fielitz A, et al. (2014) 'Neutrophil gelatinase-associated lipocalin as a biomarker of acute kidney injury: a critical evaluation of current status', Ann Clin Biochem, 2014 51(0 3): 335–351. doi:10.1177/0004563214521795



The test does not require any proprietary instrumentation, thereby avoiding any requirement for capital purchase arrangements by the customer that could otherwise add months to the sales cycle.

Figure 1: Progression of kidney damage in AKI as illustrated by the Company.

As illustrated in the figure above, The NGAL Test identifies damage to the kidney as quickly as two hours after insult to the kidney, whereas the current standard of care, sCr, identifies potential kidney dysfunction after 48 to 72 hours. This difference in both speed and more specific detection of kidney injury is important for clinical patient management as early detection of kidney damage can allow earlier and more tailored approaches. For example, actions that can be taken include the close control of fluid levels, heightened attention to nephrotoxic drugs, and consideration of renal replacement therapy, which all can be initiated to improve the chances of kidney recovery. Furthermore, NGAL may detect patients with kidney damage in whom sCr levels do not rise, a condition called "subclinical AKI" that has been shown to lead to in-hospital mortality in over 12% of patients. [4]

The sCr tests have been the standard of care diagnostic tests for kidney damage for more than 50 years, and therefore, the Company and its KOLs believe that new biomarkers are needed to improve the care of patients at risk of AKI.

5.5.1.1. About AKI

AKI is a rapid loss of kidney function that typically occurs as a complication of another serious illness or intervention, such as sepsis or cardiac surgery. Episodes of in-hospital AKI are growing – the U.S. saw an increase of 230% in the period from 2000-2014 among non-diabetics, and of 139% in patients with diabetes.[5] Risk factors influencing the increase in AKI include the use of mechanical ventilation, extracorporeal membrane oxygenation, and sepsis, as well as improved recognition of the condition due to consensus definitions of AKI that have developed in recent decades. AKI affects both adults and children, with one in five adults[6] affected with AKI during a hospital setting of care and one in four children[7] affected with AKI during their admissions to the ICU.
Patients most at risk of developing AKI in a hospital setting of care are those that:

- undergo cardiac surgery (up to 30%)[8;]
- are receiving mechanical ventilation for respiratory support (29%)[9]
- are being treated for sepsis (26-50%)[10;] or

[4] Haase M. et al. (2011) 'The Outcome of Neutrophil Gelatinase-Associated Lipocalin (NGAL)-positive Subclinical Acute Kidney Injury: A Multicenter Pooled Analysis of Prospective Studies', J Am Coll Cardiol. 2011;57(17):1752–1761
[5] Pavkov ME. (2018) 'Trends in Hospitalizations for Acute Kidney Injury — United States, 2000–2014', MMWR Morb Mortal Wkly Rep. 2018;67.
[6] Susantitaphong P. (2014) Correction, Clin J Am Soc Nephrol, CJASN. 2014;9(6)
[7] Kaddourah A. (2017) 'Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults', N Engl J Med. 2017;376(1)
[8] O'Neal JB. (2016) 'Acute kidney injury following cardiac surgery: Current understanding and future directions', Crit Care. 2016;20(1)
[9] Lombardi R. et al. (2011) 'An assessment of the Acute Kidney Injury Network creatinine-based criteria in patients submitted to mechanical ventilation', Clin J Am Soc Nephrol. 2011;6(7)
[10] Alobaidi R. et al. (2015) 'Sepsis-associated acute kidney injury', Semin Nephrol. 2015;35(1)

- are receiving nephrotoxic medications (14-26%)[11].

AKI can be difficult to identify, because acute symptoms, such as pain and other symptoms, do not usually occur. However, to preserve kidney function, it is essential that AKI is detected early and managed promptly. Therapies for AKI do not yet exist, so treatment is supportive and aimed at minimizing kidney insults to support renal recovery and prevent further damage. Patients that develop AKI are at an increased risk of poor outcomes, including: an increased risk in cardiovascular events (58% increase in developing heart failure[12]), longer hospital/intensive care unit (ICU) stays and inpatient charges (increase of over 50 days in hospital/ICU stays in neonatal intensive care unit ("**NICU**")[13], increased risk of developing chronic kidney disease ("**CKD**"), especially for those patients requiring dialysis during their AKI event, and increased mortality.[14] The burden of AKI also impacts hospital operations,[1516] including longer length of hospital stay (7-29 days), increased use of renal replacement therapy and prolonged time on mechanical. [17] In addition to creating hospital-based challenges, AKI can also have long-term effects on patients. Individuals who have had even one episode of AKI have been found, from one to five years post-discharge, to have:

- a 30% higher risk of hospital re-admission; [18]
- be 38% more likely to have a major cardiac event; [19] and
- progress to chronic kidney disease (25% of patients). [20]

Based on recent studies, the Company estimates AKI to be the third largest cause of in-hospital death in the U.S after heart diseases and cancer.[21] Of those who survive, 59% have one or more kidney abnormalities.[22]

The financial costs of AKI are substantial. Particularly when recognized late in its course, AKI can require costly and intensive interventions, such as dialysis. In the U.S., data has shown that Length of Stay ("**LOS"**)-related increase in cost due to AKI ranges from USD 13K in the adult ICU to USD 280K in the NICU[23]. The prevalence of AKI, along with its short- and long-term health and economic costs are significant motivators for innovation in the management of patients with AKI.

5.5.1.2. AKI Risk Assessment in the Intensive Care Unit

For critically ill patients, critical care physicians seek to identify AKI quickly, as sustained injury may result in irreversible loss of function and/or CKD (chronic kidney disease) with the risk of end-stage kidney disease ("**ESKD"**) and need of renal replacement therapy (dialysis or kidney transplantation). [24] Unfortunately, the tools available to physicians for the early identification and management of AKI are limited, primarily to measurements of sCr and UOP. Each represents a physiologic endpoint that is delayed, non-specific, and impacted by extra-renal factors such as nutritional status, fluid levels and muscle mass. sCr, for example, does not rise for 48-72 hours following injury. [25] In addition, more than half of an individual's kidney function can be lost due to an acute insult before creatinine levels rise. [26] As a result, sCr often fails to identify AKI.

5.5.1.3. Regulatory Approval and Pathway of The NGAL Test

The NGAL Test is currently CE marked for measurement of NGAL in adults in the ICU and is available for IVD use in Europe and other geographies. In addition, the Company is focused on being able to market the test in the U.S., which requires clearance by the FDA. There is currently no biomarker approved or cleared in the U.S. for use in children to predict AKI development. Through the Company's discussions with the FDA, The NGAL Test was accepted into the FDA's Breakthrough Device Program, demonstrating that the clinical application and population that the Company seeks to address represent a significant unmet medical need. [27] See "*5.12. Business – Regulatory environment*" for further information on the process for regulatory approval of The NGAL Test in the U.S. The Breakthrough Devices Designation facilitates prioritized review on regulatory submissions.

In 2019, the Company submitted an application to the FDA for The NGAL Test in pediatric risk assessment of AKI for patients admitted to the ICU based on a retrospective analysis. The samples used in this analysis were originally collected for a groundbreaking study on the epidemiology of

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[11] Perazella MA. (2018) 'Pharmacology behind Common Drug Nephrotoxicities', Clin J Am Soc Nephrol. 2018;13(12)
[12] Odutayo, A. et al. AKI and long term risk for cardiovascular events and mortality. J Am Soc Nephrol JASN. 2017; 28(1):377-387.
[13] Maryland SID 2019
[14] Lo, LJ. Kidney Int. 2009;76(8):893-899.
[15] Sutherland SM. et al. (2013) 'AKI in hospitalized children: epidemiology and clinical associations in a national cohort', Clin J Am Soc Nephrol. 2013;8(10)
[16] Hoste EA. et al. (2015) 'Epidemiology of acute kidney injury in critically ill patients: the multinational AKI-EPI study', Intensive Care Med. 2015;41(8)
[17] Kaddourah A. (2017) 'Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults', N Engl J Med. 2017;376(1)
[18] Hessey E. et al. (2018) 'Healthcare Utilization after Acute Kidney Injury in the Pediatric Intensive Care Unit', Clin J Am Soc Nephrol, 2018;13(5)
[19] Odutayo A. et al (2017) 'AKI and Long-Term Risk for Cardiovascular Events and Mortality', JASN. 2017;28(1)
[20] Horne KL. et al. (2017) 'Three-year outcomes after acute kidney injury: results of a prospective parallel group cohort study', BMJ Open. 2017;7(3)
[21] Management estimates based on the following sources: Brown J.R. et al. (2016) 'Hospital Mortality in the United States following Akute Kidney Injury', https://www.hindawi.com/journals/bmri/2016/4278579/, and the National Center for Health Statistics for death and mortality in the U.S., https://www.cdc.gov/nchs/fastats/deaths.htm
[22] Askenazi DJ et al. (2006) Kidney Int: 69(1), https://pubmed.ncbi.nlm.nih.gov/16374442/
[23] Maryland SID 2019; The Henry J. Kaiser Family Foundation, Hospital adjusted expenses per inpatient day; 2019 (Cited 13 May 2021); HCUP Characteristics of 30-Day All-Cause Hospital Admissions; 2010-2016 Nationwide Children's Price information https://nationwidechildrens.org/your-visit/billing-and-insurance/pay-my-bill/price-information-list; Halpern, Neil A. and Stephen M. Pastores, "Critical Care Medicine Beds, Use, Occupancy and Costs in the United States: A Methodological Review." Critical Care Medicine vol 43, 11. (2015):2452-9.;
[24] Van Duijl TT. et al. (2019) 'Kidney Injury Biomarkers in an Academic Hospital Setting: Where Are We Now?', Clin Biochem Rev. 2019;40(2)
[25] Devarajan P. (2010) ' Neutrophil gelatinase-associated lipocalin: a promising biomarker for human acute kidney injury', Biomark Med. 2010;4(2)
[26] Desanti De Oliveira B. et al. (2019) 'Molecular nephrology: types of acute tubular injury', Nature Reviews Nephrology 2019:15
[27] Per https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s1

AKI in children, called the AWARE study, published in NEJM in 2016.[28] Based on the methods by which the samples in this study had been collected, the FDA was concerned about clinician bias, and it was determined that the Company needed to conduct a prospective study to further support the pediatric application to FDA. As part of the Breakthrough Device Designation program, the Company engaged with the FDA through the pre-submission process in early 2020 to align with the FDA on the analytical and clinical protocols necessary for the Company's planned De Novo submission.

Following the FDA feedback in early 2020, the clinical protocol was finalized with FDA alignment, the clinical study planning and contracting was conducted. However, both the contracting and enrollment of patients were delayed due to the COVID-19 pandemic. Despite these delays, the clinical study and analytical work are both currently underway, with the clinical study being conducted by a consortium of 15 leading U.S. hospitals, including Cincinnati Children's Hospital, Boston Children's Hospital, Children's Hospital of Colorado, Children's Healthcare of Atlanta, Stanford Health, Cohen's Children Hospital, and Texas Children's Hospital. Enrollment and sample analysis has been completed for 2 of the 3 studies comprising the clinical trials. These studies were designed based on FDA feedback from pre-submission meetings associated with the FDA's Breakthrough Device Designation (see *"5.12. Business – Regulatory environment"*). The studies were designed to, respectively, establish reference range(s) of NGAL in healthy individuals, define NGAL cutoff levels for prospective test results, and enroll subjects at risk of Stage 2 or 3 AKI to evaluate the clinical performance characteristics of The NGAL Test. The Company presently expects to finalize data collection for the third study in the first half of 2022. After the compilation of the study results and subject to the results meeting the primary outcomes previously committed to the FDA and demonstrating that the benefits of the device outweigh the associated risks, the Company presently expects to submit a De Novo application to the FDA. The FDA targets up to 150 days following such submission to respond, excluding any time it takes for the Company to respond to additional inquiries by the FDA during the review process. See "*5.12. Business – Regulatory environment*" for further information on De Novo requests in relation to 510(k) applications to the FDA.

Following the potential FDA approval of The NGAL Test for risk assessment of moderate to severe AKI in children on the Roche cobas c501 laboratory instrument analyzer, the Company intends to apply the reagent to other instruments using internal documentation or 510(k) submissions per FDA guidance. In the event that the Company is not able to reuse the samples collected in connection with the ongoing pediatrics trial for sample testing in connection with expanding a potential FDA clearance for additional instruments, additional clinical trials may be required. In addition, the Company currently plans to develop study protocols, sites, and contracts, engage with the FDA, and begin working on a submission for use of The NGAL Test in adult populations, with the intention of filing an appropriate submission using the pediatric test as its predicate. Assuming the development of such protocols etc. are successful, a pre-submission to the FDA may potentially take place concurrently with FDA's review of the aforementioned De Novo application, with related clinical trials and analytical testing taking place thereafter.

5.5.1.4. Future Applications for The NGAL Test

Assuming that the first two clearances (pediatric/adult) for The NGAL Test are obtained, the Company intends to expand the indications for testing to populations beyond the ICU. Clinical areas for expansion could include the use of NGAL for ruling out the risk of AKI in the emergency department, as there are an estimated 5.2 million emergency department visits in the U.S. each year where a sCr test or kidney function panel is ordered.[29] Other future claims could focus on applications to identify patients who are experiencing kidney injury due to nephrotoxins. With 32% of the top 200 prescribed drugs undergoing renal elimination, the kidney is one of the most frequent targets of drug-induced toxicity.[30] Expanded testing could be both for the initial identification of nephrotoxicity as well as for ongoing therapeutic monitoring and could include patients taking drugs for diseases ranging from oncology, to cardiac, to autoimmune disorders.[31] The Company estimates a total of approximately 16 million US patients are at risk for AKI each year in critical care units, non-ICU hospitals and out-patient settings.

5.5.1.4.1. Use of NGAL in clinical studies of drug-induced kidney injury

An additional application of NGAL in nephrotoxicity is the use in clinical studies of drug-induced kidney injury ("**DIKI**"). Although toxicity testing is an integral part of drug development, many drugs pass through toxicity protocols in preclinical and early clinical development stages only to fail in later stages. Nephrotoxicity is typically identified by drugmakers late in their development programs, with only 2% of drug attritions happening in preclinical studies but 19% during phase 3 studies.[32] Failure to identify toxicity issues early costs the pharmaceutical industry billions of dollars for continued development of drugs that may never be commercialized. There are ongoing efforts to improve toxicity assessment, but challenges and deficiencies remain. These include challenges with markers of kidney function (sCr, urine albumin, UOP, etc.) similar to the clinical challenges already described, resulting in difficulties detecting renal injury or toxicity early in the drug development process.

In response to these challenges, a 6-biomarker kidney injury panel (including NGAL) – the PFC composite – has been approved under the FDA's Center for Drug Evaluation and Research ("**CDER**") Biomarker Qualification Program ("**BQP**") for use in phase 1 healthy volunteer studies.[33] These

[28] Kaddourah A. (2017) 'Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults', N Engl J Med. 2017;376

[29] National Hospital Ambulatory Medical Care Survey: 2017 Emergency Department Summary Tables: Table 18, https://www.cdc.gov/nchs/data/nhamcs/web_tables/2017_ed_web_tables-508.pdf

[30] Bajaj PI. et al. (2018) 'Emerging Kidney Models to Investigate Metabolism, Transport, and Toxicity of Drugs and Xenobiotics', DMD Journals, Aug 2018:40(11), http://dmd.aspetjournals.org/content/dmd/46/11/1692.full.pdf

[31] Perazella MA. (2018) 'Pharmacology behind Common Drug Nephrotoxicities', Clin J Am Soc Nephrol. 2018;13(5)

[32] Bajaj PI. et al. (2018) 'Emerging Kidney Models to Investigate Metabolism, Transport, and Toxicity of Drugs and Xenobiotics', DMD Journals, Aug 2018:40(11), http://dmd.aspetjournals.org/content/dmd/46/11/1692.full.pdf

[33] FDA (2018) 'CDER Biomarker Qualification Program', https://www.fda.gov/drugs/drugdevelopment-tool-ddt-qualification-programs/cder-biomarker-qualification-program

biomarkers are not yet required by the FDA in renal safety testing, but the BQP represents an established pathway to work towards gaining acceptance of NGAL and other renal biomarkers for drug-induced renal safety and toxicity testing.

Because clinical practice guidelines, regulatory guidance, and new drug application ("**NDA**") submission requirements provide the foundation for pharmaceutical sponsors to demonstrate an acceptable safety profile for a study drug, the Company anticipates that following potential FDA clearance of The NGAL Test and its adoption in clinical practice guidelines, NGAL will be a desirable marker for pharmaceutical DIKI testing. The Company's full NGAL product portfolio – including preclinical ELISA assays in species ranging from mouse to monkey – is also of potential value for pharmaceutical sponsors, as they can aid in the translation of new drug development from preclinical study to clinical analyses.

The U.S. market for clinical trials is significant, with the cost of laboratory testing ranging from 4-12% of trial costs, depending on the phase.[34]

5.5.1.4.2. Potential future applications

The Company has identified the following potential future applications for The NGAL Test, each of which will require further investigation, development and commercialization efforts:

- Nephrotoxicity: Cardiology, oncology, diabetes, transplant, autoimmune
- Therapeutic monitoring of renally cleared drugs
- Diagnosis of AKI

5.5.2. The Generic Rapid Assay Device (gRAD) Platform

The Company's proprietary gRAD platform enables rapid development of lateral flow assays through the identification of the analyte(s) of interest. It is based on in-licensed patents from Rapid Assays ApS (see "*14. Material agreements*"). gRAD's features include optimization with two printed lines: a test line for a biotinylated antibody (or biotinylated protein), and a control line designed to capture any mouse, rabbit, or goat antibody. The biological recognition between the specific capture antibody, the antigen in the sample, and the detection antibody occurs in solution, meaning unlike most lateral flow assays, specific antibodies do not need to be immobilized on the strip during the manufacturing process. Typically, the assay incubation time is short, about 10-15 minutes. Because a gRAD strip is not analyte dependent, it creates an open, flexible and versatile platform that can be applied to a wide variety of antibodies – requiring only a matched antibody pair.

Leveraging the gRAD platform, the Company is currently performing feasibility studies, in conjunction with expert academic partners, on the below emerging applications:

- **NGALds for point-of-care applications:** A near-patient test for NGAL levels
- **Two COVID-19 assays:** i) A diagnostic test for the identification of the active virus (antigen test); and ii) a serology-based test for the identification of possible immunity or prior virus exposure (antibody test)
- **Thrombomodulin assay:** A blood test using antibodies to thrombomodulin, in patients with sepsis, to identify patients with endothelial injury that would benefit from prostacyclin therapy

5.5.2.1. The NGALds for Point-of-Care Applications

The Company is using its gRAD platform to create a lateral flow test for semi-quantitative determination of NGAL levels, expanding the potential applications for this unique biomarker into settings beyond the hospital laboratory, such as in physician offices, in urgent care clinics, or even on the battlefield for rapid triage of wounded soldiers.

This product, called The NGALds, has been tested in several research environments, including a study by Dr. Stuart Goldstein, a pioneer in the use of NGAL for AKI. This study compared NGALds results to results obtained with The NGAL Test and showed a 100% sensitivity and 89.3% specificity at the 300 ng/mL cutoff between the two methods.[35] This early study illustrates the potential clinical accuracy that a novel near-patient test option may offer. The Company received a CE mark for The NGALds in December 2020 and is evaluating commercialization options of this test in applicable markets.

5.5.2.2. Rapid Test for Thrombomodulin

The Company is supporting Rigshospitalet ("**RH**"), one of the largest hospitals in Denmark, with quantitative thrombomodulin tests based on its gRAD technology. Thrombomodulin is a marker of endothelial injury that can occur as a result of sepsis, COVID, myocardial infarction, and other disease states. RH is investigating the use of a thrombomodulin assay in patients with sepsis to indicate who could benefit from treatment with the drug prostacyclin. RH is summarizing findings from its feasibility study and plans to publish the results after completing its assessment.

[34] Sertkaya A. et al. (2014) 'Examination of Clinical Trial Costs and Barriers for Drug Development', https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development

[35] Goldstein S. et al. (2019), 'Point-of-Care Urinary Neutrophil Gelatinase-Associated Lipocalin Readings Are Highly Predictive of Formal Laboratory Levels', https://www.asn-online.org/education/kidneyweek/2019/program-abstract.aspx?controlId=3224791

5.5.3. ELISA Kits and Antibodies

The Company's library of over 150 monoclonal antibodies, its historical expertise in using antibodies for research, and its experience developing ELISA kits have provided a source of revenue for the Company. In addition, providing research antibodies and ELISA kits serves as a source of connections to academic researchers and institutions throughout the world, introducing important new product development opportunities to the Company.

5.5.3.1. ELISA Kits

The Company offers NGAL ELISA kits for human use (CE marked) and six additional species, ranging from mouse to monkey, for research applications. These NGAL ELISA kits target different forms of NGAL and help scientists bridge their development work from preclinical study through clinical development. These research tools are often used to investigate nephrotoxicity during the development of new pharmaceutical compounds and to investigate additional potential applications of NGAL. The Company does not intend to either actively develop new ELISA kits as a driver of its business strategy or seek FDA approval for its ELISA kits. However, the Company will continue to include ELISA kits as part of its product offering, as these kits may serve as research tools that could evolve into Future products in the form of FDA cleared or approved actionable biomarkers.

5.5.3.2. Antibodies

The Company's library of highly specific monoclonal antibodies for scientific, pharmaceutical, and clinical research includes specific antibodies for NGAL as well as for important areas such as allergy and immune system disorders. Off-the-shelf antibodies are available in small quantities, and the Company provides in-house scaled up production of custom antibodies in bulk volumes to meet specific program needs, such as for diagnostic kit manufacturers.

5.6. Markets

5.6.1. The NGAL Test

TOTAL GLOBAL ADDRESSABLE MARKET: ~$3 BILLION

Estimated NGAL Market Opportunity

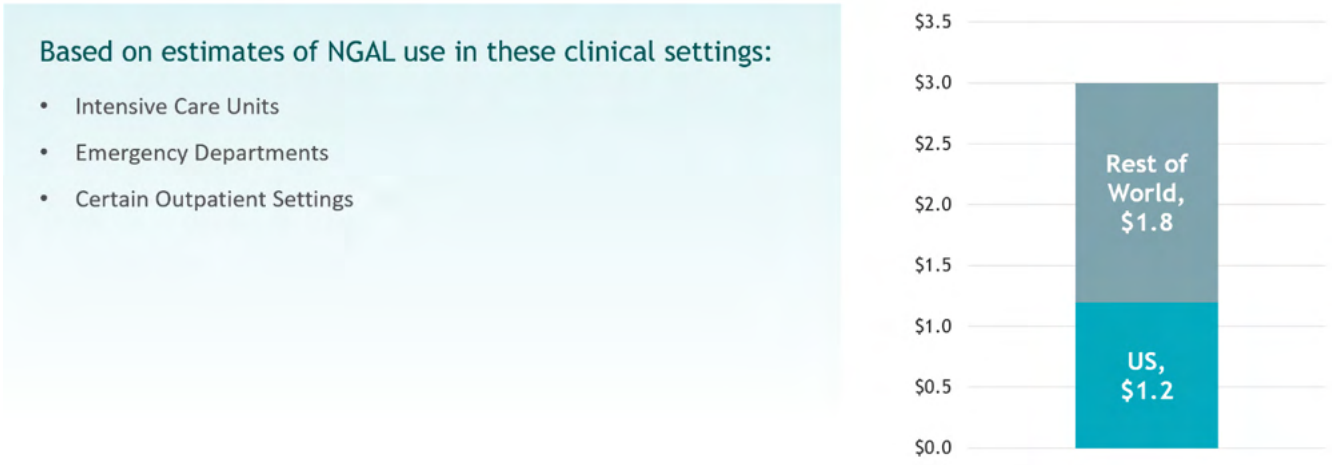

Figure 2: Management's estimated market opportunity for The NGAL Test

In 2021, the Company engaged a third-party market research organization to provide an assessment of the US opportunity for The NGAL Test based on the Company's initial focus in the intensive care setting, and its long-term expansion into new indications, such as nephrotoxicity monitoring, testing in the emergency department, and other out-patient applications. On the basis of this assessment, the Company estimates that there is a total addressable opportunity in the US for pediatric and adult ICU/medical-surgical patients of approximately USD 500 million annually. Based on expanded indications for the emergency department and out-patient uses, the projection for the addressable market in the U.S. could increase to over USD 1 billion. As the U.S. constitutes approximately 40% of the Company's market, Management assumes that the global addressable market for The NGAL Test could have an annual value of around USD 3 billion. The addressable market for The NGAL Test represents the potential for an early biomarker for AKI and is not an indication of the Company's revenue predictions. Further, access to the addressable U.S. market and continued access to the EU market is conditioned upon a variety of factors detailed elsewhere in this Prospectus, including in particular for the U.S. market with respect to obtaining FDA approval, successful commercialization of The NGAL Test, and accomplishing IVDR compliance ahead of the relevant deadline.

5.6.1.1. The U.S. Market Opportunity

The Company is expecting to conclude the pediatric patient accrual for The NGAL Test and complete the study in the first half of 2022. The Company expects to then prepare and submit a De Novo application to the FDA if the data from the study meets the primary outcomes previously committed to the FDA and demonstrates that the benefits of the device outweigh the risks following analysis. Only after the Company receives FDA approval of The NGAL Test for pediatric use would the Company initiate the regulatory activities for submission relating to use of The NGAL test in adults. The Company has previously submitted applications for clearance of The NGAL Test for use in adult populations to the FDA with unsuccessful results – see "*1.2.1 Risk factors – 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*".

The first indications for use of The NGAL Test will be for patients who are in the ICU, given their high risk of developing AKI. According to a recent multinational study (2015), 57.3% of adult ICU patients had AKI,[36] and another separate study in pediatrics revealed that 26.9% developed AKI.[37] The Company estimates that the total addressable market in the U.S. for pediatric and adult ICU patients is approximately USD 500 million annually. According to the Society for Critical Care Medicine ("**SCCM**"), "*More than 5 million patients are admitted annually to U.S. ICUs for intensive or invasive monitoring; support of airway, breathing, or circulation; stabilization of acute or life-threatening medical problems; comprehensive management of injury and/or illness; and maximization of comfort for dying patients. ICU patients are a heterogeneous population, but all share the need for frequent assessment and a greater need for technological support than patients admitted to non-ICU beds."*[38]

In the U.S, ICU beds are divided by population according to the type of care required. The largest number of beds are dedicated to adults (70% of beds) and to neonates (23% of beds), with about 5% being dedicated to pediatrics.[39] With the first anticipated FDA approval in pediatrics, the Company will focus on hospitals with ICUs treating children under the age of 22 (pediatric ICUs, "**PICU**s"). The PICU represents an ideal early target for the Company, as it is readily addressable by a small and focused sales effort. There are 344 hospitals with PICUs in the U.S., and of the approximately 5,900 PICU beds in the U.S., nearly half are located in just 63 hospitals.[40] The adult market for The NGAL Test is significantly larger than the pediatric market, as adults have many more underlying conditions, such as diabetes and hypertension that contribute to kidney damage and increased risk of AKI. For example, cardiovascular surgery is a significant risk factor for kidney injury in adults; it is estimated that in 2011 there were over 2.1 million cardiovascular operations performed in the U.S.[41]

5.6.1.2. U.S. Go-to-Market Approach

North America represents the largest market share of the IVD market, with the U.S. as the driver behind the market growth in the region.[42] Accordingly, the U.S. is the focus of the Company's commercial strategy for The NGAL Test. The approach has been designed to reflect the need to build a market for urinary biomarkers in AKI. Starting in the smaller, focused pediatric market will help to build awareness and momentum ahead of launch in the larger adult market. In addition to being a narrow target market, there is an established network of pediatric critical care physicians and nephrologists who are KOLs in the field of AKI. These physicians understand the value of NGAL, have published extensively on the biomarker, are key voices during scientific meetings, and hold prominent positions at large pediatric academic hospitals such as Cincinnati Children's Hospital, Children's Healthcare of Atlanta, Nationwide Children's Hospital, Children's Hospital of Colorado, and Boston Children's Hospital. Based on feedback received, the Company believes that relevant KOLs and MSLs have favorable opinions of the use of NGAL as a biomarker for diagnosis of AKI and as such the market potential for The NGAL Test.

The commercial strategy for the pediatric launch of NGAL rests on deploying initiatives in three focus areas:

- **Peer-to-peer education:** Leveraging KOLs (Key Opinion Leaders) and other experts to describe the value of using NGAL in daily practice to other doctors. This is done through grand round presentations, hosted speaker events, webinars, testimonials and podium presentations at scientific meetings.
- **Clinical sales representatives:** Having a dedicated sales team with clinical experience will allow the Company to engage with doctors at prospective accounts, have detailed clinical discussions about the product and its use and connect prospective customers with reference customers who are champions of The NGAL Test. Clinical sales representatives will be responsible for active promotion through visits (virtual or face-to-face), direct phone and email communications, as well as through KOL-driven educational meetings.
- **MSLs:** Building a dedicated MSL (Medical Science Liaison) team is critical to furthering deep clinical discussions with doctors. This team will be comprised of professionals with pediatric and adult ICU experience, for example former critical care nurses, who can engage in scientific discourse about how NGAL can be used in the medical management of AKI. The MSLs will also work with academic clinician

[36] Hoste EA. et al. (2015) 'Epidemiology of acute kidney injury in critically ill patients: the multinational AKI-EPI study', Intensive Care Med. 2015;41(8)
[37] Kaddourah A. (2017) 'Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults', N Engl J Med. 2017;376(1)
[38] Halpern NA., SCCM., https://www.sccm.org/Communications/Critical-Care-Statistics
[39] Halpern NA. et al., SCCM (2020), https://www.sccm.org/getattachment/Blog/March-2020/United-States-Resource-Availability-for-COVID-19/United-States-Resource-Availability-for-COVID-19.pdf?lang=en-US.Accessed June 2020
[40] Horak RV. et al. 'Growth and Changing Characteristics of Pediatric Intensive Care 2001-2016', Crit Care Med. 2019;47(8)
[41] Weiss AJ., Elixhauser A. (2014) 'Trends in Operating Room Procedures in U.S. Hospitals, 2001–2011', HCUP Healthcare Cost and Utilization Project] Statistical Brief, no. 171, https://www.hcup-us.ahrq.gov/reports/statbriefs/sb171-Operating-Room-Procedure-Trends.pdf
[42] Grand View Research (2019) 'In Vitro Diagnostics Market Size, Share & Trends Analysis Report By Product, By Technology (Molecular Diagnostics, Clinical Chemistry), By Application, By End Use, And Segment Forecast, 2020-2027, https://www.grandviewresearch.com/industry-analysis/in-vitro-diagnostics-ivd-market

researchers to identify areas of future study that are of interest to the Company and will act as the point of contact between these experts and the Company's clinical development and R&D team.

Adult hospitals that also care for children in PICUs are expected to provide a bridge to the adult ICU market, as the laboratories in these hospitals will already be exposed to The NGAL Test, and adult physicians will be able to speak to their pediatric colleagues about NGAL's utility. The Company estimates that this will give the Company a head-start on entering the adult market, speeding uptake if the expected FDA clearance of The NGAL Test for adults is granted.

It is anticipated that adult physicians may not be as open to innovation in preventative medicine as are their pediatric counterparties, and that adoption of The NGAL Test in this market will be more gradual than what is expected in pediatrics. With a view to further penetrate the adult market over time, the Company's strategy will expand to include two additional strategic initiatives:

- **Distribution partnerships**: Working collaboratively with instrument manufacturers, for example, Roche, Siemens and Abbott, to enable laboratories with any instrument platform to order and run The NGAL Test. The broad reach of these companies, and their deep relationships with the laboratory is expected to accelerate the adoption of The NGAL Test across the U.S. The Company has already established a distribution agreement with Roche, who represent the one of the largest players[43] in the immunochemistry core lab market.
- **Collaboration with advocacy groups**: A key longer-term goal is to persuade the organizations that set clinical guidelines to include NGAL testing in their recommendations. To this end, the Company has established connections with three key organizations, the National Kidney Foundation, KDIGO, a global organization to develop and implement evidence-based clinical practice guidelines in kidney disease, and ADQI, an international organization of academic researchers and clinicians focused on setting new standards for the diagnosis and management of AKI and other kidney-related disorders.

5.6.1.3. Rest of World: The NGAL Test

5.6.1.3.1. CE Mark & History in Europe

In 2012, The NGAL Test received a CE mark, allowing it to be sold in the EU as an IVD biomarker for AKI in the ICU. After obtaining the CE Mark, the Company launched The NGAL Test in the EU with a combination of direct and distribution sales leveraging the knowledge of select local distributors. In addition to the CE-Mark, The NGAL Test is registered for and/or received regulatory approval for IVD use in Argentina, Australia, Bosnia Herzegovina, Canada, Columbia, Croatia, Guatemala, India, Israel, Montenegro, Myanmar, Paraguay, Philippines, Serbia, South Korea, Thailand, Turkey, Ukraine and Vietnam, allowing it to be sold in these markets.

5.6.1.3.2. Market Sizes: Targeted Geographies[44,45]

Global epidemiology of AKI shows that high-income countries have a lower incidence of AKI than low-to-middle-income countries. Further, access to expensive clinical chemistry analyzers is extremely limited in low-income countries. The Company expects it will focus on expanding penetration of The NGAL Test primarily in the EU, Asia and the Middle East, which represent the majority of the addressable market outside North America that have higher average selling price opportunities.

In these areas, AKI occurs at rates similar to those in the U.S. population of adults and children.[46] As a result, the commercial strategy is similar to the one planned for the U.S., which is to target use in patients undergoing cardiac surgery, in critically ill patients and in patients with sepsis, consistent with the labeling of the product.

5.6.1.3.3. Rest of the World Go-To-Market Approach

Though the Company has a CE mark for The NGAL Test in Europe, the Company's commercial efforts will first be focused on the U.S. market. The U.S. market is both the largest single IVD market, and also the market that has historically more readily adopted new biomarkers, e.g., cardiac markers such as natriuretic peptides and Troponin. As a result, Management has decided to focus the Company's limited resources on establishing regulatory clearance in the U.S. prior to undertaking significant product launches in Europe and in the rest of the world.

In markets inside the EU, the Company's sales approach is a combination of direct sales and leveraging independent distribution networks. Sales in South Korea and the Middle East will be pursued through close collaboration with local distributors. As NGAL is already approved for IVD use in these jurisdictions for the adult patient population, our efforts are focused on NGAL measurements in connection with cardiac surgery.

The recent pediatric approach focuses on identifying KOLs at key pediatric centers to help lead a multi-disciplinary effort to implement NGAL across the various clinical specialties, including cardiac surgery, critical care, nephrology and laboratory medicine. Once identified, key sites will be

[43] https://www.nsmedicaldevices.com/analysis/biggest-in-vitro-diagnostics-companies/
[44] Mehta RL. et al. (2016) 'Recognition and management of acute kidney injury in the International Society of Nephrology 0by25 Global snapshot: a multinational cross-sectional study', Lancet 2016;387(10032)
[45] Hoste EA. et al. (2018) 'Global epidemiology and outcomes of acute kidney injury', Nat Rev Nephrol, 2018;14(10)
[46] Hoste EA. et al. (2018) 'Global epidemiology and outcomes of acute kidney injury', Nat Rev Nephrol, 2018;14(10), https://www.researchgate.net/publication/327159529_Global_epidemiology_and_outcomes_of_acute_kidney_injury

contacted, and clinical discussions will be initiated to identify the important players and plan an account-by-account approach for broad clinical use. It is expected that the U.S. pediatric FDA approval will smooth the path for more rapid uptake in these accounts.

5.6.1.4. Customers for The NGAL Test

5.6.1.4.1. Direct Customers

The Company has an ongoing partnership with Roche (see "*14. Material agreements*"). This relationship helps provide access to new markets, key hospitals, and institutions, and is expected to accelerate validation of The NGAL Test in laboratories, due to widespread laboratory customer relationships. To facilitate adoption across laboratories, the Company will focus on making the test available on all major clinical chemistry analyzers (see "*5.5.1.3. Business – Products and Product Pipeline – The NGAL Test – Regulatory Approval and Pathway of The NGAL Test*").

5.6.1.4.2. Global End-users and Decision Makers

5.6.1.4.2.1. Clinicians

Physicians that care for critically ill patients are the clinical customers for The NGAL Test. They can initiate demand for the test and include four primary specialties:

- **Intensivists:** Doctors that are responsible for the care of patients in the ICU. As the physician closely overseeing the patient, the intensivist (also known as a critical care physician) is the primary target for routine ordering of NGAL.
- **Nephrologists:** Specialists that are called in to consult on patients in the ICU when kidney complications arise. Nephrologists need to be persuaded of the value of an NGAL result and how it can be used in patient care, such as in the management of fluids and the use of nephrotoxins. They can also often order the test, particularly if engaged early in the patient's ICU stay.
- **Surgeons, particularly cardiac surgeons:** Cardiac surgery is a primary risk factor for AKI, and cardiac surgeons are aware of the risks that being on cardiopulmonary bypass ("**CPB"**) has for the kidneys. These surgeons could order NGAL routinely on their CPB patients, including doing an assessment prior to surgery, in the first 12 hours after surgery, and potentially even perioperatively.
- **Critical care pharmacists**: These individuals are part of the ICU team that manages the drugs prescribed for critically ill patients. As many drugs are nephrotoxic, ICU pharmacists could potentially use NGAL levels to indicate when dosing adjustments should be made, or when drug regimens should be modified to limit kidney injury.

5.6.1.4.2.2. Laboratory Medicine

Pathologists or laboratory medicine professionals are the technical buyers of The NGAL Test, and their employees in the chemistry lab are the users of The NGAL Test. In order to win a hospital account, these individuals generally need to be persuaded of the clinical and economic value of The NGAL Test, and then they would be responsible for the process of approving, purchasing and validating the test. They also coordinate with the hospital's IT team to make The NGAL Test available in the hospital's ordering system, with results available in the electronic medical record.

5.6.1.4.2.3. Hospital Management

Because The NGAL Test is designed to help improve the management of AKI, it ultimately can have a positive impact on metrics that the administration and "C-level" executives in a hospital monitor, including LOS, readmission rates, costs of care and quality of care. Following FDA clearance and launch of The NGAL Test, the Company intends to develop a value-based model for the use of NGAL within a hospital system, in order to help broaden the availability of the test, and also to promote the standardization of its use. This aligns well with current trends in hospital management, which are focused on value-based care and quality initiatives.

5.6.1.4.2.4. Payors

In the U.S. market, hospital coding impacts hospital payments, primarily driven by the procedures related to each patient. These are accomplished through diagnosis (ICD-10) codes and DRGs (diagnosis related groups). Because it is used in the ICU, the cost of performing The NGAL Test will not require its own reimbursement code, as it will be included in the "bundle" of care that a patient is provided during their hospital stay. The presence or absence of AKI could impact DRG assignments, which in turn could impact the level of payment related to a particular DRG. As the Company expands into other products and product formats, developing strong value analyses to support the coverage, coding and payment of these tests will become an increasingly important focus area.

In markets other than the U.S., the payor is typically the government, with varying processes for assessing the value of any new medical product and assigning allowable payment rates.

5.6.1.5. Competitive Landscape for The NGAL Test

Standard assessments of kidney function, particularly sCr, but also blood urea nitrogen tests and UOP tests, are the main competitors to The NGAL Test. While the limitations of the sCr test as a diagnostic tool are widely published, it nevertheless has been available for over 50 years and is routinely used both for AKI and many other diagnoses. The challenge and opportunity for NGAL, as for all novel biomarkers, is to educate clinicians that there are now better tools to assess the risk of AKI earlier in diagnosis and help improve management of patients at risk of AKI.

Of the novel renal biomarkers that have been studied, some of the more published or newly launched products for IVD use include:[47]

(i) Cystatin C, which is complementary to NGAL as it is a marker of glomerular function and not of tubular injury. Cystatin C's intended use is for the quantitative in vitro measurement of Cystatin C in serum/plasma as an aid in the diagnosis and treatment of renal diseases. Cystatin C is available as a CE mark and FDA cleared product on many major IVD clinical chemistry laboratory instruments;

(ii) NephroCheck, which is a combination of the two markers TIMP-2 and IGFBP-7, and is an indicator of kidney stress, intended for use in the adult ICU to assess the likelihood of developing moderate to severe AKI within 12 hours. The test is primarily performed using single-use cartridges and a stand-alone meter (Astute 140 Meter), although there are some applications for use on Ortho VITROS 3600 and 5600 and BioMerieux Vidas instruments outside the US. NephroCheck is a CE Marked product and was FDA cleared in 2014 (stand-alone meter only);

(iii) NephroClear CCL-14, a test for the quantitative measurement of CCL-14 in urine using the stand-alone Astute 140 Meter, for use in conjunction with clinical evaluation of adult patients who are in the hospital for an acute illness or have moderate to severe AKI, as an aid in the risk assessment of developing PS-AKI (persistent severe acute kidney injury) defined as Stage 3 AKI lasting more than 3 days. . The product recently received a CE mark and will be exclusively distributed by Baxter in western Europe launching in 2022 and in the US pending clearance from the FDA.

(iv) Abbott has a CE-marked NGAL product that runs on Abbott's proprietary immunoassay instruments (Architect/Alinity). Therefore, this test can only be performed in laboratories that have the Abbott instruments, unlike The NGAL Test which has applications for several of the major diagnostic clinical chemistry instruments in hospital laboratories.

5.6.1.6. Market Potential: NGALds

The NGALds is a lateral flow test for semi-quantitative determination of NGAL levels, potentially expanding the applications for this biomarker into several novel areas for future exploration and development, as appropriate. These include:

- Emergency departments for AKI triage
- Nephrotoxicity testing
- Military applications for combat triage[48]
- Cardiac care
- Post-transplant surgery

5.6.2. Markets for ELISA Kits and Antibodies

The overall research antibodies market is expected to grow from USD 10.1billion in 2020 to USD 14.10 billion by 2025, at a CAGR of 6.7% from 2020 to 2025, as these are critical components in life sciences research.[49] In this market, high quality antibodies are essential for research reproducibility, with growth being driven by expanding R&D activities across academia and industry. The Company's library of 150 specific monoclonal antibodies are sold to participants in this sector.

The Company's ELISA products are currently focused on NGAL, offering the ability to test for NGAL in a variety of species, from mouse to monkey, for preclinical applications, as well as in humans for scientific and clinical research. These kits are used in research related to new applications of NGAL and in the development of pharmaceutical compounds, which must be assessed for nephrotoxicity during early compound evaluation.

5.7. Suppliers and Production

The Company relies on key suppliers and vendors for the production of materials and components for The NGAL Test. For example, the Company ships its proprietary antibody cell lines for The NGAL Test to a subcontractor that uses the cell lines to isolate and purify the antibodies for the test. These reagents are then provided to another vendor that incorporates the antibodies into and with other test components to complete the manufacturing of the product. The product is then shipped to the Company's headquarters in Hellerup, Denmark for final assembly, labeling and packaging. Distribution to commercial partners and direct customers across the world is managed from headquarters.

Antibodies for direct sale and for use in gRAD products are developed by and sourced from established antibody producers, according to the Company's specifications. Manufacturing of the gRAD "blank" test strip is outsourced, while final kitting takes place at the Company's headquarters in Hellerup, Denmark.

All of the Company's ELISA kits are manufactured and distributed by the Company from Hellerup, Denmark.

[47] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7443517/
[48] Beyer CA. et al. (2019) 'Point-of-Care Urinary Biomarker Testing for Risk Prediction in Critically Injured Combat Casualties', JACS 2019. 229(5)
[49] Markets and Markets 'Research Antibodies Market by Product (Antibodies (Primary, Secondary)(Mouse, Rabbit)), Reagents), Technology (Western Blot, Flow Cytometry, Elisa, Immunofluorescence, Immunohistochemistry), Application, & End User - Global Forecast to 2025', https://www.marketsandmarkets.com/Market-Reports/research-antibodies-reagents-market-94212793.html

5.8. Organization

The Company is located in Copenhagen, Denmark with its primary address at Tuborg Havnevej 15, ground floor, DK-2900 Hellerup. As of 1 January 2022, the Company had a total of 33 employees (32 FTEs), including 9 employees in the U.S and 23 at the Company's headquarters. Most of the staff is engaged in the development of strategies, design, planning, procurement and project management and execution of clinical trials and studies and the required regulatory interaction. An overview of the development in the Company's total full-time equivalent (FTEs) staff is presented below.

Period	FY2021	FY2020	FY2019
Total no. of FTE (average over the-period)	29	28	34

The Company also has an office outside of Boston, Massachusetts, U.S., which will be the location of the local commercial organization following FDA clearance of The NGAL Test, and which has capacity to expand to include other departments to support further growth.

5.9. Proprietary Rights

Through research and development efforts, the Company has developed expertise in the development of research and diagnostic assays to detect analytes present in various disease states. The Company's antibodies and other aspects of its diagnostic products are proprietary and fundamental to the Company's business. To protect the Company's proprietary technology and prevent unauthorized use of the Company's antibodies, the Company relies on a combination of patents and trade secret laws in the EU, the United States, and other jurisdictions; license and confidentiality agreements; and, software security measures to further protect our proprietary technology and brand. The Company generally seeks to protect its trade secrets by entering into non-disclosure agreements with its employees, suppliers, and certain customers, and historically has restricted access to its device master records, design history files, and related documentation, which the Company regards as proprietary information.

The Company has obtained or applied for patent protection with respect to some of its intellectual property and has registered or applied to register some of its trademarks in the United States, the EU and selected other jurisdictions, including validations of patents in specific EU member states.. In the United States and the EU, the Company is generally able to maintain its patents and patents that it has licensed for up to 20 years from the earliest effective filing date, and to maintain its trademark registrations for as long as the trademarks are in use. Certain of the Company's patents are due for expiry in the near term (see "*1.4.1. Risk factors – 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*").

While the Company considers its intellectual property rights to be valuable, the Company does not believe that its competitive position in the industry depends solely on obtaining legal protection for its diagnostic products and technology. Instead, the Company believes that the success of its business also depends on the Company's ability to commercialize its Products and Future Products, as well as maintaining a reputational leadership position in relation to NGAL by continuing to develop innovative antibodies and diagnostic products utilizing the NGAL biomarker and other health related biomarkers, including for kidney health. In addition, the Company will not be able to obtain and rely solely on intellectual property right protection of its Products and Future (NGAL) Products, as the diagnostic landscape continues to evolve and may allow competitors to penetrate the market. Further, competitors may use the Company's technologies in jurisdictions where the Company does not pursue and obtain patent protection. The Company's ability to obtain patent protection for its Products and Future (NGAL) Products may also be uncertain due to several other factors (see "*1.4. Risk factors – Risks related to the Company's Intellectual Property*").

5.10. Changes in the Company's regulatory environment

See "*5.12. Business – Regulatory environment*".

5.11. Investments

As of the Prospectus Date, a clinical study for The NGAL Test in pediatrics is the Company's only significant investment in progress for FY2022. The Company currently expects to invest a total of DKK 23 million, of which approximately DKK 16million has been invested as of the Prospectus Date. Approximately DKK 9 million of the investment is committed to a clinical research organization assisting the Company in performing the study. Additional costs will be incurred to take place through the submission to the FDA, and then supplemented by any regulatory, clinical, or related activities that may be required to be performed as a result of the FDA's review.

The Company expects to finance the investment with the Company's current cash holdings. Investments in clinical studies are not capitalized but shown in the Company's income statement as part of the item "Research and development costs" in accordance with the Company's accounting policies. Other than that which is set out above, the Company has not made any material investments, is not in the process of making any material investments and/or has no firm commitments to make any material investments.

5.12. Regulatory environment

5.12.1. The European Economic Area

5.12.1.1. Regulation of In Vitro Diagnostic Medical Devices

In Europe, the Company's in vitro diagnostic products are marketed as in vitro diagnostic medical devices.

The regulatory framework concerning the commercialization of the Company's Products is to a large extent harmonized by EU directives a implemented into the respective national legislation of the EU member states (the "**IVD Directives**"), including Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (the "**IVDD**"), Directive 93/42/EEC of 14 June 1993 concerning medical devices (the "**MDD**"), and Directive 2001/95/EC of 3 December 2001 on general product safety. This legislation aims at protecting the health and safety of patients and users of medical devices and governs, among other things, the following product-related activities in which the Company and its manufacturers, contract testing laboratories and suppliers are involved, including development, testing, manufacturing, labeling, safety, storage, market access, advertising and promotion, import and export, sales and distribution, performance/effectiveness, monitoring, maintenance and refurbishment.

Pursuant to the IVDD, in vitro diagnostic medical devices are assigned to regulatory classes or categories based on their intended purpose and inherent risk, which determine the level of control deemed necessary to assure their safety and effectiveness. In vitro diagnostic medical devices are placed within the following major categories: Other/general devices; devices for self-testing that does not fall into a high risk category; devices for performance evaluation; devices which, amongst others, include reagents and products for rubella, toxoplasmosis and phenylketonuria as well as devices for self-testing for blood sugar (devices found in Annex II, List B of the IVDD); and devices, which include reagents and products for human immunodeficiency virus I and II, hepatitis B, C and D (devices found in Annex II, List A of the IVDD). In order to commercialize the Company's Products, the Company is required to comply with the essential requirements of the relevant IVD Directive. Compliance with these requirements entitles the Company to affix the CE conformity marking to the in vitro diagnostic medical devices. A CE marking is required in order to commercialize the Products in the European Economic Area. The European standard setting bodies, mainly the European Committee for Standardization (CEN/CENELEC), have adopted numerous harmonized standards covering a wide range of devices or specific devices or device categories. Compliance with the relevant harmonized standards applicable to a given medical device provides a presumption of conformity with the essential requirements. The European Commission has adopted various guidelines, consensus statements and interpretative documents aimed at ensuring the uniform application of the provisions of the IVD Directives. In order to demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity marking, the Company must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices, where the manufacturer can issue an EC declaration of conformity based on a self-assessment of the conformity of its Products with the essential requirements of the IVD Directives, a conformity assessment procedure requires the intervention of Notified Body to conduct a conformity assessment. Typically, a Notified Body, during the course of reviewing the Company's product application (design dossier) and depending on the classification of the product, confirms that the Company's quality system certifications are being upheld through ongoing assessments, which are conducted separately and must be in evidence to complete the conformity assessment.

The lawful affixing of the CE marking authorizes the Company to commercialize its Products anywhere within the European Economic Area and in certain non-European Economic Area countries that recognize the CE marking. Additional national requirements of the respective member states may also apply.

Failure to comply with the applicable laws and regulations could result in, among other things, delays in obtaining market access, product recalls, product seizures, interruptions of production, operating restrictions, suspension or withdrawal of product market access, injunctions, and civil or criminal sanctions. See "*1.5 - Risk factors - Risks related to legal and regulatory matters*".

On 5 April 2017, the IVDR, and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (the "**MDR**") were adopted. The regulations entered into force on 25 May 2017 and will subsequently replace the existing IVDD and MDD.

The new regulations will apply after a transitional period. The MDR will apply from 26 May 2021 and the IVDR will apply from 26 May 2022. The new regulations will apply directly in all EU member states with the intention of providing more legal certainty for market stakeholders as compared to EU member states having to transpose EU directives into national law.

On Oct 14, 2021, the European Commission proposed extending the regulation's 2-year transitional phase by 1 to 3 years with the transitional period ending in May 2027.

On Dec 15, 2021 the European Parliament approved the proposal, and the extension will provide more time for test makers to get products certified and for notified bodies to come online before the regulation takes effect. The transition period for BioPorto's devices is extended until May 2026. The IVDR itself is not postponed and the date of application remains 26 May 2022. It applies in full to CE marked IVDs that do not require the involvement of a Notified Body such as class A non-sterile devices and new IVDs that are not covered by a certificate or a manufacturer's declaration of conformity issued prior to IVDR implementation.

The Company has until May 2026 to fully comply with the IVDR regulations for The NGAL Test as it is a moderate-risk class C IVD reagent. However, some of the enhanced requirements of the IVDR will need to be met in 2022 such as those for vigilance and market surveillance. Furthermore, products sold under CE mark of IVD-D cannot have any significant changes made to it without being upgraded and become compliant to IVDR.

For manufacturers, the IVDD and the IVDR entail largely the same basic regulatory process. None of the existing requirements under the IVDD have been removed. However, the IVDR introduces certain new requirements, specifically with regard to risk classification of in vitro diagnostic medical devices and the role of Notified Bodies. Under the IVDR, in vitro diagnostic medical devices will be divided into four risk classes: class A, class B, class C and class D. The four classes imply increasing risk levels, taking into account the intended purpose of the devices and their inherent risks, whereby class A is low risk, class C is medium risk, class D is high risk and class B serves as a default class.

The new regulations apply to the Company's Products and Future (NGAL) Products. They stipulate additional requirements, including:

- Re-assessment of products regarding their intended purpose and risk class, leading for certain product types to up-classification and, consequently, increased involvement of Notified Bodies.
- Extension of retention period to ten years for related documents.
- Technical documentation to contain more detailed information and requirements to provide information in the languages of the EU member states targeted for sales will be widened.
- Manufacturers must have available within their organization at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of in vitro medical devices.
- Additional regulatory responsibilities will be extended to importers, distributors and the person responsible for regulatory compliance.
- A system for product registrations, the Unique Device Identification, and for the identification of the person or persons responsible for regulatory compliance will be established.
- Content on labeling artifacts and promotional materials needs to be expanded, e.g., intended purpose in instructions for use.
- Combinations of products must be identified and marked as such.
- Post-market surveillance plans (as part of the products' technical documentation) need to be established for the entire life cycle of a product.
- In addition, post-market surveillance reports and periodic safety update reports are to be implemented. A system of trend codes must be put in place. A 15-day reporting timeline for serious incidents must be followed. Previously, the reporting timeline was 30 days.
- Broadened requirements on clinical/performance evaluation.

As mentioned above, the IVDR apply from 26 May 2022, and in general, the IVDD will be repealed with effect from this date. However, under certain conditions, devices with valid certificates issued under the IVDD can continue to be placed on the market until 26 May 2026. See *"1.2.3. Risk factors – Risks related to the Company's Products and Future (NGAL) Products – 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".*

5.12.1.2. Clinical trials in EU

Clinical trials (also called performance studies) of in vitro diagnostic medical devices in the EU must be conducted in accordance with EU legislation, relevant national legislation of the EU member state and good clinical practices. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles originating from the Declaration of Helsinki, and that the clinical trial data are credible.

Currently, clinical trial authorization applications must be submitted to the regulatory authority in each EU member state in which the trial will be conducted. Under the IVDR, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities only have limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to, or approved by, the relevant competent authorities and ethics committees.

5.12.1.3. Regulations on Advertising and Promotion

The advertising and promotion of the Company's Products are subject to additional European Economic Area directives concerning misleading and comparative advertising and unfair commercial practices, as well as other national legislation of each European Economic Area member state governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of the Company's Products to the general public and may impose limitations on the Company's promotional activities with healthcare professionals.

5.12.1.4. GDPR

Processing of personal data is subject to data protection laws, privacy requirements and other regulatory restrictions in the various jurisdictions in which the Company operates, including GDPR.

The GDPR imposes a number of mandatory requirements, including, but not limited to; (i) ensuring that the basic principles for processing of personal data are met; (ii) ensuring appropriate and sufficient legal bases for processing of personal data; (iii) providing information to the individuals regarding the processing of their personal data; (iv) responding to requests from individuals to exercise their rights in relation to processing of their personal data; (v) implementing appropriate security measures to protect personal data; (iv) entering into data processing

agreements with third parties who process personal data on behalf of the Company and ensuring that these parties do so in compliance with the applicable requirements; (vi) keeping records of processing activities; (vii) reporting personal data breaches to the competent national supervisory authority and, where applicable, the affected individuals; (vii) appointing data protection officers; (viii) conducting data protection impact assessments; and (ix) ensuring an adequate protection for personal data transferred to jurisdictions outside the European Economic Area, such as the U.S.

5.12.1.5. Post-Approval of in vitro diagnostic medical devices

After CE marking, numerous regulatory requirements continue to apply. These include:

- ISO 13485 Quality Management System, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and unique device identification requirement;
- advertising and promotion requirements;
- restrictions on sale or distribution of a device;
- Both IVD Directives and IVDR, which require that manufacturers report to EU countries if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- Both IVD Directives and IVDR, which require that manufacturers report to EU countries if field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation that may present a risk to health;
- mandatory recall if a Notified Body finds there is a reasonable probability that the device would cause serious adverse health consequences or death;
- device tracking requirements; and
- post-market surveillance, which applies when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The Company is subject to unannounced audits by Notified Bodies to determine compliance with ISO 13485 and other applicable regulations, and these audits may include the manufacturing facilities of suppliers. The Company is in compliance with ISO 13485. Failure to comply with applicable regulatory requirements may result in enforcement action by a Notified Body or other negative consequences, which may include any of the following:

- withdrawal of CE mark or ISO 13485 certification;
- unanticipated expenditures, repair, replacement, refunds, recall or seizure of the Company's Products; and/or
- operating restrictions, partial suspension or total shutdown of production.

5.12.1.6. Fraud and Abuse

The Company is also subject to healthcare fraud and abuse regulation and enforcement by the countries in which the Company conducts its business. Healthcare regulation varies significantly from country to country depending on the relevant jurisdiction's regulation on the advertising and promotions of medical devices. Some countries have enacted transparency reporting laws and regulations (so-called sunshine acts), in particular concerning interactions with healthcare professionals.

If the Company's operations are found to be in violation of any of these healthcare laws or regulations, the Company may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from reimbursement programs, and the curtailment or restructuring of the Company's operations.

Any penalties, damages, fines, exclusions, curtailment or restructuring of the Company's operations could adversely affect the Company's ability to operate the Company's business and the Company's financial results and prospects. The risk of the Company being found in violation of these laws and regulations is increased by the fact that many of these laws and regulations are broad and their provisions are open to a variety of interpretations. Any action against the Company for violation of these laws or regulations, even if the Company successfully defends against it, could cause the Company to incur significant legal expenses and divert the Management's attention from the operation of the Company's business.

5.12.2. The U.S.

The Company's Products and operations are subject to extensive and rigorous regulation by the FDA and other federal, state and local authorities. FDA regulates, among other things, the research, development, testing, design, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post-approval monitoring and reporting as well as the import and export of medical devices in the U.S. to assure they are safe and effective for their intended use. The Federal Trade Commission also regulates the advertising of medical devices in the U.S. Further, the Company is subject to laws directed at preventing fraud and abuse. The Company's sales and marketing, training and other practices are subject to rigorous government scrutiny.

5.12.2.1. Regulation of Medical Devices

Unless an exemption applies, each medical device commercially distributed in the U.S. requires either FDA clearance of a premarket notification (a "**510(k)**"), granting of a De Novo Request for Classification or approval of a premarket approval application (a "**PMA**"). Under the Federal Food, Drug and Cosmetic Act (the "**FDCA**") medical devices are classified into three classes: Class I, Class II and Class III. The device classification depends on the degree of risk associated with the specific medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and those for which safety and effectiveness can be assured by adherence to FDA's general controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, facility registration and product listing, reporting of adverse medical events and truthful and non-misleading labeling, advertising and promotional materials. Class II devices are subject to FDA's general controls and special controls as deemed necessary by FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance and patient registries. While most Class I devices are exempt from the 510(k) requirement, manufacturers of most Class II devices are required to submit to FDA a 510(k) and obtain clearance prior to legally marketing the device. . The De Novo request provides a marketing pathway to classify novel Class I or II medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. Devices deemed by FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices are placed in Class III, requiring FDA approval of a PMA.

5.12.2.2. 510(k) Marketing Clearance Pathway

To obtain 510(k) Clearance, the Company must submit to FDA a 510(k) demonstrating that the proposed device is at least as safe and effective, that is, "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is either a pre-amendment device (a device that was legally marketed prior to 28 May 1976) which is not subject to a PMA, a device that can be legally marketed (i.e., approved PMA or granted De Novo) has been reclassified from Class III to Class II or Class I, or a device that has obtained 510(k) Clearance. Following receipt of a 510(k), FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not considered complete, FDA will refuse to accept the application. If it is considered complete, FDA will accept the 510(k) for filing and begin the review. FDA has a performance goal to make decisions regarding 510(k) within 90 calendar days following receipt of a complete submission, excluding days the submission was placed on hold for additional information requests. In practice, however, FDA's clearance process may take significantly longer due to submissions being put on hold for up to 180 days to allow the company to respond to the FDA's request for additional information. FDA may require additional information, including clinical data, analytical data and/or labeling changes to make a determination regarding substantial equivalence.

If FDA agrees that the device is substantially equivalent to a predicate device, it will grant 510(k) Clearance to commercially market the device. If FDA determines that the device is not substantially equivalent to a previously cleared device, the applicant may resubmit another 510(k) with new data, request a Class I or Class II designation through the De Novo classification process (as described below), file a reclassification petition with FDA or submit a PMA.

After a device receives 510(k) Clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, requires a new 510(k) Clearance or, depending on the modification, a De Novo classification or PMA. FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications to 510(k)-cleared devices today can be validated and documented using internal documentation and do not require another submission to FDA. FDA can request to review the internal documentation of the changes in an inspection. If FDA disagrees with a manufacturer's determination, FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) Clearance or PMA is obtained. Also, in these circumstances, the company may be subject to significant regulatory fines or penalties.

5.12.2.3. De Novo Classification Process

Medical device types that FDA has not previously classified as Class I, Class II or Class III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a route to market for low-to-moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the De Novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act (the "**FDASIA**") in July 2012, a medical device could only be eligible for De Novo classification if the manufacturer first submitted a 510(k) and received a determination from FDA that the device was not substantially equivalent (an "**NSE Determination**"). FDASIA streamlined the De Novo classification pathway by permitting manufacturers to request De Novo classification directly without first submitting a 510(k) to FDA and receiving a NSE Determination. Manufacturers who have submitted a 510(k) to FDA and have received a NSE Determination may seek De Novo classification only if the NSE Determination was based on the lack of an identifiable predicate device, a new intended use for the device, or different technological characteristics of the device that raise different questions of safety and effectiveness, but not if FDA's NSE Determination was based solely on lack of performance data. FDA has performance goals to classify the device within 150 days following receipt of the De Novo application; provided, however, that the FDA may pause the tolling of that time frame to request additional information from the manufacturer, and that pause indeed routinely occurs (see "*1.2.1. Risk factors – 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 revenues, future growth prospects, future cash-flows and future results of operations")*.

If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, FDA may reject the De Novo application if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

5.12.2.4. Breakthrough Devices Program

The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for PMA, 510(k) Clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

Devices subject to PMAs, 510(k)s or De Novo Requests for Classification are eligible for breakthrough device designation if both of the following criteria are met:

- The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.
- The device also meets at least one of the following:
    - Represents breakthrough technology
    - No approved or cleared alternatives exist
    - Offers significant advantages over existing approved or cleared alternatives
    - Device availability is in the best interest of patients

A breakthrough designation request for a device can be submitted at any time prior to sending a marketing submission (for example, PMA, 510(k), or De Novo classification request) using a Q-submission (pre-submission). FDA's decision to grant or deny the breakthrough device designation request is typically communicated within 60 calendar days of the FDA receiving the request. If a device is granted the breakthrough device designation, there are a variety options to interact with the FDA to obtain feedback on the device development including sprint discussions, a request for discussion on a data development plan, and a request for clinical protocol agreement. Prioritized review on future regulatory submissions, including Q-submissions, Investigational Device Exemption ("**IDE**") applications, and marketing submissions is given for devices granted breakthrough device designation. Although priority review for devices is intended to help expedite patient access to certain devices important to public health, previous devices with breakthrough designation and the Priority Review Program demonstrate that review times for marketing submissions may take longer for breakthrough devices than for other devices because of the novel scientific issues these devices may raise.

5.12.2.5. Emergency Use Authorizations

The EUA authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear ("**CBRN**") threats by facilitating the availability and use of medical countermeasures ("**MCMs**") needed during public health emergencies. Under section 564 of the FDCA, the FDA commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved and available alternatives. These medical products include drugs (e.g., antivirals and antidotes), biological products (e.g., vaccines, blood products and biological therapeutics) and devices (e.g., in vitro diagnostics and personal protective equipment).

Before FDA may issue an EUA, the secretary of the U.S. Department of Health and Human Services ("**HHS**") must declare that an emergency exists to justify the authorization. In appropriate circumstances, an HHS EUA declaration may support issuance of more than one EUA. For example, based on an HHS EUA declaration that circumstances exist to justify the authorization of emergency use of diagnostics for a specified biological agent, FDA may authorize emergency use for multiple diagnostic tests to meet the need, provided that each EUA meets the statutory criteria for issuance.

EUAs need to demonstrate that they "may be effective" to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by the CBRN threat agent. This is a lower standard than "effectiveness" that is required for FDA product approvals. FDA recommends that a request for an EUA include a well-organized summary of the available scientific evidence regarding the product's safety and effectiveness, risks (including an adverse event profile) and benefits, and any available, approved alternatives to the product. The exact type and amount of data needed to support an EUA submission may vary depending on the nature of the declared emergency or threat of emergency and the nature of the candidate product. For in vitro diagnostic medical devices, device performance data to support the intended use such as analytical sensitivity and analytical specificity, and data from testing fresh, contrived, banked or archived specimens is required.

FDA does not have set timelines for EUA submission review and they often vary on a case-by-case basis dependent on several factors including the nature of the emergency, the number of other EUA related submissions and FDA resources. FDA is prepared to issue EUAs expeditiously (e.g., within hours or days) when circumstances warrant, and adequate information has been made available. FDA may refuse to grant an EUA for several reasons if the product does not meet the necessary criteria established for authorization.

FDA may establish conditions on an EUA necessary or appropriate to protect the public health including providing information about the EUA product (e.g., labeling, fact sheets, etc.), monitoring and reporting adverse events, maintaining records and granting FDA access to these records, placing requirements on distribution and administration of the product, and placing restrictions on advertising or promotion of the product. FDA

may also waiver compliance to other regulations such as cGMP on a case-by-case basis with consideration of the emergency and implementation of other alternative proposed approaches.

In general, an EUA will remain in effect for the duration of the EUA declaration under which it was issued. However, an EUA issued to allow an unapproved use of an approved product may no longer be needed if that product is later approved by FDA for the use permitted by the EUA. When an EUA declaration is terminated, then any EUA(s) issued based on that declaration will no longer remain in effect and the products and labeling must be disposed. Any study or future use of an EUA product beyond the term of a declaration is subject to investigational product regulations.

5.12.2.6. The IDE Process

In the U.S., absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and approval from the Institutional Review Board (the "**IRB**") is obtained. If the device presents a "significant risk" to human health, as defined by FDA, the sponsor must submit an IDE application to FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. The IDE application must demonstrate that there is reason to believe that the risks to human subjects from the proposed investigation are outweighed by the anticipated benefits to subjects and the importance of the knowledge to be gained, that the investigation is scientifically sound and that there is reason to believe that the device as proposed for use will be effective. The IDE application must be approved in advance by FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE application will result in the ability to commence clinical trials, and although FDA's approval of an IDE application allows clinical testing to go forward for a specified number of subjects, it does not bind FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with FDA's regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support a PMA, a 510(k) Clearance, or granting of a De Novo for numerous reasons, including, but not limited to, the following:

- FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse events;
- patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- device malfunctions occur with unexpected frequency;
- IRB and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements;
- third-party investigators are disqualified by FDA;
- the sponsors, investigators or third-party organizations do not perform data collection, monitoring or analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records and reports regarding clinical trials;
- third-party clinical investigators have significant financial interests related to the company or the company's study such that FDA deems the study results unreliable, or the company or investigators fail to disclose such interests;
- regulatory inspections of the company's clinical trials or manufacturing facilities, which may, among other things, require the company to undertake corrective action or suspend or terminate its clinical trials;
- changes in government regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or
- FDA concludes that the trial design is inadequate to demonstrate safety and efficacy.

5.12.2.7. Post-Approval Regulation of Medical Devices

After FDA permits a device to enter commercial distribution, numerous regulatory requirements continue to apply. These include:

- FDA's Quality System Regulations, which require manufacturers, including third party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- registration of medical device manufacturing facilities and listing of medical devices that are manufactured;

- labeling regulations and unique device identification requirement;
- advertising and promotion requirements including FDA prohibitions against the promotion of products for uncleared or unapproved indications;
- restrictions on sale or distribution of a device;
- annual reporting requirements for PMA applications;
- clearance of product modifications to 510(k) cleared devices or devices granted a De Novo that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- medical device reporting regulations, which require that manufacturers report to FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- voluntary recall actions to protect the public health and well-being from medical devices that present a risk of injury or gross deception or are otherwise defective;
- mandatory recall if FDA finds there is a reasonable probability that the device would cause serious adverse health consequences or death;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

FDA has broad post-market and regulatory enforcement powers. Companies are subject to unannounced inspections by FDA to determine compliance with the Quality System Regulations and other applicable regulations, and these inspections may include the manufacturing facilities of suppliers. The Company believes that the Company is in compliance with the Quality System Regulations. Failure to comply with applicable regulatory requirements can result in enforcement action by FDA or other negative consequences, which may include any of the following:

- Warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures, repair, replacement, refunds, recall or seizure of the Company's Products;
- operating restrictions, partial suspension or total shutdown of production;
- FDA's refusal of the Company's requests for 510(k) Clearance or PMA of new products, new intended uses or modifications to existing products;
- FDA's refusal to issue a Certificate to Foreign Governments which foreign governments frequently require for assurance that products are in compliance with U.S. law or regulations;
- withdrawing 510(k) Clearance or PMA that have already been granted; and
- criminal prosecution.

5.12.2.8. Fraud and Abuse

The Company is also subject to healthcare fraud and abuse regulation and enforcement in the U.S. The U.S. federal anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federal financed healthcare programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and any remuneration to or from a prescriber or purchaser of healthcare products or services may be subject to scrutiny if they do not qualify for an exception or safe harbor. The Company's practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting or causing to be presented a false claim for payment to the federal government, or knowingly making or causing to be made a false statement to get a false claim paid. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items or services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of payor. These false claims statutes allow any person to bring suit in the name of the government alleging false and fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in the healthcare industry in recent years. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and the narrowness of the safe harbors and exceptions, it is possible that some of the Company's business activities could be subject to challenge under one or more of such laws, which could have a material adverse effect on the Company's business.

The Patient Protection and Affordable Care Act imposes reporting and disclosure requirements on device and drug manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of USD 150,000 per year (and up to an aggregate of USD 1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission.

In addition, there has been a trend of increased federal and state regulation of payments made to physicians. The shifting compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company many violate one or more of the requirements.

The Federal Civil Monetary Penalties Law prohibits the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. If the Company's operations are found to be in violation of any of the laws described above or any other applicable government regulations, the Company may be subject to civil and criminal penalties, damages, fines and the curtailment or restricting of the operations. Any penalties, damages, fines, curtailment or restructuring or the operations could harm the ability to operate the business and the financial results. Any action against the Company for violation of these laws, even if the Company successfully defend against it, could cause the Company to incur significant legal expenses and divert the Management's attention from operation of the business. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly.

5.12.2.9. Commercialized Products, Previous Submissions and Clinical Trials

The NGAL Test was CE marked in 2012 and has been available for IVD use in Europe and other geographies through direct sales from the Company or select distributors.

In late 2016, the Company filed a pre-submission with the FDA and followed in 2017 with a multisite clinical trial for >500 patients at medical centers in the U.S. In July 2018, the Company filed an application for the clearance of The NGAL Test for risk stratification to rule out AKI in adults within 48 hours in the ICU. In October 2018, the FDA responded that they required further data to support the application.

In May 2019, the Company submitted an application to the FDA for approval of The NGAL Test for risk assessment of AKI in children under the age of 22 (pediatrics) and was granted breakthrough designation status. In July 2019, the FDA requested additional information, and the Company decided to conduct a prospective study after reaching alignment with FDA to support the pediatric application. The company plans to pursue adult claims following the FDA granting of the de novo for the pediatric application.

6. Trend information

6.1. Significant recent trends in production and sales

There has been no significant change to trends in production, sales and inventory, nor in costs or selling prices since the end of the period covered by the FY2020 Financial Statements other than as stated in the 3rd Quarter 2021 Financial Statements regarding production and sales (which is incorporated herein by reference).

6.2. Significant change in the financial performance

There has been no significant change to the financial performance of the Company since the end of the period covered by the FY2020 Financial Statements other than as reflected in the Half Year 2021 Financial Statements and the 3rd Quarter 2021 Financial Statements (both of which are incorporated herein by reference). Over the period, the Company has realized revenue and operating loss (EBIT) consistent with its estimate for 2021 and Preliminary Guidance for 2022. The company's cash balance as at the Prospectus Date is approximately DKK 34 million (unaudited).

6.3. Other trends

6.3.1. COVID-19

The COVID-19 pandemic has since publication of the FY2020 Financial Statements and the 3rd Quarter 2021 Financial Statements continued to cause delays of both ongoing and new clinical studies across the globe. As the Company announced in November 2021, enrollment in the Company's clinical trial was on-going, but slower than expected due to such delays.

As new variants of COVID-19 emerge, this will continue to influence the Company's ability to perform clinical studies and other verification studies as access to Hospitals, laboratory and clinical sites are limited. This will influence the time it takes to perform clinical studies, validation, and verification studies.

The staff and the Company's operation are also affected by the COVID-19 situation. On-site activities are subject to more restrictions, and there is a higher degree of employees that must remain in self isolation and increased levels of illness because of the COVID-19 pandemic.

6.3.2. Regulatory changes

The Company operates in a highly regulated industry, with a number of regulatory requirements which are subject to change due to political and other factors. As such, the Company is routinely required to adapt to and comply with new complex regulations (see "*5.12. Business – Regulatory Environment*"). Further, in the U.S., and other principal markets in which the Company may sell its Products and Future (NGAL) Products, there is a continued economic, regulatory and political pressure to promote changes in healthcare systems to reduce healthcare costs, which may negatively impact the sale of such products.

7. Consolidated Prospective Financial Information

7.1. Statement by Management

The prospective consolidated financial information for FY2021 (the "**Estimate for FY2021**") and the preliminary consolidated prospective financial information for FY2022 (the "**Preliminary Guidance for FY2022**") is presented below (jointly the "**Consolidated Prospective Financial Information**").

We have prepared and presented the Consolidated Prospective Financial Information, including the key assumptions set out in "*7.2.2. Consolidated Prospective Financial Information – Consolidated Prospective Financial Information of the Company – Methodology and assumptions*". The Consolidated Prospective Financial Information has been compiled and prepared on a basis which is both comparable with the financial information in the Annual Report 2020 and consistent with the accounting policies as those applied in the FY2020 Financial Statements.

The Consolidated Prospective Financial Information has been prepared for the purpose of this Prospectus.

The Consolidated Prospective Financial Information is based on a number of factors, including certain estimates and assumptions. The material assumptions on which the Consolidated Prospective Financial Information is based are described in "*7.2.2. Consolidated Prospective Financial Information – Consolidated Prospective Financial Information of the Company – Methodology and assumptions*".

The Consolidated Prospective Financial Information represents the best estimates of Management at the Prospectus Date. Actual results are likely to be different from the Consolidated Prospective Financial Information since anticipated events may not occur as expected, or may materially differ from the forecast provided. The Consolidated Prospective Financial Information in this section should be read in conjunction with "*1. Risk factors*" and "*2.9. Certain information regarding the Prospectus and the Offering – Forward-looking statements*" included elsewhere in this Prospectus.

Copenhagen, 7 March 2022

Board of Directors

Christopher James Lindop
Chairman

John Patrick McDonough
Deputy Chairman

Michael Scott Singer
Board member

Donnie McCoy Hardison Jr
Board member

Jan Leth Christensen
Board member

Peter Mørch Eriksen
Board member

Executive Management

Anthony Paul Pare
CEO

Neil A. Goldman
CFO

7.2. Consolidated Prospective Financial Information of the Company

7.2.1. Introduction

The Company has prepared the Consolidated Prospective Financial Information for use in this Prospectus in accordance with applicable laws, rules and regulations.

While this Consolidated Prospective Financial Information is presented with numerical specificity, this information is based upon a number of assumptions and estimates which the Company considers reasonable. As a result, this Consolidated Prospective Financial Information is inherently subject to significant business, operational, economic and competitive uncertainties and contingencies, and upon future business decisions that are subject to change.

Therefore, the Company's expectations presented in the Consolidated Prospective Financial Information as to future developments may deviate substantially from actual developments, and the Company's actual results of operations are likely to be different from the Consolidated Prospective Financial Information since anticipated events may not occur as expected, or may materially differ from the forecast provided. Accordingly, potential investors should treat this information with caution and not place undue reliance on the expectations set forth below.

7.2.2. Methodology and assumptions

The Consolidated Prospective Financial Information has been prepared in accordance with the accounting policies presented in the FY2020 Financial Statements which have been prepared in accordance with IFRS.

The Consolidated Prospective Financial Information is prepared for the purpose of this Prospectus.

The Consolidated Prospective Financial Information has been based on the Board of Directors and Executive Management's guidance for FY2021 and the budget for FY2022, prepared in accordance with the Company's forecasting and budgeting procedures and on a basis comparable to the FY2020 Financial Statements.

The Consolidated Prospective Financial Information is based on a number of factors, including certain estimates and assumptions. The key assumptions concerning the future, and other key sources of estimation uncertainty as of the date of the Consolidated Prospective Financial Information that have a significant risk of causing a material adjustment to the prospective amounts of expenses, assets and liabilities within the period that the respective financial periods concern, are listed below. The Company based its assumptions and estimates on information available when the Consolidated Prospective Financial Information was prepared.

Certain assumptions, uncertainties and contingencies relating to the Consolidated Prospective Financial Information are wholly or partly within the control of the Company, while others are outside or substantially outside the control of the Company.

While the Company has presented the key assumptions on which the Consolidated Prospective Financial Information is based below, it is likely that one or more of the assumptions that the Company has relied upon will not prove to be accurate in whole or in part.

The Company's result of operations could deviate materially from its forecasts as a result of other factors, including but not limited to those described in "*2.9. Certain information regarding the Prospectus and the Offering – Forward-looking statements*" and "*1. Risk Factors*".

For the purpose of preparing the Consolidated Prospective Financial Information, the Company has applied the key assumptions below:

7.3. Key assumptions relating to Consolidated Prospective Financial Information

As a general overriding assumption, the Consolidated Prospective Financial Information assumes completion of the Offering with net proceeds of a minimum of DKK 66.4 million. Other key assumptions in relation to the Consolidated Prospective Financial Information are the following:

7.3.1. Estimate for FY2021

BioPorto estimates revenue and operating loss (EBIT) for 2021 consistent with its most recent guidance for 2021 as announced in the 3rd Quarter 2021 Financial Statements:

- Revenue of approximately DKK 24 million.
- Operating loss (EBIT) of approximately DKK 65 million.

7.3.2. Assumptions relating to revenue – Estimate for FY2021

The Company's estimates as to its FY2021 revenue are based on and assume the following:

- The Company's transaction processing, analysis, and internal financial reporting processes being accurate throughout the financial year 2021 (within the Company's control)
- The Company's internal year-end closing procedures, and thereafter, external audit (partly outside the Company's control).

7.3.3. Assumptions relating to EBIT – Estimate for FY2021

The Company's estimates concerning EBIT for FY2021 are also based on and assume the following:

- The Company's transaction processing, analysis, and internal financial reporting processes being accurate throughout the financial year 2021 (within the Company's control).
- The Company's internal year-end closing procedures, and thereafter, external audit (partly outside the Company's control).

7.3.4. Preliminary Guidance for FY2022

Based principally on the assumptions below and methodology as set out above, the Company's preliminary guidance for FY2022 is as follows:

- Revenue of approximately DKK 24 - 26 million
- Operating loss (EBIT) of approximately DKK 95 - 100 million

7.3.5. Assumptions relating to revenue – Preliminary Guidance for FY2022

The Company's estimates concerning revenue for FY2022 are principally based upon and assume the following

- Revenue will be supported by a modest increase in NGAL product sales across regions compared to FY2021 (partly outside the Company's control).
- Sales of antibodies and ELISA kits are assumed to decline due to the Company's increasing focus on sales of NGAL products compared to FY2021 (partly outside the Company's control).
- Revenue does not include any launch of The NGAL Test for pediatrics in 2022 (within the Company's control).
- Currency exchange rates assumed to be USD/DKK: 6.50 (outside the Company's control).

In the case that either of the assumptions listed above proves to be incorrect, the outcome of the preliminary guidance could materially change.

7.3.6. Assumptions relating to EBIT – Preliminary Guidance for FY2022

In addition to the Company's assumptions as to revenue, the Company's estimates concerning EBIT for FY2022 are principally based upon and assume the following:

- EBIT is assumed to be affected negatively by the full year impact of 2021 hires of management and other team members (within the Company's control).
- EBIT from 2021 was favorably impacted on a non-cash basis by approximately DKK 4 million from the forfeiture of warrants and related reversal of equity compensation expenses for members of management and other team members that resigned. Such forfeitures are not expected in 2022, so EBIT for 2022 is assumed to be negatively impacted (also on a non-cash basis) by an additional approximately DKK 11 million for the full year impact of equity compensation expenses related to new members of management and other team members, including certain of such expenses that will be amortized on an accelerated basis. The combined non-cash, negative impact of this accounting treatment is approximately DKK 15 million of EBIT loss compared to 2021 (partially outside the Company's control).
- Costs related to clinical studies are assumed to be comparable to FY2021 (within the Company's control).
- The regulatory clinical trial of The NGAL Test in pediatrics can complete enrollment of patients at the selected clinical sites in the U.S. and thus not be further delayed by COVID-19 (outside the Company's control).

- Costs related to sales & marketing are assumed to increase compared to FY2021 associated with the preparation for commercializing The NGAL Test in the U.S. and increasing costs to expand support for distribution in the rest of the world (within the Company's control).
- Cost related to R&D (including quality, regulatory, and non-clinical trial medical affairs costs) are assumed to increase compared to 2021, including as a result of the full year impact of 2021 hirings, investments in quality systems (e.g. in preparation of the coming into effect of the IVDR), and other costs related to preparing and submitting the De Novo application of The NGAL Test in the U.S. to the FDA (within the Company's control).
- Costs related to production and depreciation are assumed at FY2021 levels (within the Company's control).

In the case that either of the assumptions listed above proves to be incorrect, the outcome of the preliminary guidance could materially change.

8. Board of directors, executive management and key employee

8.1. Overview

The Company has a two-tier governance structure consisting of the Board of Directors and the Executive Management. The two bodies are separate and have no overlapping members. The Executive Management is supported by the Company's Key Employee (the **Key Employee** together with the Executive Management, the "**Corporate Management**"). The business address of the Board of Directors, Executive Management and the Key Employee is Tuborg Havnevej 15, ground floor, DK-2900 Hellerup, Denmark.

For a description of the remuneration of the Board of Directors, Executive Management and Key Employee, including ownership of Shares and holding of Share related instruments granted under the Company's current incentive schemes, see the FY2020 Financial Statements and company announcement no. 24, dated 31 December 2021 regarding new grant of warrants.

In addition to statutory governance boards, the Company is in the process of establishing a scientific advisory board ("SAB"), which is planned to consist of a number of KOLs. From time to time, the Company also engages individual KOLs on an ad hoc basis to conduct studies etc. for the Company. The KOLs are independent from the Company but receive a fee for their advisory board work or ad hoc assignment, in each case in accordance with applicable regulations.

8.2. Board of Directors

The Board of Directors is responsible for the overall and strategic management and proper organization of the Company's business and operations and supervises the Company's activities, management and organization. The Board of Directors appoints and dismisses the members of the Executive Management, who are responsible for the day-to-day management of the Company.

In accordance with article 11 of the Articles of Association, the general meeting of the Company shall elect not less than three and not more than seven members to the Board of Directors. The Board of Directors elects a chairman (the "**Chairman**") and a deputy chairman ("**Deputy Chairman**") of the Board of Directors among its members.

The members of the Board of Directors elected by the general meeting are elected for a term of one year. Members of the Board of Directors may be re-elected.

At the date of this Prospectus, the Board of Directors comprises of six members elected by the general meeting including the Chairman, the Deputy Chairman and four additional board members.

The following table presents an overview of the current composition of the Board of Directors:

Name	Position	Independent[1]	Year of first appointment	Expiration of term
Christopher James Lindop	Chairman	Independent	2019	2022
John Patrick McDonough	Deputy Chairman	Independent	2021	2022
Jan Leth Christensen	Member	Independent	2021	2022
Peter Mørch Eriksen	Member	Non-Independent	2021	2022
Donnie McCoy Hardison Jr	Member	Independent	2021	2022
Michael Scott Singer	Member	Independent	2019	2022

[1] The Company has based its assessment of independence on the criteria set out in the recommendations on corporate governance published by the Committee on Corporate Governance.

8.3. Board of Directors – Biographies

Other than as presented below, none of the members of the Board of Directors has been a member of the administrative, management or supervisory bodies of a company or a partnership or been a partner in a partnership outside the Company within the past five years.

Christopher James Lindop (born 1957, British and American nationality) has been a member of the board of directors of the Company since 2019 and became chairman in 2021. Christopher James Lindop qualified as a chartered accountant and certified public accountant and was previously a partner with Arthur Andersen LLP and Ernst & Young LLP. He took the position as chief financial officer of Inverness Medical Ltd., before being appointed chief financial officer and VP of Business Development at Haemonetics Corporation Ltd. (HAE). Christopher James Lindop was chief financial officer of Quotient Limited (QTNT) until his retirement in May 2020. Christopher Lindop was also a member of the board of directors of Parexel International (PRXL) where he served as chairman of the audit committee and as a member of the nominating and governance committee. As a result, he has considerable experience in the management of U.S. listed health care and diagnostic companies and within the functional areas

of finance and reporting, corporate governance, mergers & acquisitions, public and private market financing and strategy development and execution.

Current management positions

- BioPorto A/S, Chairman of the Board of Directors

Previous management positions in the past five years

- Parexel International, Board member
- Quotient Limited, Chief Financial Officer
- BioPorto A/S, Board member

John McDonough (born 1959, American nationality) has been a member of BioPorto's board of directors since 2021 and currently serves as the deputy chairman of the board of directors. John McDonough previously served as President and chief executive officer, of T2 BioSystems, Inc., a diagnostics company focused on the rapid detection of sepsis-causing pathogens. John held several positions at Cytyc Corporation, a company focused on women's health, and ultimately served as president of Cytyc Development Corporation. He also led the efforts that resulted in Cytyc's acquisition by Hologic Inc. for over $6 billion. John McDonough is currently a member of the board of directors at Solace Therapeutics and Cytrellis Biosystems. He earned his undergraduate degree in business from Stonehill College.

Current management positions

- Cytrellis Biosystems, Inc., Chairman of the Board of Directors
- Solace Therapeutics, Board member
- BioPorto A/S, Deputy Chairman of the Board of Directors

Previous management positions in the past five years

- T2 Biosystems, Founding CEO, President and Board member
- T2 Biosystems, Chairman of the Board of Directors
- Seventh Sense Biosystems, Chief Executive Officer
- BioPorto A/S, Board member

Michael Scott Singer (born 1973, American nationality) has been a member of BioPorto's board of directors since 2019. He is currently Chief Scientific Officer (CSO) and co-founder of Cartesian Therapeutics, Inc, a US biotech company that develops RNA-modified cell therapies. Prior to founding Cartesian, he was co-founder and CSO of two startups: Topokine and HealthHonors. Dr. Singer previously served as Director of Translational Medicine at the Novartis Institutes for Biomedical Research. He is a licensed physician and has been admitted to practice patent law. He serves as an adjunct professor at the Yale University School of Medicine. Dr. Singer completed residency at Harvard and holds a BS, MD, and PhD from Yale University.

Current management positions

- Cartesian Therapeutics, Inc., Board member
- Cartesian Therapeutics, Inc., Chief Scientific Officer, Vice President
- Pykus Therapeutics, Inc., Board member
- Anodyne Nanotech, Inc., Board member
- BioPorto A/S, Board member

Previous management positions in the past five years

- N/A

Donnie McCoy Hardison Jr (born 1950, American nationality) has been a member of BioPorto's board of directors since 2021Don Hardison most recently served as President, Chief Executive Officer, and as a member of the board of directors of Biotheranostics, Inc., an oncology-focused molecular diagnostics company which was acquired by Hologic Inc. Prior to Biotheranostics, he was the President and Chief Executive Officer and Director of Good Start Genetics, a molecular diagnostics company focused on reproductive health. Earlier in his career, he held many executive and senior management positions at a number of public companies including Laboratory Corporation of America and Quest Diagnostics, the two largest US clinical laboratories; Exact Sciences Corporation, a molecular diagnostics company; and SmithKline Beecham Corporation, a pharmaceutical company. He currently serves on the board of directors of publicly held companies HTG Molecular and MdxHealth and several privately held companies including Stemina Biomarker Discovery Inc., YourBio, and Iquity, Inc. He also served on the board of directors of Exact Sciences Corporation, through its initial public offering. He received his Bachelor of Arts in Political Science from the University of North Carolina, Chapel Hill.

Current management positions

- HTG MOLECULAR, INC., Board member
- IQUITY, Board member
- MDXHEALTH, Board member
- DMH CONSULTING, sole proprietor
- Stemina Biomarker Discovery Inc., Board member
- YourBio, Board member
- BioPorto A/S, Board member

Previous management positions in the past five years

- GOOD START GENETICS, INC., President, CEO & Director
- BIOTHERANOSTICS, INC, Board member
- BIOTHERANOSTICS, INC., President, CEO & Director

Jan Leth Christensen, (born 1963, Danish nationality) has been a member of BioPorto's board of directors since 2021. Jan Leth Christensen is an attorney-at-law and is currently a board member and partner at Lønberg & Leth Christensen Advokataktieselskab. He serves as Chairman of Havnens Bygningsudlejnings A/S, Best Ejendomme A/S, and Advokaternes Ejendomsadministration A/S, and is also a member of the executive management and/or the board of directors of several other companies and foundations. Jan Leth Christensen holds a Master's degree in Law from the University of Copenhagen.

Current management positions

- Ejendomsselskabet Jano ApS, Member of the executive Management & Board member
- Kannike v/Jan Leth Christensen, Sole proprietor
- Murermester Willy Lynggard Petersens Familiefond, Board member
- Leth Christensen Advokatanpartsselskab Holding, Member of the executive management
- Rolf Krake Fonden, Board member
- Hyldegårdsvej 40 A/S, Chairman of the Board of Directors
- WRP-Holding A/S, Board member
- K/S Hørsvinget, Board member
- Esplanaden Berlin Holding A/S, Board member
- Havnen Lersø Parkallé 107 ApS, Chairman of the Board of Directors
- Lønberg & Leth Christensen Advokataktieselskab, Board member and member of the executive management
- Søndre Løkker ApS, Member of the executive management
- NER-FINANS ApS, Member of the executive management
- Havnens Bygningsudlejning A/S. Chairman of the Board of Directors
- W. Lynggard Petersen Holding A/S, Board member
- Residuum ApS, Member of the executive management
- Nordre Kystvej 30-32 ApS, Member of the executive management
- Nordre Kystvej Holding ApS, Member of the executive management
- Store Torv 12 ApS, Member of the executive management
- JLC E.G. Kapital Holding ApS, Member of the executive management
- OGOV 50 Holding ApS, Member of the executive management
- OGOV 50 ApS, Member of the executive management
- Erokito ApS, Member of the executive management
- Søborgstræde 2 A/S, Chairman of the Board of Directors
- Best Ejendomme A/S, Chairman of the Board of Directors
- Advokaternes Ejendomsadministration A/S, Chairman of the Board of Directors
- T Røffel ApS, Member of the executive management
- Toldbodgade 36 A-B ApS, Member of the executive management
- Jano Agro ApS, Member of the executive management
- E.G. Frederikssundsvej ApS, Member of the executive management
- E.G. Kapital ApS, Member of the executive management
- BioPorto A/S, Board member

Previous management positions in the past five years

- Best Ejendomme ApS, Board member
- DAJ Ejendomsselskab A/S, Member of the executive management
- Storebælt Camping- og Feriecenter ApS, Chairman of the Board of Directors & Member of the executive management
- Komplementaranpartsselskabet Strandvejen 195-199, Member of the executive management
- K/S Strandvejen 195-199, Deputy Chairman of the Board of Directors
- Dronningens Tværgade 6 B-C ApS, Member of the executive management
- DK Resi PropCo Esplanaden ApS, Member of the executive management
- Willemoesgade 70-74 Holding ApS, Member of the executive management
- Willemoesgade 70-74 ApS, Member of the executive management
- DK Resi PropCo Smallegade 34 ApS, Member of the executive management
- GGRC Holding ApS, Member of the executive management
- Jagtvej 213 ApS, Member of the executive management
- DK Resi HoldCo Smallegade 4-6 ApS, Member of the executive management
- Hyldegårdsvej 40 Holding ApS, Member of the executive management
- Istedgade 48-50 ApS, Member of the executive management
- Raven 14 ApS, Member of the executive management
- Vigerslevvej 256 Holding ApS, Member of the executive management
- Vigerslevvej 256 ApS, Member of the executive management

Peter Mørch Eriksen, (born 1960, Danish nationality) has been a member of BioPorto's board of directors since 2021 and served as CEO of BioPorto from 2013 – 2021. Peter Mørch Eriksen has spent more than 20 years in the MedTech/life science industries, including as CEO of Sense A/S and VP of Medtronic. From these positions, Peter Mørch Eriksen has extensive experience in creating growth, restructuring and funding in technology-intensive and complex companies. Peter Mørch Eriksen is an experienced leader with a record of business within the medical device industry, and has broad experience selling and developing medical devices for both small and large MedTech companies. Peter Mørch Eriksen has an accounting background, supplemented with management experience. He is chairman of the board of directors in FluoGuide A/S, member of the Advisory Board at Lund University Diabetes Centre, member of the Advisory Board at the Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Center in Cincinnati, Ohio (US) and member of the executive management in PME Holding ApS.

Current management positions

- FluoGuide A/S, Chairman of the Board of Directors
- PME Holding ApS, Member of the executive management
- Lund University Diabetes Centre, Board member
- The Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Center, Board member
- BioPorto A/S, Board member

Previous management positions in the past five years

- JGN 1 3-12-2018 ApS, Chairman of the Board of Directors
- JGN 2 3-12-2018 ApS, Chairman of the Board of Directors
- JGN 3 Glamsbjerg ApS, Chairman of the Board of Directors
- Fonden Mtic, Medtech Innovation Center, Chairman of the Board of Directors
- Online Grænsehandel Group A/S, Board member
- On Line Group, Board member

8.4. Executive Management

According to article 12 of the Articles of Association, the Board of Directors appoints an executive management consisting of one or more members. The primary task of the executive management is to carry out the day-to-day management of the Company with the support of the Key Employee.

The following table presents an overview of the current members of the Executive Management:

Name	Position	Year of first appointment	Year of appointment to current position
Anthony Paul Pare	Chief Executive Officer	2021	2021
Neil Allan Goldman	Executive Vice President and Chief Financial Officer	2021	2021

8.5. Executive Management – Biography

Other than as presented below, the member of the Executive Management has not been members of the administrative, management or supervisory bodies of a company or a partnership or a partner in a partnership outside the Company within the past five years.

Anthony Paul Pare (born 1962, American nationality) was appointed Chief Executive Officer (CEO) of BioPorto in November 2021. Anthony Paul Pare has led product development, commercialization, marketing, operations, and business development in leading medical device and diagnostic companies for 25 years. Previously, Anthony Paul Pare was the Chief Commercial Officer (CCO) at T2 Biosystems, a US Nasdaq-listed in vitro diagnostics company. He held the same role at Hemanext (US), a pre-commercial company marketing blood transfusion technology. He also held various leadership roles at Haemonetics (US), specializing in blood processing and diagnostic technologies. In addition to being CEO of BioPorto, Tony is actively participating on advisory boards, and mentoring startup medical technology companies in the Boston (US) area. Anthony Paul Pare holds a Bachelor of Science in Marine Engineering and a Master's of Engineering Administration from George Washington University (US).

Current management positions

- BioPorto A/S, Chief Executive Officer

Previous management positions in the past five years

- New Health Sciences d/b/a Hemanext, Chief Commercial Officer
- T2 Biosystems Inc., Chief Commercial Officer

Neil Allan Goldman (born 1967, American nationality) has served as Executive Vice President and Chief Financial Officer of BioPorto since November 2021. He previously served as the Executive Vice President and Chief Financial Officer of Chembio Diagnostics, Inc. (Nasdaq:CEMI). He has been the Executive Vice President-Corporate Development and Chief Financial Officer at J.S. Held LLC, a construction consulting firm. He was the Global Finance Director for the Delphi Data Connectivity division of Delphi Corp. (now Aptiv plc, NYSE:APTV), an automotive supplier, following Delphi's acquisition of Unwired Technology LLC ("Unwired"), a tier-1 global automotive electronics manufacturer and distributor, from a private equity firm. At Unwired, he was the Executive Vice President-Corporate Development and Chief Financial Officer, the Senior Vice President-Chief Operating and Financial Officer, and previously Chief Financial Officer. He also served as the Chief Financial Officer at EPPCO Enterprises, Inc., an importer and manufacturer of consumer and aftermarket products, and as a Senior Manager at Ernst & Young LLP and its successor Cap Gemini Ernst & Young LLC. Since 2010, Neil Goldman has been a member of the board of directors of Ohio Bridge Corp. He is a Certified Public Accountant and received a Bachelor of Science degree in Business-Accountancy from Miami University (Ohio).

Current management positions

- BioPorto A/S, Executive Vice President and Chief Financial Officer
- Ohio Bridge Corp., Member of the Board of Directors

Previous management positions in the past five years

- J.S. Held LLC, Executive Vice President, Corporate Development and Chief Financial Officer
- Chembio Diagnostics, Inc., Executive Vice President and Chief Financial Officer

8.6. Key Employee

The Key Employee is employed by the Company or its affiliates with responsibility for his functional areas. The Company's current Key Employee is:

Name	Position	Year of first appointment	Year of appointment to current position
Christopher Bird	Chief Medical Officer	2019	2019

8.7. Key Employee – Biography

Other than as presented below, the Key Employee has not been a member of the administrative, management or supervisory bodies of a company or a partnership or a partner in a partnership outside the Company within the past five years.

Christopher Bird (born 1977, American nationality) was appointed Chief Medical Officer of the Company in August 2019. Christopher Bird has a robust scientific background and a track record of delivering strong results in business development, finance, sales and marketing. He most recently served as Head of North American Medical and Scientific Affairs at Roche Diagnostics Corp., where he had responsibility for strategy and execution of all clinical education, study management and field support during his 10-year tenure. Christopher Bird has a BA in Physiology from Brigham Young University, a MA in Biochemistry and Molecular Biology from University of California Los Angeles and a DPhil in Molecular Immunology from Oxford University, where he was an Abraham Scholar.

Current management positions

- BioPorto A/S, Chief Medical Officer
- Chimeris, Chairman of the Board of Directors

Previous management positions in the past five years

- Connor Prairie, Board member
- Roche Diagnostics Corp., Corporate Executive

8.8. Statement of kinship

There are no family ties among the members of the Board of Directors, the Executive Management or the Key Employee.

8.9. Statement on past records

During the past five years, none of the members of the Board of Directors, the Executive Management or the Key Employee have been (i) convicted of fraudulent offenses; (ii) directors or officers of companies that have entered into bankruptcy, receivership, liquidation or companies put into administration, or (iii) subject to any official public incrimination and/or sanctions by statutory or regulatory authorities (including designated professional bodies), and have not been disqualified by a court from acting as a member of an issuer's board of directors, executive management or supervisory body or from acting in the management or conduct of the affairs of any issuer.

8.10. Statement on conflicts of interest

No actual or potential conflicts of interest exist between any of the duties of the members of the Board of Directors, the Executive Management and the Key Employee and their private interests or other duties, it being noted that the board member Jan Leth Christensen is a controlling shareholder in Ejendomsselskabet JANO ApS, which is a Major Shareholder (as hereinafter defined) of BioPorto A/S and a Guarantor in the Offering (see "*9. Major shareholders.*").

It follows from the Rules of Procedure of the Company's Board of Directors and the Danish Companies Act that a member of the Board of Directors or the Executive Management shall not participate in the preparation, discussions or the decision-making process concerning an agreement between the Company and the member in question or concerning legal proceedings between the member in question and the Company or an agreement between the Company and any third party or legal proceedings brought against any third party if the member in question has a significant interest therein that may conflict with its interests.

9. Major shareholders

Pursuant to section 38 of the Danish Capital Markets Act and section 55 of the Danish Companies Act, the Company has as at the Prospectus Date received notifications of holdings of 5% or more of the share capital or voting rights from the shareholders (the "**Major Shareholders**") below:

Shareholder	Ownership interest as per latest notification
Media-Invest Danmark A/S	10.38%
Ejendomsselskabet Jano ApS	>10%

The Company is not authorized to issue company announcements regarding major shareholdings unless the Company has received a prior notice to that effect from a shareholder. Thus, the actual ownership interest of the Major Shareholders stated in the specification above may have changed.

The Major Shareholders do not have voting rights that differ from other shareholders. All Shares in the Company rank pari passu, including with respect to voting rights. All Shares will carry one (1) vote per nominal value of DKK 1.

The Company is not aware of being owned or controlled, directly or indirectly, by others, and the Company is not aware of any agreements that could later result in others taking over the control of the Company.

10. Related party transactions

The Company has on February 1, 2022, entered into an agreement with PME Holding ApS, an entity wholly owned and controlled by the board member Peter Mørch Eriksen, regarding Peter Mørch Eriksen's provision of consulting and advisory services to the Company in relation to the Offering. The agreement will terminate at such time the provision of consultancy services under the agreement are completed, but in no event later than 31 March 2022. The Company considers the agreement to be consistent with market terms.

Other than as set out above and except for compensation and benefits received as a result of membership of the Board of Directors and Executive Management or employment with the Company and the advance commitment and guarantee undertakings from the Board of Directors and Executive Management described under *"20.16.2. Terms and conditions of the offer of securities to the public – Placing and underwriting – Advance commitments and guarantees",* the Company has not entered into any related party transactions (within the meaning of IFRS) since the FY2020 Financial Statements and the 3rd Quarter 2021 Financial Statements.

See the FY2020 Financial Statements and the 3rd Quarter 2021 Financial Statements for related party transactions incorporated into this Prospectus by reference.

11. Information on assets and liabilities, financial position, results and dividends

11.1. Financial statements

The information explicitly listed in the table below has been incorporated by reference into this Prospectus pursuant to Article 19 of the Prospectus Regulation. Non-incorporated parts of the documents incorporated by reference are either not relevant for the investor or covered elsewhere in this Prospectus. Direct and indirect references in the documents included in the table below to other documents or websites are not incorporated by reference and do not form part of this Prospectus. The documents speak only for the period in which they are in effect and have not been updated for purposes of this Prospectus. Potential investors should assume that the information in this Prospectus as well as the information incorporated by reference herein is accurate only in the period in which they are in effect.

The information incorporated by reference into this Prospectus is exclusively set out in the cross reference table below, and is available on the Company's website https://bioporto.com/investor-relations/.

Document/information:
FY2019 Financial Statements
Published on 11 March 2020
Management statement, page 75
Independent auditor's report, pages 76-77
Consolidated financial statement including notes, pages 34-74
FY2020 Financial Statements
Published on 17 March 2021
Management statement, page 72
Independent auditor's report, pages 73-74
Consolidated financial statement including notes, pages 31-71
Half Year 2021 Financial Statements
Published on 18 August 2021
Management statement, page 8
Consolidated financial statement including notes, pages 9-14
3rd Quarter 2021 Financial Statements
Published on 17 November 2021
Management statement, page 9
Consolidated financial statement including notes, pages 10-15
Articles of Association
Dated 2 March 2022

11.2. Auditing of financial statement

The audit report for the FY2019 Financial Statements is included in this Prospectus by reference.

The audit report for the FY2020 Financial Statements is included in this Prospectus by reference.

The Half Year 2021 Financial Statements and the 3rd Quarter 2021 Financial Statements are both unaudited.

See *"11.1. Information on assets and liabilities, financial position, results and dividends – Financial statements"*.

11.3. Legal and arbitration proceedings

As of the Prospectus Date, the Company is involved in litigation regarding the Company's patents (see "*1.4.3. Risk factors – Risks related to the Company's Intellectual Property – The Company may be unable to protect or effectively enforce its intellectual property rights and such rights may be found invalid or unenforceable*").

As part of its ordinary course of business, the Company is, and will from time to time be, involved in discussions, disputes and legal proceedings, including claims relating to, for example, commercial counterparties, employees, intellectual property infringement or violations and other business-related disputes.

The results of such disputes and legal proceedings may be hard to predict, and the Company's assessment of the relevant disputes and proceedings may change as they unfold. The Company expenses legal fees as incurred and records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. An unfavorable outcome to any material legal matter may result in damages being awarded, injunctions and/or termination of product lines, all of which could have financial implications exceeding any provisions made and therefore have an adverse effect on the Company's business, operating results, cash flow and financial position.

Other than set out above, the Company is currently not involved in any governmental, legal or arbitration proceedings, and the Executive Management is not aware of any such proceedings being threatened that the Company considers could have a significant effect on the Company's financial position or profitability, nor has the Company been involved in any such governmental, legal or arbitration proceedings during the previous 12 months as of the Prospectus Date.

11.4. Significant change in the issuer's financial position

There have been no significant changes to financial position of the Company since the end of the period covered by the 3rd Quarter 2021 Financial Statements. Over the period, the Company has realized revenue and operating loss (EBIT) consistent with its Estimate for 2021 and Preliminary Guidance for 2022. The Company's cash balance as at the Prospectus Date is approx. DKK 34 million (unaudited). As reflected in the Working Capital statement set out in *"Key information on persons involved in the Offering, capitalization and use of proceeds – Working capital statement"*, the Company is of the opinion that, as at the Prospectus Date, and without taking into account any net proceeds the Company may raise through the Offering and potential other equity offerings in the period, its present working capital, including its current cash position and other sources of funds, is not sufficient to meet the Company's present requirements considering a twelve months' period after the Prospectus Date being 7 March 2022

11.5. Pro forma financial information

No pro forma financial information has been included in this Prospectus.

11.6. Dividend policy

The Company has not declared or made any dividend payments for the last financial year. Currently, the Company intends to use all available financial resources as well as free cash flow, if any, for purposes of the Company's current and future business. As of the date hereof, the Company does not expect to make dividend payments within the foreseeable future.

Any future determination related to the Company's dividend policy and the declaration of any dividends will be made at the discretion of the Board of Directors subject to approval at the Company's general meeting and will depend on a number of factors, including the Company's results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law, and other factors the Board of Directors deems relevant. There can be no assurances that the Company's performance will facilitate dividend payments, and, in particular, the Company's ability to pay dividends may be impaired if any of the risks described in this Prospectus were to occur. See "1. *Risk factors*".

As at the Prospectus Date, the Board of Directors is not authorized to distribute extraordinary dividends.

All Shares in the Company rank *pari passu* in respect of, inter alia, eligibility to receive dividends and participate in share buybacks. Upon the issuance and registration of the New Shares with the Danish Business Authority, the New Shares will be entitled to receive dividends to the extent any dividends are declared and payable with respect to the Shares.

12. Additional information

12.1. Share capital before and after the Offering

As of the Prospectus Date, the Company's registered share capital had a nominal value of DKK 267,754,404 divided into 267,754,404 Existing Shares with a nominal value of DKK 1 each and all issued within the same share class. No shares carry special rights. All Existing Shares are issued and fully paid up.

Assuming completion of a fully-subscribed Offering and registration of the capital increase with the Danish Business Authority, the Company's registered share capital will be nominally DKK 334,693,005 divided into 334,693,005 Shares with a nominal value of DKK 1.

12.2. Incentive warrant program

12.2.1. Warrants

The Company has a long-term share-based incentive warrant program for members of management and certain key employees. A total of 15,300,000 warrants are outstanding from the various grants. As reflected in the Company's remuneration policy, most recently amended at the Company's annual general meeting in April 2021, the purpose of incentive-based remuneration is to encourage employees and management to contribute to fulfil the Company's long-term goals as determined by the Board of Directors, including long-term value creation.

Grants of warrants under the program are made at the discretion of the Board of Directors. Vesting of warrants granted in 2018 are subject to KPIs defined by the Board of Directors. The warrants granted in 2019, 2020 and in February 2021 vest two years after grant. The warrants granted in December 2021 generally vest over a period of four years. Out of these, 1.45 million warrants are subject to accelerated vesting upon U.S Food & Drug Administration approval of The NGAL Test for pediatric use.

Exercise periods for the warrants vary, and the warrants expire no later than five years after the date of grant. Warrants that are not exercised on or before their expiration date lapse without compensation or other consideration. Vesting and exercise may in some cases be accelerated, including without limitation in case of take-overs, change of control and/or other business combinations. The warrants are subject to good/bad leaver provisions and claw back provisions that are, where applicable, documented in Appendix 1 of the Company's Articles of Association.

The number of warrants and/or exercise prices associated therewith will generally be adjusted in case of changes in the company's share capital structure affecting the value of the warrants. Further, the warrants may be adjusted (and/or vesting and exercise may accelerate) in certain extraordinary events, including without limitation a resolution to liquidate or delist the Company, the sale of all the Company's activities or licensing of all material rights, certain (de)mergers, and third parties' redemption of the Company's shareholders. Certain U.S. based participants are entitled to compensation for taxes exceeding taxation as U.S. tax resident only.

The terms governing the Company's warrant program are attached to the Articles of Association which are collectively incorporated herein by reference and available on the Company's website.

12.2.2. Outstanding warrants

At the time of publication of the Prospectus, warrants representing a total of 5.41% of the Company's share capital on a fully diluted basis are outstanding. Annexes 1.3 and 1.4 to Appendix 1 of the Articles of Association (which are incorporated by reference in this Prospectus) set out the individual warrants grants, including vesting requirements, exercise prices and applicable vesting and exercise periods and acceleration events. The outstanding warrants will be adjusted in connection with the Offering to account for the dilutive effects of the Offering. A list of the outstanding warrants before adjustments is set out below:

Warrants outstanding at Prospectus Date (pre-adjustment)

Time of grant	No. of outstanding warrants	Exercise price in DKK	Exercise period
August 2018	400,000	2.28	August 2022 – August 2023
August 2019	1,250,000	1.70	August 2021 – August 2024
May 2020	1.150.000	1.48	May 2022 – May 2025
February 2021	350,000	6.11	February 2023 – February 2026
December 2021	12,150,000	2.47	December 2022– December 2026 (vesting schedule applies)
	15,300,000	N/A	N/A

12.3. Trademarks – all rights reserved

The BioPorto name is a trademark registered to the Company and other terms, including product names, and the BioPorto logo are the Company's trademarks. For convenience, such trademark appears in this Prospectus without ® and ™ symbols, but that practice does not mean that BioPorto will not assert, to the fullest extent under applicable laws, its rights to such trademarks.

13. Regulatory disclosures

Below is a summary of the inside information published by the Company in accordance with Regulation (EU) 596/2014 on market abuse ("**Market Abuse Regulation**") during the 12 months preceding the Prospectus Date:

13.1. Financial information

On November 17, 2021, the Company published its interim report for the 3rd quarter 2021.

13.2. Products

On June 29, 2021, the Company announced that it expected completion of its clinical study and submission of a De Novo application to the FDA for pediatric use of The NGAL Test during the summer, and that the Company awaited US test results for the rapid gRAD-based SARS-CoV-2 assay (before determining to proceed towards EUA and CE mark in the second quarter of 2021).

On August 31, 2021, the Company announced that it had successfully completed an interim analysis of data from its clinical trial evaluating The NGAL Test in pediatrics with encouraging results.

On November 3, 2021, the Company announced its decision to continue patient enrollment for its pediatric clinical trial of NGAL beyond its original goal of December 31, 2021, into the first half of 2022.

On November 19, 2021, the Company announced that the FDA had recommended the Company not to pursue an EUA for its NGAL assay for the prediction of renal replacement therapy in COVID-19 patients.

13.3. Appointments

On April 26, 2021, the Company announced that it had initiated a search for a new Chief Financial Officer as Ole Larsen had resigned. On May 5, 2021, the Company announced that Peter Mørch Eriksen had resigned as Chief Executive Officer, but would continue to support the Company until January 2022.

On October 20, 2021, the Company announced appointment of Anthony Paul Pare as new Chief Executive Officer as well as certain changes to the Board of Directors, which included election of Christopher Lindop as chairman for the Board of Directors. On October 20, 2021, the Company also announced appointment of Neil Allan Goldman as chief financial officer and executive vice president.

13.4. Related party transactions

In addition, the Company disclosed certain transactions with persons discharging managerial responsibilities in the Company in accordance with Article 19 of the Market Abuse Regulation.

14. Material agreements

This section contains brief summaries of: (i) material agreements, other than agreements entered into in the ordinary course of business, to which the Company or its wholly owned subsidiary BioPorto Diagnostics A/S ("**BioPorto Diagnostics**") is a party, for the two (2) years immediately preceding publication of this Prospectus; and (ii) other agreements (not being agreements entered into in the ordinary course of business) entered into by the Company or BioPorto Diagnostics which contain provisions under which the Company or BioPorto Diagnostics has an obligation or entitlement which is material as of the Prospectus Date.

14.1. Non-exclusive Licensing Agreements with Abbott Laboratories

As part of an agreed patent settlement, BioPorto Diagnostics entered into several agreements with Abbott in 2014 in order to license their respective NGAL Patents and applications, with the only remaining substantive agreement being the non-exclusive, worldwide, royalty-bearing license to Abbott within specific fields of use to BioPorto Diagnostics' NGAL Patents and applications. This agreement will remain in full force and effect until all licensed patents under the agreement have expired.

14.2. Exclusive In-licensing Agreement with The Trustees of Columbia University

In December 2016, the Company entered into an exclusive, worldwide, sub-licensable, royalty-bearing license agreement with The Trustees of Columbia University for several NGAL blood/serum/plasma patents/applications and later amended to add urine patents and patent applications. With respect to certain NGAL urine patents, the license is semi-exclusive. Pursuant to the agreement, the Company has certain milestone obligations. The agreement will remain in full force and effect until the expiration of the last valid claim under the licensed patents and is subject to commercially agreed termination provisions.

14.3. Exclusive License Agreement with Rapid Assays ApS

In January 2018, the Company entered into an exclusive, worldwide, royalty-bearing, sub-licensable license from Rapid Assays ApS for patents related to gRAD and a license to manufacture, develop and commercialize gRAD. The agreement remains in full force and effect until the expiration of the last valid claim under the licensed patents.

14.4. Supply and Distribution Agreement with Siemens Healthcare Diagnostics Products GmbH

In December 2015, the Company entered into a worldwide, exclusive supply and distribution agreement with Siemens for The NGAL Test for use with the Siemens' proprietary BN series instrument systems (BN II and BN ProSpec). Pursuant to the agreement, the Company manufactures and supplies The NGAL Test to Siemens, and Siemens has exclusive authority to market, resell and distribute The NGAL Test in conjunction with Siemens' proprietary BN series instrument systems. The agreement has been terminated by Siemens and expires at the end of 2022 (see *"1.1.7. Risk factors – Risks related to the Company's businesss – The Company is dependent on third-party partners to sell 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.")*

14.5. Supply and Distribution Agreement with Roche Diagnostics GmbH

In February 2018, BioPorto Diagnostics entered into a worldwide supply and distribution agreement with Roche Diagnostics GmbH ("**Roche GmbH**"), under which BioPorto Diagnostics shall supply Roche with The NGAL Test for use on Roche GmbH's analyzers (Roche cobas c501/c502 analyzers) and pursuant to which Roche GmbH has exclusivity to distribute The NGAL Test on Roche GmbH's analyzers under BioPorto Diagnostics' label. The agreement is subject to commercially agreed termination provisions.

14.6. Agreement for Manufacturing and Supply of Components for The NGAL Test

The Company has entered into an agreement with a foreign manufacturing company for the manufacturing and supply of components for The NGAL Test. The agreement includes the Company's retaining the exclusive benefits of certain intellectual property and is subject to commercially agreed termination provisions.

14.7. Purchase Agreement for NGAL Antibodies

In May 2019, BioPorto Diagnostics entered into an agreement with a foreign manufacturing company for the manufacturing of the Company's NGAL antibodies, which are used in the production of NGAL products sold by BioPorto Diagnostics. The agreement is subject to commercially agreed termination provisions.

14.8. Service Agreement for clinical study relating to The NGAL Test

In February 2020, the Company entered into an agreement with a foreign contract research organization for support and service of a clinical study relating to the NGAL Test. The agreement is subject to commercially agreed termination provisions.

14.9. Subscription Commitments

See "*20.16.2. Terms and conditions of the offer of securities to the public – Placing and underwriting – Advance commitments and guarantees*" for a description of the Subscription Commitments.

15. Documents available

For the term of this Prospectus, the following documents are available for inspection at the Company's registered office:

- The Company's Memorandum of Association and Articles of Association.
- The FY2019 Financial Statements.
- The FY2020 Financial Statements.
- The Half Year 2021 Financial Statements.
- The 3rd Quarter 2021 Financial Statements.
- The Prospectus related to the Offering.

Any request for copies of the Prospectus may be made to: Karen Stendal, Legal Counsel ks@bioporto.com.

The Memorandum of Association, Articles of Association, the FY2019 Financial Statements, the FY2020 Financial Statements, the Half Year 2021 Financial Statements, the 3rd Quarter 2021 Financial Statements, and the Prospectus can also be downloaded from the Company's website: https://bioporto.com/investor-relations/. Except for the information expressly incorporated herein by reference, the contents of the Company's website do not form part of the Prospectus and are not incorporated herein.

THE OFFERING

16. Persons responsible, third party information, experts' report and competent authority approval

16.1. Persons responsible and approval from competent authorities

See "*3. Responsibility Statement and Persons Responsible*".

16.2. Experts report and third party statements

See "*2.11. Certain information regarding the Prospectus and the Offering – Third party information.*"

17. Risk factors

See "*1. Risk factors*".

18. Key information on persons involved in the Offering, capitalization and use of proceeds

18.1. Interests of natural and legal persons involved in the issue/offer

Certain members of the Board of Directors and the Executive Management are also shareholders, directly or indirectly, in the Company, and may have provided, directly or indirectly, guarantees or advance undertakings in relation to the Offering. In addition, completion of the Offering and the use of proceeds from the Offering may directly or indirectly be a precondition to the potential satisfaction of performance targets in the Company's incentive programs for the Executive Management and certain employees. Further, the Executive Management holds warrants under the Company's incentive warrant program, which entitles the holders under certain conditions to subscribe for Shares in the Company. These persons therefore have an interest in the completion of the Offering.

The Company is not aware of any other potential interests, including conflicting ones, of natural or legal persons involved in the Offering that may have a material interest in the Offering.

18.2. Reasons for the offer and use of proceeds

The purpose of the Offering is to strengthen the Company's capital resources and advance implementation of the Company's strategic priorities (*see "5.3. Business – Strategic Priorities"*).

If the Offering is completed, the Offering will raise gross proceeds of at least approximately DKK 73.5 million. If fully subscribed, the Offering will raise gross proceeds of approximately DKK 100.4 million. The net proceeds to the Company from the issue of the New Shares in a completed Offering are expected to be at least approximately DKK 66.4 million, and the net proceeds to the Company from a fully subscribed Offering are expected to be approximately DKK 93.3 million, in each case after deduction of costs and expenses payable by the Company in relation to the Offering.

The Company will retain broad discretion over the use of the net proceeds from the Offering, but expects that the 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 as further described in "5.3 Business – Strategic Priorities". Pending the application of the net proceeds, the Company expects to invest the proceeds in investment-grade, interest-bearing instruments or other securities.

In the event that the Offering is not fully subscribed, the Company's activities and investments will be adjusted accordingly, with a related impact on the timing and planned attainment, if at all, of the strategic priorities, as well the potential timing and amount associated with the Company being required or choosing to raise additional capital (see "*1.6.1. Risk factors – 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*").

18.3. Working capital statement

The Company is of the opinion that, as at the Prospectus Date and without taking into account any net proceeds the Company may raise through the Offering and potential other equity offerings in the period, its present working capital, including its current cash position and other sources of funds, is not sufficient to meet the Company's present requirements over the twelve month period after the Prospectus Date of 7 March 2022.

Based on the Company's Consolidated Prospective Financial Information (see "*7. Consolidated Prospective Financial Information*") and the anticipated use of proceeds (see "*18.2. Key information on persons involved in the Offering, capitalization and use of proceeds – Reasons for the offer and use of proceeds*"), the Company expects that if the Offering is completed with gross proceeds of DKK 80 million or more, the Company's cash position following the Offering will be sufficient to meet the Company's present requirements considering a twelve month period after the Prospectus Date. This assessment relies on the assumptions applied in the Company's budgets and forecasts as well as customary sensitivities, existing capital resources and assumptions concerning the timing, costs and resources required to undertake the Company's strategic priorities, including the Company's ongoing clinical trials and planned FDA submission of The NGAL Test in the U.S all of which under current circumstances remain difficult to predict. Further, this assessment is subject to the risk factors applicable to the Company. In the event that any of the risk factors relating to the Company materialize, including if the adverse U.S. clinical trial environment associated with the outbreak of COVID-19 worsen or persist longer than expected, the Company's capital resources (including the proceeds from the Offering) may be significantly and adversely affected to an extent where they are insufficient to meet the Company's present capital requirements considering a twelve months' period after the Prospectus Date. In such case, or in case the Offering is completed with gross proceeds below DKK 80 million, the Company will take mitigating actions to seek to protect or further strengthen its financial position, including reducing costs and potentially by raising further capital, although there can be no assurance that any such future cost reduction efforts will be successful or that additional capital will be available to the Company on acceptable terms, or at all (see "*1.6.1. Risk factors – 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*").

In the event that the Offering is completed and the Company's ongoing R&D, ongoing clinical trials and planned FDA submission of The NGAL Test in the U.S, and/or commercialization efforts are more positive than expected, the Company may choose to accelerate projects and/or increase spending, in which case the Company may be required or may choose to raise additional capital prior to the twelve month period after the Prospectus Date.

If, contrary to the Company's expectations, the Offering is not completed, the Company expects based on current budgets and forecast that it will require additional financing sometime in the second half of 2022. The Company would thus proceed to take mitigating actions to seek to protect or further strengthen its financial position, including by reducing costs and seeking additional financing. The amount of potential cost reductions and required additional financing would depend on a range of circumstances, and the Company's priorities at the time, and therefore cannot be reasonably predicted. Further, there can be no assurance that any such future cost reduction efforts will be successful or that additional capital will be available to the Company on acceptable terms, or at all, and ultimately a lack of financing may lead to the Company to divest or wind up its operations.

18.4. Capitalization and indebtedness

The following tables set forth the unaudited consolidated capitalization, indebtedness (distinguishing between guaranteed and unguaranteed, secured and unsecured) and cash, cash equivalents, and securities of the Company as of 31 December 2021, reflecting the carrying amounts on the internal bookkeeping of the Company. These tables should be read in conjunction with the FY2020 and FY2019 Financial Statements, the Half Year 2021 Financial Statements, and the 3rd Quarter 2021 Financial Statements, and each of the footnotes thereto.

Capitalization

DKK million	**As of 31 December 2021 (unaudited)**
Current debt	
Guaranteed	-
Secured	0.9
Unguaranteed / unsecured	23.9
Total current debt	**24.8**
Non-current debt	
Guaranteed	-
Secured	-
Unguaranteed / unsecured	10.5
Total non-current debt	**10.5**
Share capital and reserves	
Share capital	267.8
Exchange-rate adjustments	(0.1)
Retained earnings	(222.5)
Total share capital and reserves	**45.1**
Total capitalization	**80.4**

Indebtedness

DKK million	**As of 31 December 2021 (unaudited)**
Cash	
Cash	45.5
Liquidity	**45.5**
Total financial assets	**45.5**
Current financial liabilities	
Current portion of non current debt	3.0
Total current financial liabilities	**3.0**
Non-current financial liabilities	
Other non-current loans	10.5
Total non-current financial liabilities	**10.5**
Total financial indebtedness	**13.5**
Excess of financial assets over financial indebtedness	**32.0**

It is the Company's assessment that there has not been any material change to its capitalization or its total net financial indebtedness since 31 December 2021, other than changes resulting from the ordinary course of business.

19. Information concerning the securities to be offered/admitted to trading

19.1. Type of security, amount of New Shares and ISIN codes

The Offering comprises up to 66,938,601 New Shares, each with Pre-emptive Rights for the Existing Shareholders. Further, the Prospectus comprises the admission of the New Shares to trading and official listing on Nasdaq Copenhagen in connection with the completion of the Offering (see "*20.14 Terms and conditions of the offer of securities to the public – Completion of the Offering*").

19.1.1. Pre-emptive Rights

The Offering is being made at the ratio of 1:4, which means that each Existing Shareholder will be entitled to and will be allocated one (1) Pre-emptive Right for each Existing Share held at the Allocation Time, and that four (4) Pre-emptive Rights will be required to subscribe for one (1) New Share.

Pre-emptive Rights will be allocated free of charge to the Company's Existing Shareholders that are registered as such with Euronext Securities Copenhagen on 10 March 2022. Shares traded after 8 March 2022 will be traded without (ex) Pre-emptive Rights, assuming that such Shares are traded at a customary two-day settlement period.

The Pre-emptive Rights have been approved for trading and official listing on Nasdaq Copenhagen under the interim ISIN code: DK0061685823. An application has been made for the Pre-emptive Rights to be admitted to trading and official listing on Nasdaq Copenhagen to the effect that they can be traded on Nasdaq Copenhagen during the period of 9 March 2022 to 22 March 2022.

19.1.2. The New Shares

The Subscription Period for the New Shares will commence on 11 March 2022 and will close on 24 March 2022. The New Shares to be issued by the Company upon exercise of the Pre-emptive Rights will be of the same class as the Existing Shares. The New Shares are offered at DKK 1.5 per New Share.

After payment of the Subscription Price, the New Shares will be issued under the temporary ISIN code DK0061685906. The New Shares will be registered with Euronext Securities Copenhagen under the temporary ISIN code but will not be admitted to trading and official listing on Nasdaq Copenhagen.

As soon as reasonably possible after registration of the New Shares with the Danish Business Authority, expectedly on 1 April 2022, the New Shares will be admitted to trading and official listing on Nasdaq Copenhagen under the permanent ISIN code for the Existing Shares DK0011048619, expectedly on 4 April 2022, and the temporary ISIN code of the New Shares will be merged with the ISIN code of the Existing Shares, expectedly on 5 April 2022.

19.2. Currency

The Offering will be carried out and trading in the Pre-emptive Rights will each be in DKK. The New Shares are denominated in DKK.

19.3. Resolutions, authorizations and approvals

The New Shares will be issued pursuant to the authorization in articles 16a and 16c of the Articles of Association, according to which the Board of Directors is authorized to increase the Company's share capital by up to nominally DKK 120,000,000 with pre-emptive rights for the Company's shareholders.

The Board of Directors adopted a resolution on 7 March 2022 to exercise the authorization and increase the Company's share capital by between nominally DKK 49,000,000 and nominally DKK 66,938,601 by issue of up to 66,938,601 New Shares with a nominal value of DKK 1.00 each. The capital increase will be effected with Pre-emptive Rights for the Existing Shareholders.

19.4. Transferability of the securities

The Shares, including the New Shares, are negotiable instruments and the Articles of Association contain no restrictions on the transferability of the Shares. Further, no restrictions under Danish law will apply to the transferability of the Shares, including the New Shares.

The acquirer of a New Share may not exercise rights belonging to a shareholder unless such acquirer has been registered in the register of shareholders or has notified and provided proof of the acquisition to the Company. However, this does not apply to the right to receive dividends or other disbursements or to the right to subscribe for New Shares in the event of capital increases.

19.5. Rights attaching to the Pre-emptive Rights and the New Shares

19.5.1. Pre-emptive Rights

Four (4) Pre-emptive Rights carry the right to subscribe for one (1) New Share.

If any of the Pre-emptive Rights are not exercised during the Subscription Period, those Pre-emptive Rights will lapse with no value, and the holder of such Pre-emptive Rights will not be entitled to any kind of compensation (see "*1.7. Risk factors – Risks related to the Offering and the Shares*"). If the holder does not wish to exercise the Pre-emptive Rights to subscribe for New Shares, the holder can sell the Pre-emptive Rights during the above-mentioned Rights Trading Period.

19.5.2. The New Shares

Dividend rights

The New Shares will, when fully paid up and registered with the Danish Business Authority, have the same rights as the Existing Shares, including with respect to eligibility for any dividends after the completion of the Offering (see "*1.7. Risk factors – Risks related to the Offering and the Shares*"). Consequently, the New Shares are eligible for dividends as at the date of registration with the Danish Business Authority, which is expected to take place on 1 April 2022 and in any event before listing of the New Shares.

Any dividends will be paid in DKK to the shareholder's account with Euronext Securities Copenhagen. No restrictions on dividends or special procedures apply to holders of New Shares who are not residing in Denmark. Dividend withholding tax may be withhold by the Company in accordance with applicable Danish law.

Dividends that have not been claimed by shareholders within three (3) years from the time they are payable will in accordance with applicable Danish law be forfeited and will accrue to the Company.

Voting rights

Each New Share will carry 1 vote per nominal value of DKK 1.00

Liquidation rights

In case of the dissolution or winding-up of the Company, the New Shares will be entitled to a proportionate part of the Company's assets after payment of the Company's creditors.

Pre-emptive rights

Under Danish law, the shareholders generally have pre-emptive rights if the general meeting of the Company resolves to increase the share capital by cash payment. However, the pre-emptive rights of the shareholders may be derogated from by a majority comprising at least 2/3 of the votes cast and of the share capital represented at the general meeting if the share capital increase is made at market price.

Redemption and conversion provisions

Except for as provided for in the Danish Companies Act, no shareholder is under an obligation to have his or her Shares redeemed in whole or in part by the Company or by any third party, and none of the Shares carry any redemption or conversion rights or any other special rights.

19.6. Danish legislation on takeovers

19.6.1. Mandatory takeover bids

Applicable rules on mandatory takeover bids are set out in part 8 of the Danish Capital Markets Act and the Executive Order no. 636 of 15 May 2020 on takeover bids issued pursuant thereto.

If a shareholding is transferred, directly or indirectly, to an acquirer or to persons acting in concert with such acquirer (the concert parties), the acquirer and the concert parties must enable all shareholders of the company the option to dispose of their shares on identical terms if such transfer involves the acquirer or the concert parties obtaining control.

Control is obtained when the acquirer or the concert parties directly or indirectly holds at least one-third of the voting rights in a company, unless – under special circumstances – it can be demonstrated that such ownership does not constitute control. An acquirer or concert parties who do not hold more than one-third of the voting rights in a company will, nevertheless, have control if the acquirer or the concert parties have at their disposal (in Danish "*besidder*") at least one-third of the voting rights of a company by virtue of an agreement or have the right to appoint or dismiss the majority of the members of a company's board of directors.

If special conditions apply, the Danish Financial Supervisory Authority may grant an exemption from the obligation to make a mandatory offer.

19.6.2. Squeeze-out

Pursuant to Section 70 of the Danish Companies Act, shares in a company may be redeemed in whole or in part by a shareholder holding more than nine-tenths of the shares and the corresponding voting rights in the company.

Further, pursuant to Section 73 of the Danish Companies Act, a minority shareholder may require that a majority shareholder holding more than nine-tenths of the shares and the corresponding voting rights redeem the minority shareholder's shares.

19.6.3. Major shareholdings

Pursuant to Section 38 of the Danish Capital Markets Act, a shareholder of a company whose shares or financial instruments are admitted to trading on a regulated market within the European Union is required to notify the listed company and the Danish Financial Supervisory Authority as soon as possible if the shareholder's shareholding directly or indirectly represents 5% or more of the voting rights or the share capital, and if the shareholders' shareholding directly or indirectly entails that the 5%, 10%, 15%, 20%, 25%, 50% or 90% thresholds and the thresholds of one-third or two-thirds of the voting rights or the share capital are reached or no longer reached.

The notification must comply with the requirements for the contents thereof set out in Sections 15 and 16 of the Danish Executive Order on Major Shareholders, including the identity of the shareholder and the date when the threshold is reached or no longer reached. Failure to comply with the disclosure requirements is punishable by a fine. When the Company has received such notification, it must publish the contents of such notification no later than within three business days.

Further, the general duty of notification under the Danish Capital Markets Act applies as well as special duties of notification in respect of the Company's insider group pursuant to the Market Abuse Regulation.

19.7. Public takeover bids for the Company

No public takeover bids have been made by any third party in respect of the Existing Shares during the past financial year or the current financial years.

19.8. Taxation

The following summary of Danish taxation is based on applicable Danish laws, rules and regulations, as exist as of the date of this Prospectus. Such laws, rules and regulations could be subject to change, possibly on a retroactive basis. The summary is only meant to provide general guidelines and does not deal with all aspects that could be important for potential investors. It is assumed that the shareholders are the beneficial owners of the shares and dividends. The tax treatment of each investor may depend on the individual investor's specific situation. Potential investors are encouraged to consult their own tax advisors in order to assess specific taxation consequences associated with investment in the Company and how taxation issues might possibly apply locally and abroad, or what the implications involved are, inter alia, possible changes in applicable taxation. Any reference to a "Danish shareholder" or a "foreign shareholder" in the summary below refers to the tax residency and not the nationality of such shareholder.

19.8.1. Taxation of shareholders resident in Denmark for tax purposes

Individuals and companies etc. with Danish tax residency are normally fully liable to pay tax in Denmark. The income of foreign individuals and companies allocated to a Danish permanent establishment will generally also be subject to Danish tax. Further, the income of foreign companies controlled from Denmark having income mainly of a financial nature may be taxable in Denmark. The income of foreign companies will generally also be subject to Danish tax if a Danish affiliated company has opted for international joint taxation under Danish tax rules.

In case the individual or company is also fully liable to pay tax in another country, specific rules not mentioned in this summary may apply.

19.8.2. Taxation of dividends

Individuals

For individuals, dividends are taxed as share income. In the income year 2022, a tax rate of 27% must be paid on the annual share income up to DKK 57,200 (DKK 114,400 for married couples cohabiting at the end of the income year) and 42% of the annual share income exceeding DKK 57,200 (DKK 114,400 for married couples cohabiting at the end of the income year).

The thresholds are adjusted annually and include all share income of the individual/couple concerned during the year. In case of dividend payments, 27% dividend tax is normally withheld by the company.

Special rules apply to individuals' investment of pension savings. See "*19.8.3. Information concerning the securities to be offered/admitted to trading – Taxation – Capital gains taxation"* below for a description of the tax treatment of investment of pension savings.

Individuals, investing through an investment savings account (Aktiesparekonto)

Dividends paid to individuals on shares held through an investment savings account will be taxed according to the same rules as for sale of shares held by individual shareholders investing through an investment savings account. See *"19.8.3. Information concerning the securities to be offered/admitted to trading – Taxation – Capital gains taxation"* below.

Companies etc.

In general, a company holding shares in another company admitted to trading on a regulated market is liable for tax on dividends received on the shares. The dividends are taxable at a corporate income tax rate of 22%, which is withheld by the company distributing the dividends in connection with the payment of dividends.

Regardless of ownership period, companies may receive tax-exempt dividends in case the shares are subsidiary shares or group company shares. See "*19.8.3. Information concerning the securities to be offered/admitted to trading – Taxation - Capital gains taxation"* below regarding the definition of subsidiary shares and group company shares.

19.8.3. Capital gains taxation

Individuals

Capital gains realized on shares are taxed as share income. In the income year 2022, 27% tax must be paid on the annual share income up to DKK 57,200 (DKK 114,400 for married couples cohabiting at the end of the income year) and 42% of the annual share income exceeding DKK 57,200 (DKK 114,400 for married couples cohabiting at the end of the income year). The maximum amounts allowed are adjusted annually and include all share income of the individual/couple concerned during the year.

In case of loss on shares admitted to trading on a regulated market, the loss may be offset against taxable income (capital gains and dividends) from other shares admitted to trading on a regulated market. If the individual is married and the total loss on shares admitted to trading on a regulated market exceeds the individual's capital gains and dividends realized on other shares admitted to trading on a regulated market, the remaining loss is offset against the spouse's share income pursuant to similar rules provided that the spouses are cohabiting at the end of the income year. In case there are still unutilized losses, these may be carried forward indefinitely to be offset against future income from similar shares.

It is a condition for offsetting losses on shares admitted to trading on a regulated market that the Danish tax authorities have received information on the identity of the shares, the quantity, the acquisition date, and the acquisition price before expiry of the deadline for filing the tax return for the income year in which the shares were acquired. The information is generally provided to the Danish tax authorities automatically when the shares are placed in a custody account with a Danish financial institution.

Capital gains and losses are calculated pursuant to the average cost formula according to which the acquisition price of each specific share is calculated as a proportionate part of the total acquisition price for the shareholder's total number of shares in the issuing company.

Individuals, investment of pension savings

Within certain limits, investors have the possibility of placing pension savings in shares having the effect that the net profit will be subject to the Danish Pension Returns Tax Act. The net profit is calculated as the annual realized and unrealized capital gains and losses and added any other profits (such as dividend etc.). The annual net profit is taxed at a rate of 15.3%. Pension return tax is normally settled by the pension company. A transfer from a pension savings custody account to the individual's ordinary custody account is considered a disposal and must be made at market value.

Individuals, capital gains taxation in respect of investment through an investment savings account (Aktiesparekonto)

Gains and losses on shares owned through an investment savings account are taxable according to the mark-to-market principle. According to the mark-to-market principle, each year's taxable gain or loss is calculated as the difference between the market value of the shares at the beginning and end of the tax year plus any dividend received on shares owned through the investment savings account. Any annual gain will be subject to 17% taxation, and any loss will be deferrable. In 2022, the account is limited to a deposit of DKK 103,500.

Taxation will take place on an accrual basis even if no shares have been disposed of and no gains or losses have been realized. If the shares owned through an investment savings account are sold or otherwise disposed of before the end of the income year, the taxable income of that income year equals the difference between the value of the shares at the beginning of the income year and the realization sum. If the shares owned through an investment savings account are acquired and realized in the same income year, the taxable income equals the difference between the acquisition sum and the realization sum. If the shares are acquired in the income year and not realized in the same income year, the taxable income equals the difference between the acquisition sum and the value of the shares at the end of the income years.

Companies etc.

Irrespective of the period of ownership, companies are liable for tax on capital gains and losses on shares admitted to trading on a regulated market except in case of subsidiary shares and group company shares. The annual realized and unrealized capital gains are taxed pursuant to the mark-to-market principle and is included in the statement of taxable income. Losses calculated pursuant to the mark-to-market principle may be deducted in the statement of taxable income, including in other corporate income. The taxable corporate income is taxed at a rate of 22%.

Capital gains and losses incurred in connection with the sale of group company shares and subsidiary shares are not included in the statement of taxable income of companies. "Subsidiary shares" is generally defined as shares owned by a company holding at least 10% of the share capital of the company issuing the shares. "Group company shares" is generally defined as shares owned by a company, which is jointly taxed (pursuant to section 31 of the Danish Corporation Tax Act) with the company in which shares are owned or which may be internationally jointly taxed (pursuant to section 31 of the Danish Corporation Tax Act) with the company in which shares are owned.

For tax purposes, the transition from subsidiary share status and group company share status to portfolio share status and vice versa is treated as a disposal of shares and acquisition at market value at the time of the transition of status.

Special anti-avoidance rules may apply to prevent, e.g., that shareholdings are pooled in an intermediary holding company in order to avoid taxation of dividends and capital gains. These rules are not further described in this summary.

19.8.4. Anti-avoidance rules

As a general note, Danish law has both specific and general anti avoidance rules (the "GAAR"), which will not be described in detail. The GAAR focuses on substance over form. Under the GAAR the Danish Tax Authorities can set aside a setup, which constitutes a fictitious arrangement, which is carried out for the main purposes (or with one of the main purposes) of tax avoidance and resulting in no taxes being paid. This is the case where the relevant scheme presents a number of unusual features which suggest that it had not been entered into for commercial business reasons, but to unduly obtain tax benefits. Subject to the conditions of the GAAR an investor might be denied the benefits of the Council Directive 2011/96/EU of 30 November 2011 as amended (the "**Parent-Subsidiary Directive**") or a tax treaty, and Danish withholding tax of 27 % will in such cases be levied.

19.8.5. Danish taxation of investors not fully liable to pay tax in Denmark

19.8.5.1. Taxation of dividends

Individuals

As a main rule, individuals who are not Danish tax residents are subject to a 27% withholding tax on dividends from Danish companies.

However, it is possible to apply for partial reimbursement of Danish withholding tax if the individual (i) is entitled to a reduction of the Danish tax under a double taxation treaty concluded between Denmark and the tax jurisdiction in which the shareholder is resident; or (ii) holds less than 10% of the Danish company and the competent authority in the state, or in Greenland or in the Faroe Islands, where the person is resident is required to exchange information with the Danish tax authorities according to a double taxation treaty, another international agreement or an administrative agreement of assistance in tax issues. If the shareholder is resident in a country outside the EU, it is also a condition that the shareholder, together with related parties, holds less than 10% of the Danish company. The amount of the reimbursement in question (i) depends on the provisions of the specific double taxation treaty whereas the final withholding tax rate (which also determines the amount of reimbursement) and in situation (ii) constitutes 15%.

Regardless of whether the (final) taxation is reduced as described above, the Danish dividend-distributing company is, as a main rule, obliged to withhold 27% dividend tax. Consequently, the said foreign shareholders subject to a reduced taxation need to file an online application to the Danish tax authorities for the repayment of the excess amount of withholding tax.

Individuals, dividends in respect of investments through an investment savings account (Aktiesparekonto)

Individuals residing outside Denmark will be subject to 15% taxation on any dividend on shares owned through an investment savings account. In 2022, the account is limited to a deposit of DKK 103,500.

For individual shareholders residing outside of Denmark, only dividends paid in respect of shares in Danish companies are included in the 15% taxation.

Companies etc.

As a main rule, companies that are not Danish tax residents are subject to a 27% withholding tax on dividends from Danish companies.

In general, a foreign company may, however, always apply for partial reimbursement of Danish withholding tax down to 22% (similar to the Danish corporate income taxation).

Moreover, companies may apply for reimbursement if the shareholder (i) is entitled to a reduction of tax under the double taxation treaty concluded between Denmark and the tax jurisdiction in which the shareholder is resident; or (ii) holds less than 10% of the Danish company and the competent authority in the state, or in Greenland or in the Faroe Islands, where the person is resident is required to exchange information with the Danish tax authorities according to a double taxation treaty, another international agreement or an administrative agreement of assistance in tax issues. If the shareholder is resident in a country outside the EU, it is also a condition that the shareholder, together with related parties, holds less than 10% of the Danish company. The amount of the reimbursement in question (i) depends on the provisions of the specific double taxation treaty whereas the final withholding tax rate (which also determines the amount of reimbursement) and in situation (ii) constitutes 15%.

Regardless of whether the (final) taxation is reduced as described above, the Danish dividend-distributing company is, as a main rule, obliged to withhold 27% dividend tax. Consequently, the said foreign shareholders subject to reduced taxation need to file an online application with the Danish tax authorities for the repayment of the excess amount of withholding tax.

A foreign company is exempt from withholding tax on dividends received from a Danish company if the foreign company:

a) receives dividends on subsidiary shares and may rely on either reduction or elimination of Danish dividend tax according to the Parent-Subsidiary Directive or according to a double taxation convention between the foreign company's tax jurisdiction and Denmark; or b) receives dividends on group company shares, which are not shares in subsidiaries, when (i) the company receiving the dividends is resident in an EU/EEA member state; and (ii) the taxation of dividends should be waived or reduced according to the provisions of the Parent-Subsidiary Directive or a double taxation convention between the foreign company's tax jurisdiction and Denmark if the shares had qualified as shares in subsidiaries. Accordingly, dividend tax will not be withheld in those two cases.

Increased Danish source taxation of dividend paid to affiliated shareholders resident in certain countries

A 44% Danish withholding taxation/source taxation applies to dividends paid to affiliated individual shareholders and affiliated corporate shareholders if the relevant shareholder is tax resident in a country which is "blacklisted" by EU (i.e. at present American Samoa, Anguilla, Barbados, U.S. Virgin Islands, the Republic of Fiji, Guam, Republic of Palau, Panama, the Independent State of Samoa, Republic of Seychelles, Republic of Trinidad and Tobago and the Republic of Vanuatu).

19.8.5.2. Capital gains taxation

Individuals

As a main rule, individuals who are not Danish tax residents are not liable to pay tax in Denmark on capital gains on the sale of shares in Danish companies.

However, capital gains and losses on shares in Danish companies are taxable in Denmark pursuant to the same rules that apply to individuals resident in Denmark in case the shares are attributable to a permanent establishment in Denmark. Special rules apply to distributions in connection with capital reductions or the resale of shares to the issuing company.

Companies etc.

As a main rule, companies that are not Danish tax residents are not liable to pay tax in Denmark on capital gains on the sale of shares in Danish companies. Capital gains and losses on shares in Danish companies are taxable in Denmark pursuant to the same rules that apply to corporate investors resident in Denmark in case the shares are attributable to a permanent establishment in Denmark.

Special rules apply to distributions in connection with capital reductions or the resale of shares to the issuing company as well as sale of shares to a group company.

19.8.6. Share transfer duty

There is no share transfer duty in Denmark.

19.8.7. Announced alterations of the Danish tax law

Dividends - proposal for a Net-Withholding Mechanism

The Danish Government has published a proposal for a so-called 'net-withholding mechanism' for the handling of dividend withholding taxation of 1) non-resident individuals having shares in Danish listed companies; and 2) non-resident corporate entities having portfolio shares in Danish listed companies (i.e. shares not being subsidiary shares or group company shares).

The key point in the proposed mechanism is the elimination of the dividend tax reclaims, as dividend payments from Danish listed companies to non-resident shareholders will be distributed on a net basis and no longer on a gross basis. From a technical perspective, this requires that non-resident shareholders must disclose certain key information to their respective custodian bank(s), including, inter alia, the characteristics of the entity, domicile state for tax purposes, a statement of beneficial ownership of the shares for Danish tax purposes and a power of attorney granted to the custodian.

Based on this information, the Danish Tax Authority then issues a unique taxpayer identification number, which grants a right to receive dividends net of the rate of withholding tax applicable in the relevant tax treaty, e.g., most often 15% (if applicable).

Non-resident shareholders eligible for a special tax treatment different from the general tax rate according the relevant tax treaty, e.g. pension funds with a right to 0% in Danish dividend withholding tax, must obtain an advance approval from the Danish Tax Authority to qualify for such special treatment.

Once the non-resident shareholders have submitted information and received a unique taxpayer identification number, they will receive dividends net of the applicable rate.

Non-resident shareholders encompassed by the new net-withholding mechanism will no longer be able to request a reclaim under the current procedure. Instead, there is a 45 days rectification period subsequent to a dividend decision. Furthermore, a relief mechanism in a tax treaty is still available for a non-resident shareholder.

Share income tax rate – proposal of an increase from 42% to 45%

The Danish Government has in September 2021 announced that it is contemplating to increase the tax rate for share income for annual share income in excess of DKK 57,200 (DKK 114,400 for married couples cohabiting at the end of the income year) from 42% to 45%. The details of the proposal have not yet been announced.

20. Terms and conditions of the offer of securities to the public

20.1. Subscription ratio, Subscription Price and allocation of Pre-emptive Rights

Each holder of shares registered with Euronext Securities Copenhagen on 10 March 2022 at 5:59 p.m. CET as shareholders of the Company will as Existing Shareholders be entitled to an allocation of Pre-emptive Rights. Each holder of shares will be allocated one (1) Pre-emptive Right for each Existing Share held.

For every four (4) Pre-emptive Rights, the Existing Shareholder will be entitled to subscribe for one (1) New Share against payment of the Subscription Price.

Shares traded after 8 March 2022 will be traded as ex Pre-emptive Rights provided that the Shares are traded at a customary two-day value.

The Pre-emptive Rights and the New Shares will be delivered in book-entry form through allocation to the Existing Shareholders' accounts held with Euronext Securities Copenhagen.

The Pre-emptive Rights have been approved for admission to trading and official listing on Nasdaq Copenhagen to the effect that they can be traded on Nasdaq Copenhagen during the period from 9 March 2022 at 9:00 a.m. CET to 22 March 2022 at 5:00 p.m. CET.

The New Shares will be issued under the temporary ISIN code DK0061685906.

Upon registration of the capital increase relating to the New Shares with the Danish Business Authority, the New Shares will be issued under the temporary ISIN code DK0061685906. The New Shares issued under the temporary ISIN code will not be admitted to trading and official listing on Nasdaq Copenhagen. The New Shares issued under the temporary ISIN code will solely be registered with Euronext Securities Copenhagen.

As soon as reasonably possible after registration of the New Shares with the Danish Business Authority, expectedly on 1 April 2022, the New Shares will, expectedly on 4 April 2022, be admitted to trading and official listing on Nasdaq Copenhagen under the permanent ISIN code for the Existing Shares DK0011048619, and the temporary ISIN code of the New Shares will be merged with the ISIN code of the Existing Shares, expectedly on 5 April 2022.

Upon admission to trading and official listing of the New Shares, the New Shares will be accepted for clearance through Euroclear and Clearstream.

20.2. Subscription Period

The Subscription Period of the New Shares will commence on 11 March 2022 and will close on 24 March 2022. For a description of the procedure of exercise and subscription (see *"20.8. Terms and conditions of the offer of securities to the public – Procedure for the exercise of and trading in Pre-emptive Rights"*).

20.3. Reduction of subscription

Reduction of subscription is not applicable in connection with the Offering.

20.4. Minimum or maximum subscription amounts

In connection with the Offering, the minimum number of New Shares that a holder of Pre-emptive Rights may subscribe for will be one (1) New Share, requiring the exercise of four (4) Pre-emptive Rights and the payment of the Subscription Price. The number of New Shares that a holder of Pre-emptive Rights may subscribe for is not capped. However, the number is limited to the number of New Shares that may be subscribed for through the exercise of the Pre-emptive Rights held or acquired.

20.5. Subscription for Remaining Shares

Remaining Shares may, without compensation to the holders of unexercised Pre-emptive Rights, be subscribed for by Existing Shareholders or Qualified Investors, who have made binding undertakings to subscribe for Remaining Shares before the expiry of the Subscription Period.

In case of oversubscription of Remaining Shares in connection with binding undertakings, such Remaining Shares will be allocated according to apportionment keys determined by the Board of Directors in its sole and absolute discretion.

If the subscription orders from Existing Shareholders and Qualified Investors do not exceed the number of Remaining Shares, the Company will issue the number of Remaining Shares subscribed for.

Existing Shareholders and Qualified Investors wishing to subscribe for Remaining Shares must submit the application form in Annex A to their own custodian institution or financial intermediary. The application form must be submitted within an appropriate amount of time for the custodian institution or the financial intermediary to process and forward the application form to Arbejdernes Landsbank so that the application form is received by Arbejdernes Landsbank no later than on 24 March 2022 at 5:00 p.m. CET.

Payment for any Remaining Shares shall take place in accordance with the provisions set out in Annex A.

20.6. Payments and delivery

Upon exercise of the Pre-emptive Rights related to the New Shares, the holder must pay DKK 1.5 per New Share subscribed for. Payment for the New Shares will be made in DKK on the date of subscription, but no later than on 24 March 2022, against registration of the New Shares in the investor's account with Euronext Securities Copenhagen under the temporary ISIN code DK0061685906. Holders of Pre-emptive Rights are required to adhere to the account agreement with their own custodian institution or other financial intermediary through which they hold Existing Shares in accordance with the rules of such institution or intermediary. Financial intermediaries through which a holder may hold Pre-emptive Rights may require payment by an earlier date.

20.7. Announcement of the results of the Offering

The results of the Offering will be communicated in a company announcement expected to be published through Nasdaq Copenhagen no later than two (2) Trading Days after the expiry of the Subscription Period (expected to be on 28 March 2022).

20.8. Procedure for the exercise of and trading in Pre-emptive Rights

Holders of Pre-emptive Rights who wish to subscribe for New Shares will be required to do so through their own custodian institution or other financial intermediary in accordance with the procedures of such institution or intermediary. The deadline for notification of exercise depends on the holder's agreements with and the rules and procedures of the relevant custodian institution or other financial intermediary, and the deadline may be earlier than the last day of the Subscription Period. Once a holder has exercised its Pre-emptive Rights, such exercise may not be revoked or modified, except as set forth in this Prospectus with respect to any withdrawal rights in connection with the filing of a supplement as a result of a material change that may affect the evaluation of the Pre-emptive Rights, the New Shares or the Existing Shares.

Exercise instructions without the necessary documentation which originates from a person located in the U.S., or which are postmarked in the U.S. or such other jurisdiction in which it would not be permissible to subscribe for the New Shares, will be deemed to be invalid, and no New Shares will be credited to institutions with addresses in the U.S. or any other jurisdictions in which it would not be permissible to subscribe for the New Shares without the required documentation. The Company reserves the right to reject any exercise of the Pre-emptive Rights on behalf of persons who fail to present the required documentation and (i) who for acceptance or delivery of New Shares indicate an address in the U.S. or any other jurisdiction in which it would not be permissible to subscribe for the New Shares; (ii) who cannot show or prove that they are not in the U.S. or any other jurisdiction in which it would not be permissible to subscribe for the New Shares; (iii) who act on behalf of persons in the U.S. or any other jurisdiction in which it would not be permissible to subscribe for the New Shares, unless it is effected on a discretionary basis; or (iv) who, in the opinion of the Company or its agents, have given their exercise instructions or certifications in or sent such instructions or certifications from the U.S. or any other jurisdiction in which it would not be permissible to offer the New Shares (see "*20.17. Terms and conditions of the offer of securities to the public – Transfer restrictions*").

Any holders who exercise their Pre-emptive Rights will be deemed to have represented that they have complied with all applicable legislation. Custodian institutions exercising Pre-emptive Rights on behalf of beneficial owners will be deemed to have represented that they have complied with procedures set out in this Prospectus. Neither the Pre-emptive Rights nor the New Shares have been registered under the U.S. Securities Act of 1933, as amended, (the "**U.S. Securities Act**") or any state securities legislation in the U.S. The Subscription Period will close on 23 March 2022 at 5:00 p.m. CET.

During the Rights Trading Period, holders of Pre-emptive Rights who do not wish to exercise their Pre-emptive Rights to subscribe for New Shares may sell their Pre-emptive Rights on Nasdaq Copenhagen or elsewhere, and a purchaser may use the acquired Pre-emptive Rights to subscribe for New Shares. Holders wishing to sell their Pre-emptive Rights should instruct their custodian institution or other financial intermediary accordingly. Any Pre-emptive Rights which have not been exercised during the Subscription Period will lapse without value, and the holders will not be entitled to any compensation.

20.9. Offering and proceeds

The Offering comprises up to 66,938,601 New Shares. Upon full subscription of the Offering, the gross proceeds will be approximately DKK 100.4 million and the net proceeds (gross proceeds less estimated costs to the Company related to the Offering) are expected to amount to a total of approximately DKK 93.3 million.

The Offering is conditional upon at least 49,000,000 New Shares being subscribed for, corresponding to gross proceeds of DKK 73.5 million and net proceeds of approximately DKK 66.4 million.

20.10. Withdrawal or suspension of the Offering

The Offering may be withdrawn by the Company at any time prior to registration of the capital increase relating to the New Shares with the Danish Business Authority.

If the Offering is withdrawn, any exercise of Pre-emptive Rights that has already taken place will be cancelled automatically. The subscription amount for the New Shares will be refunded (less any transaction costs) to the last registered owner of the New Shares as at the date of such withdrawal. All Pre-emptive Rights will lapse, and no New Shares will be issued.

Trades of Pre-emptive Rights executed during the Rights Trading Period will, however, not be affected. Consequently, investors who have acquired Pre-emptive Rights will incur a loss corresponding to the purchase price of the Pre-emptive Rights and any transaction costs.

Investors who have acquired New Shares will receive a refund of the subscription amount for the New Shares (less any transaction costs). Consequently, investors who have acquired New Shares may incur a loss corresponding to the difference between the purchase price and the Subscription Price of the New Shares and any related transaction costs.

The Company is not liable for any losses that investors may suffer as a result of withdrawal of the Offering including but not limited to, any transaction costs or lost interest.

A withdrawal of the Offering will be announced as a company announcement through Nasdaq Copenhagen. With respect to risks related to withdrawal of the Offering (see "*1.7. Risk factors – Risks related to the Offering and the Shares*").

20.10.1. Withdrawal of applications for subscription

Instructions to exercise Pre-emptive Rights related to the New Shares are irrevocable, except in the event that a supplement to this Prospectus is published pursuant to applicable rules and legislation in Denmark due to any material changes in connection with the information in this Prospectus which may affect the evaluation of the Pre-emptive Rights, the New Shares or the Existing Shares, which occurs or is ascertained between the time of approval of this Prospectus and the final completion of the Offering or the commencement of trading of the New Shares on Nasdaq Copenhagen. Investors who have accepted to exercise Pre-emptive Rights prior to publication of the supplement will be entitled to withdraw their acceptance for three (3) business days after the publication of such supplement. The right to withdraw acceptance under these circumstances will be available to all investors in the Offering, provided the obligation to publish a supplement to this Prospectus was triggered before the closing of the Subscription Period and provided no New Shares have been delivered. If acceptance is not withdrawn within the stipulated period, any acceptance to exercise Pre-emptive Rights in the Offering will remain valid and binding.

20.11. Plan of distribution

There is no pre-allotment of New Shares. The New Shares may be subscribed for by the Existing Shareholders of the Company according to the Pre-emptive Rights allocated.

New Shares which have not been subscribed for by holders of Pre-emptive Rights before the expiry of the Subscription Period (Remaining Shares) may, without compensation to the holders of unexercised Pre-emptive Rights, be subscribed for by Existing Shareholders or Qualified Investors, who have made binding undertakings to subscribe for the Remaining Shares according to the application form in Annex A before the expiry of the Subscription Period. In case of oversubscription of the Remaining Shares, such Remaining Shares will be allocated according to apportionment keys determined by the Board of Directors in their sole and absolute discretion.

20.12. Intentions of Major Shareholders and members of the Board of Directors and the Executive Management with regard to subscription of New Shares

The Company has entered into agreements with each of its Major Shareholders with regard to subscription of New Shares through the exercise of Pre-emptive Rights for an aggregate subscription amount of approximately DKK 24.2 million (see "*20.16.2 Terms and conditions of the offer of securities to the public – Placing and underwriting – Advance commitments and guarantees*"). One of the Major Shareholders, Ejendomsselskabet Jano ApS, is controlled by the board member Jan Leth Christensen.

20.13. Subscription Price

The New Shares are offered at the Subscription Price of DKK 1.5 per New Share (excluding fees, if any, from the investor's own custodian bank or brokers).

20.14. Completion of the Offering

The Offering will only be completed if and when the New Shares subscribed for are issued by the Company upon registration with the Danish Business Authority, which is expected to take place on 1 April 2022 before listing of the New Shares. A company announcement concerning the results of the Offering is expected to be disclosed on 28 March 2022.

20.15. Expected timetable of the Offering

The following table presents the expected timetable of principal events:

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

20.16. Placing and underwriting

20.16.1. Subscription and paying agents

Instructions to exercise Pre-emptive Rights and subscribe for New Shares must be given to each investor's custodian institution or financial intermediary.

Euroclear and Clearstream act as international payment intermediaries:

Euroclear Bank S.A./N.V.
1 Boulevard du Roi Albert II
1210 Brussels
Belgium

Clearstream Banking S A
42 Avenue JF Kennedy
1855 Luxembourg
Luxembourg

20.16.2. Advance commitments and guarantees

The Company has entered into certain advance subscription commitments and guarantee undertakings dated on or about 7 March 2022 with the Guarantors comprising a number of Existing Shareholders, institutional investors and Qualified Investors.. On the terms and conditions of the Subscription Commitments, the respective Guarantors have undertaken to exercise Pre-emptive Rights and/or to subscribe for New Shares representing aggregate gross proceeds of approximately DKK 73.85 million. The Guarantors and committed amounts to subscribe for New Shares through the exercise of Pre-emptive Rights or guarantee undertakings are as follows:

Name	**Address**	**Commitment amounts (DKK million)**
Aktieselskabet Arbejdernes Landsbank	Vesterbrogade 5, DK-1620 Copenhagen V, Denmark	24.38
Formue Nord Markedsneutral A/S	Østre Alle 102, DK-9000 Aalborg, Denmark	15
Media-Invest Danmark A/S	Gammel Kongevej 174, 4., DK-1850 Frederiksberg C, Denmark	12.14
Ejendomsselskabet Jano ApS	Toldbodgade 36A, DK-1253 Copenhagen K, Denmark	12.06

Artha Capital (Investeringsselskabet Artha Max A/S, Investeringsselskabet Optimum A/S, Investeringsselskabet Artha Responsible A/S and Investeringsselskabet Artha Safe A/S)(aggregate for the listed entities)	Strandvejen 58, 3rd floor, DK-2900 Hellerup, Denmark	10
Other institutional investors, Qualified investors or existing shareholders (aggregate)	N/A	0.27

Under the Subscription Commitments, each Guarantor will receive a fee for the subscription of the New Shares of 6% of the amount of their guarantee commitment. If the Offering is not completed, the Guarantors will not receive any fee or other remuneration. Guarantors who are Existing Shareholders will not receive any fee for the undertaking to exercise their Pre-emptive Right.

20.17. Transfer restrictions

The Offering consists of a public offering in Denmark with Pre-emptive Rights for the Company's Existing Shareholders, subject to the restrictions set out in this section 20.17.

20.17.1. General restrictions

The Offering is made pursuant to Danish law, and the Company has not taken any action or will take any action in any jurisdiction, with the exception of Denmark, which may result in a public offering of the Pre-emptive Rights and/or the New Shares.

The distribution of this Prospectus and the Offering is restricted by law in certain jurisdictions, and this Prospectus may not be used for the purpose of, or in connection with, any offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorized or to any person to whom it is unlawful to make such offer or solicitation. The Company does not accept any legal liability for any violation of these restrictions by any person, irrespective of whether such person is an Existing Shareholder or a potential purchaser of Pre-emptive Rights and/or subscriber of the New Shares.

Further, the Pre-emptive Rights and the New Shares are subject to transfer and selling restrictions in certain jurisdictions. Potential purchases of Pre-emptive Rights and/or subscribers of the New Shares must comply with all applicable legislation and regulations in countries or territories in which they acquire, subscribe for, offer or sell Pre-emptive Rights and/or New Shares or possess or distribute the Prospectus and must obtain consent, approval or permission, as required, for the acquisition of New Shares. Persons in whose possession this Prospectus may come are required by the Company to inform about such restrictions and to observe such restrictions.

All investors should examine the tax consequences of an investment in the Pre-emptive Rights and New Shares through their own advisers. This Prospectus does not constitute an offer or an invitation to purchase any Pre-emptive Rights or purchase or subscribe for any New Shares in any jurisdiction in which such offer or invitation would be unlawful.

The Prospectus may not be distributed or otherwise made available, the New Shares may not be offered, sold or subscribed for, directly or indirectly, and the Pre-emptive Rights may not be offered, sold, acquired or exercised, directly or indirectly, in any jurisdiction other than Denmark, unless such distribution, offering, sale, acquisition exercise or subscription is permitted under applicable legislation in the relevant jurisdiction. The Company may request receipt of satisfactory documentation to that effect.

Due to such restrictions under applicable legislation and regulations, the Company expects that some or all investors residing in the U.S., Canada, Australia, Japan and other jurisdictions outside Denmark may not have the Prospectus distributed to them and may not be able to exercise the Pre-emptive Rights or subscribe for the New Shares. The Company makes no offer or solicitation to any person under any circumstances that may be unlawful.

Subject to the satisfaction of certain conditions in the Subscription Commitments, up to 30,000,000 New Shares that have not been subscribed for by holders of the Pre-emptive Rights will be subscribed for by the Guarantors. The Guarantors may sell any New Shares that have not been subscribed for by holders of Pre-emptive Rights in offshore transactions in compliance with Regulation S under the U.S. Securities Act and/or in accordance with other applicable exemptions to the registration requirements of U.S. and other securities laws.

20.17.2. Selling restrictions in the U.S.

Neither this Prospectus nor any advertisement or any other offering material may be distributed, published or otherwise made available by any means or media, directly or indirectly, in whole or in part, in or into the U.S. except to persons reasonably believed to be QIBs or Accredited Investors under an exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act. Securities may not be offered or sold in the U.S. absent (i) registration under the U.S. Securities Act or (ii) an available exemption from registration under the U.S. Securities Act. Neither the Pre-emptive Rights nor the New Shares have been, or will be, registered under the U.S. Securities Act or any applicable securities laws of any state or other jurisdiction of the U.S. Due to such restrictions under U.S. legislation and regulations, the Company expects that some or all Eligible Shareholders or other investors residing in the U.S. may not have the Prospectus distributed to them and may not be entitled to exercise

the Pre-emptive Rights or subscribe for the New Shares. Any person in the U.S. that obtains a copy of this Prospectus or any pre-printed issue statement or application form and that is not a QIB or Accredited Investor is required to disregard them. The Offering is governed by Danish legislation and requirements and, therefore, any information contained in this Prospectus may not be comparable to information contained in prospectuses of U.S. companies for similar transactions.

This Prospectus does not constitute an offer of, or the solicitation of an offer to subscribe for or to buy, or to sell or transfer, any Pre-emptive Rights or New Shares to any person in the U.S. or to persons elsewhere who are U.S. persons (as defined in Regulation S) to whom it is unlawful to make such offer or solicitation or that may result in the requirement to register any Pre-emptive Rights or New Shares under the U.S. Securities Act or qualify any Pre-emptive Rights or New Shares under applicable securities laws of any state or other jurisdiction of the U.S. The New Shares will be sold only to (a) non-US Persons in "offshore transactions" as defined in and pursuant to Regulation S or (b) otherwise to a limited number of persons who are reasonably believed to be QIBs or Accredited Investors under an exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act and who have executed and delivered an investor representation letter addressed to the Company. Consequently, in the U.S., shareholders of the Company who are not QIBs or Accredited Investors cannot exercise Pre-emptive Rights or subscribe for New Shares. In connection with the rights issue, the Company will not affect any transactions or induce or attempt to induce the purchase or sale of any security in or into the U.S.

The offering of the Pre-emptive Rights and the New Shares to eligible shareholders in the U.S. will be the sole responsibility of the Company. Banks or other nominees that hold for shareholders in the Company whose holdings on the record date are nominee registered must not send this Prospectus or any pre-printed issue statement or application form to shareholders with addresses in, or who are located or resident in, the U.S. without the prior written approval of the Company.

The Pre-emptive Rights and New Shares offered by the Company to non-US persons (as applicable for purposes of Regulation S) in the Offering are subject to the conditions listed under Section 903(b)(3), or Category 3, of Regulation S. The Pre-emptive Rights and New Shares are "restricted securities" as defined in Rule 144 promulgated under the U.S. Securities Act. Purchasers of the Pre-emptive Rights or New Shares may not offer, sell, pledge or otherwise transfer those securities, directly or indirectly, in or into the United States or to, or for the account or benefit of, any U.S. person (as defined in Regulation S), except pursuant to a transaction meeting the requirements of Rules 901 to 905 (including the Preliminary Notes) of Regulation S, pursuant to an effective registration statement under the U.S. Securities Act, or pursuant to an exemption from the registration requirements of the U.S. Securities Act. All Pre-emptive Rights and New Shares are subject to these restrictions until at least the expiry of one year after the date of their admission to trading and official listing.

The Pre-emptive Rights and the New Shares have not been approved, disapproved or recommended by the U.S. Securities and Exchange Commission, any state securities commission in the U.S. or any other U.S. regulatory authority, nor have any of such regulatory authorities passed upon or endorsed the merits of the Offering or the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offence in the U.S.

20.17.3. Restrictions on sales in the European Economic Area

In relation to each Relevant Member State, no offering of Pre-emptive Rights or New Shares will be made to the public in any Relevant Member State prior to the publication of a prospectus concerning the Pre-emptive Rights and the New Shares which has been approved by the competent authority in such Relevant Member State or, where relevant, approved in another Relevant Member State and notified to the competent authority in such Relevant Member State, all pursuant to the Prospectus Regulation, except that an offering of Pre-emptive Rights and New Shares may be made to the public at any time in such Relevant Member State pursuant to the following exemptions from the Prospectus Regulation:

a) to any legal entity which is a Qualified Investor;
b) to fewer than 150 natural or legal persons other than Qualified Investors, subject to obtaining the prior written consent of the Company; or
c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation.

In any Relevant Member State other than Denmark, the Prospectus is only addressed to, and is only directed at, investors in such Relevant Member State that fulfil the criteria for exemption from the obligation to publish a prospectus, including Qualified Investors.

For the purposes of the above, the expression an "offer of Pre-emptive Rights and New Shares to the public" in relation to Pre-emptive Rights and New Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the Offering, the Pre-emptive Rights and the New Shares so as to enable an investor to decide whether to acquire the Pre-emptive Rights and acquire or subscribe for the New Shares.

20.17.4. Notice to Investors in the UK

This Prospectus is only being distributed to, and is only directed at, (i) persons outside the UK or (ii) "investment professionals" falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "**Financial Promotion Order"**) or (iii) "high net worth companies" and other persons to whom it may lawfully be communicated, falling within the meaning of Article 49(2)(a) to (d) of the Financial Promotion Order (all such persons being "**Relevant Persons**"). Pre-emptive Rights and New Shares are only available to Relevant Persons and any

invitation, offer or agreement to subscribe for, purchase or otherwise acquire such Pre-emptive Rights or New Shares will be engaged in only with Relevant Persons. Any person who is not a Relevant Person should not act on or rely upon this Prospectus or any of its contents.

20.17.5. Restrictions on sales in Canada, Australia and Japan and any other jurisdictions outside Denmark

The Pre-emptive Rights and the New Shares have not been approved, disapproved or recommended by any foreign regulatory authorities, nor have any of such authorities passed upon or endorsed the merits of the Offering or the accuracy or adequacy of this Prospectus.

This Prospectus may not be distributed or otherwise made available, the New Shares may not be offered, sold or subscribed for, directly or indirectly, and the Pre-emptive Rights may not be offered, sold, acquired or exercised, directly or indirectly, in Canada, Australia or Japan, unless such distribution, offering, sale, acquisition, exercise or subscription is permitted under applicable legislation in the relevant jurisdiction, and the Company receives satisfactory documentation to that effect.

21. Admissions to trading and dealing arrangements

21.1. Admission to trading and official listing

The Company's Existing Shares have been admitted to trading and official listing on Nasdaq Copenhagen under the ISIN code DK0011048619.

In connection with the Offering, the Pre-emptive Rights have been approved for admission to trading and official listing on Nasdaq Copenhagen to the effect that they can be traded on Nasdaq Copenhagen during the period from 9 March 2022 at 9:00 a.m. CET to 22 March 2022 at 5:00 p.m. CET.

The New Shares will be issued under a temporary ISIN code and will not be admitted to trading and official listing on Nasdaq Copenhagen under the temporary ISIN code.

The New Shares may be subscribed for during the period from 11 March 2022 at 9:00 a.m. CET to 24 March 2022 at 5:00 p.m. CET. As soon as reasonably possible after registration of the New Shares with the Danish Business Authority, expectedly on 1 April 2022, the New Shares will be admitted to trading and official listing on Nasdaq Copenhagen under the permanent ISIN code for the Existing Shares DK0011048619, expectedly on 4 April 2022, and the temporary ISIN code of the New Shares will be merged with the ISIN code of the Existing Shares, expectedly on 5 April 2022.

21.2. Market making

The Company has not entered into any market maker agreement.

21.3. Stabilization

The Company has not entered into any agreement regarding stabilization in connection with the Offering.

21.4. Share Issuing Agent

The Company's share issuing agent is:

VP Securities A/S (Euronext Securities Copenhagen)
Nicolai Eigtveds Gade 8
DK-1402 Copenhagen
Denmark

22. Selling securities holders

22.1. Shareholders who have indicated that they expect to sell their Shares or Pre-emptive Rights

There is no selling shareholder as the Offering is structured as an issue of New Shares. The Company has not received any indications from any Major Shareholder that it intends to sell its Pre-emptive Rights.

23. Expenses of the Offering

The estimated costs and expenses payable by the Company related to the Offering, assuming subscription of the maximum number of New Shares (up to 66,938,601 New Shares), are approximately DKK 7.1 million.

Further, the Company will pay Danish account holding institutions as defined in the Danish Capital Markets Act Section 190 a subscription commission of 0.125% of the market value of the New Shares subscribed for through the relevant account holding institution, in connection with the Offering.

The Company will not charge expenses to investors. Investors will have to bear customary transaction and handling fees charged by their account keeping financial institution.

24. Dilution

As a result of the Offering, the Company's share capital will be increased. If an Existing Shareholder exercises its Pre-emptive Rights in full in connection with the Offering, such shareholder's proportionate ownership interest will not be diluted. If an Existing Shareholder decides not to exercise its Pre-emptive Rights, such shareholder's proportionate ownership interest will be diluted by up to 20% depending on final number of New Shares subscribed for and issued.

25. Additional information

25.1. Advisers

Legal adviser to the Company in connection with the Offering:

Gorrissen Federspiel Advokatpartnerselskab
Axeltorv 2
DK-1609 Copenhagen V
Denmark

Auditors to the Company:

PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab
Strandvejen 44
DK-2900 Hellerup
Denmark

26. Glossary

In the Prospectus, the following words and expressions have the meanings stated below, unless the context requires otherwise.

3rd Quarter 2021 Financial Statement	Consolidated financial statement for the period 1 January 2021 – 30 September 2021.
510(k)	A 510(K) is a premarket submission made to the FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent to a legally marketed device (section 513(i)(1)(A) of the FDC) that is not subject to premarket approval.
510(k) Clearance	The FDA's written authorization to market a medical device pursuant to a premarket notification submitted under section 510 of the FDCA.
Abbott	Abbott Laboratories.
ABP	Animal by-product.
ACA	The Affordable Care Act.
Accredited Investor	Accredited investors as defined in Rule 501(a) of the U.S. Securities Act.
AICPA	The American Institute of Certified Public Accountants.
AKI	Acute kidney injury.
Allocation Time	On 10 March 2022 at 5:59 p.m. CET. The time at which any person registered with Euronext Securities Copenhagen as a shareholder of the Company will be entitled to be allocated one (1) Pre-emptive Right for each Existing Share held.
AMC	Academic Medical Center.
Arbejdernes Landsbank	Aktieselskabet Arbejdernes Landsbank, company reg. (CVR) no. 31 46 70 12, Vesterbrogade 5, DK-1620 Copenhagen V.
Articles of Association	The Company's Articles of Association of 2 March 2022.
BioPorto Diagnostics	BioPorto Diagnostics A/S, company reg. (CVR) no. 18 64 58 82, Tuborg Havnevej 15, ground floor, DK-2900 Hellerup, Denmark.
Board of Directors	The board of directors of the Company.
BQP	Biomarker Qualification Program.
CAGR	Compound annual growth rate.
CBRN	Chemical, biological, radiological and nuclear.
CDER	FDA's Center for Drug Evaluation and Research.
CET	Central European Time.
cGMP	Good manufacturing practice.
Chairman	The chairman of the Board of Directors.
CKD	Chronic kidney disease.

Company	BioPorto A/S, company reg. (CVR) no. 17 50 03 17, Tuborg Havnevej 15, ground floor, DK-2900 Hellerup, Denmark, or BioPorto A/S and its consolidated subsidiaries, respectively, considering the context in which it is used.
Consolidated Prospective Financial Information	The prospective consolidated financial information for the financial year ended 31 December 2021.
Corporate Management	The Executive Management and the Key Employee.
COVID-19	When used in this Prospectus, "COVID-19" is used as a general reference to the pandemic involving the pathogen Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2, also referred to as the "Coronavirus") (as well as any related strings of this virus both current and future), to the various political, legislative and behavioral reactions to the pandemic, and to the resulting wide range of severe consequences many of which are unfolding and therefore still subject to considerable uncertainty as to their scope and impact, including without limitation the impact on the macroeconomic environment, on industries and markets, on individual businesses, on individuals and their behavior and on society in general.
CPB	Cardiopulmonary bypass.
CPT	Current Procedural Terminology.
CVR no.	The Danish Central Business Register number.
Danish Business Authority	The Danish Business Authority (in Danish: "Erhvervsstyrelsen").
Danish Capital Markets Act	The Danish Consolidated Act no. 377 of 2 April 2020 on Capital Markets (in Danish: "kapitalmarkedsloven"), as amended.
Danish Companies Act	The Danish Consolidated Act no. 763 of 23 July 2019 on public and private limited companies (in Danish: "selskabsloven"), as amended.
De Novo	A pathway the FDA has defined for medical devices that are new and novel and have not been previously classified, but are low enough risk that they do not require a Premarket Approval (PMA) and a Class III classification.
Delegated Prospectus Regulation	Commission Delegated Regulation (EU) no. 2019/980 of 14 March 2019 as well as Commission Delegated Regulation (EU) 2019/979 of 14 March 2019.
Deputy Chairman	The deputy chairman of the Board of Directors.
DIKI	Drug-induced kidney injury.
DKK	The official currency of the Kingdom of Denmark.
DRG	Diagnosis related groups.
ED	Emergency Department.
EEA	The European Economic Area.
ELISA	Enzyme-linked immunosorbent assay.
ESKD	End-stage kidney disease.
Estimate for FY2021	The Company's consolidated prospective financial information for FY2021.
EU	The European Union.

EUA	Emergency use authorization.
Euroclear	Euroclear Bank S.A./N.V.
Executive Management	The executive management of the Company as registered with the Danish Business Authority at the Prospectus Date.
Existing Shareholders	Any person registered with Euronext Securities Copenhagen as a shareholder of the Company as at the Allocation Time.
Existing Shares	The 267,754,404 issued shares of the Company, comprising the Company's entire share capital.
FDA	The U.S. Food and Drug Administration.
FDASIA	The Food and Drug Administration Safety and Innovation Act.
FDCA	The Federal Food, Drug and Cosmetic Act.
Financial Promotion Order	Financial Services and Markets Act 2000 (Financial Promotion) Order 2005.
FTE	Full time equivalent employee.
Future (NGAL) Products	Covering both Future NGAL Products and Future Products.
Future NGAL Products	The Company's planned expansion of The NGAL Test for use on third-party systems and the use of The NGAL Test for new indications.
Future Products	The Company's new diagnostic products, e.g. on gRAD or other platforms, e.g. the NGALds.
FY2019	The Company's financial year from 1 January 2019 to 31 December 2019.
FY2019 Financial Statements	The consolidated financial statements and notes thereto of the Company for the financial year ended 31 December 2019.
FY2020	The Company's financial year from 1 January 2020 to 31 December 2020.
FY2020 Financial Statements	The consolidated financial statements of the Company and notes thereto for the financial year ended 31 December 2020.
FY2021	The Company's financial year from 1 January 2021 to 31 December 2021.
GDPR	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2020 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
GMO	Genetically modified organism.
gRAD	The Company's in-licensed generic rapid assay device.
Guarantors	The Existing Shareholders, Qualified Investors and other investors who have provided or entered into advance subscription commitments and/or guarantee commitments to or with the Company.
Half Year 2021 Financial Statements	The consolidated financial statements of the Company for the period 1 January 2021 – 30 June 2021.
HHS	The U.S. Department of Health and Human Services.
ICU	Intensive care unit.

IDE	Investigation devise exemption.
IFRS	International Financial Reporting Standards as adopted by the EU.
IRB	The Institutional Review Board.
ISIN	International Security Identification Number.
IVD	In vitro diagnostics.
IVDD	Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
IVDs	In vitro medical devices.
Key Employee	Dr. Christopher Bird.
KOL	Key opinion leaders.
LOS	Length of Stay.
Major Shareholders	Shareholders who have notified the Company that they hold more than 5% of the Company's registered share capital pursuant to the Danish Companies Act and the Danish Capital Markets Act.
Management	The Board of Directors, the Executive Management and the Key Employee.
Market Abuse Regulation	Regulation (EU) No. 596/2014 of 16 April 2014 on market abuse (market abuse regulation) and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/125/EC and 2004/72/EC.
MCMs	Medical countermeasures.
MDD	Directive 93/42/EEC of 14 June 1993 concerning medical devices.
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
MiFID II	EU Directive 2014/65/EU on markets in financial instruments, as amended.
MiFID II Product Governance Requirements	MiFID II, Articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II and local implementing measures.
MSL	Medical science liaison.
Nasdaq Copenhagen	Nasdaq Copenhagen A/S, company reg. (CVR) no. 19 04 26 77, Nikolaj Plads 6, DK-1067 Copenhagen K, Denmark.
Nasdaq Issuer Rules	Nordic Main Market Rulebook for Issuers of Shares effective from 1 October 2021, including supplements relating to Nasdaq Copenhagen.
NDA	New drug application.
NEJM	The New England Journal of Medicine.

New Shares	The Shares issued in connection with the Offering.
NGAL	Neutrophil gelatinase-associated lipocalin.
NGAL Patents	Patents relating to NGAL.
NICU	Neonatal intensive care unit.
Notified Body	An independent and neutral institution appointed by a member state of the European Economic Area to conduct a conformity assessment under the IVDR.
NSE Determination	A determination from the FDA for 510(k) submissions that a device is not substantially equivalent to the predicate device.
Offering	The offering of up to 66,938,601 New Shares at a price of DKK 1.5 per New Share with Pre-emptive Rights for the Company's Existing Shareholders at the ratio of 1:4 meaning that each Existing Shareholder will be entitled to and will be allocated one (1) Pre-emptive Right for each Existing Share held at the Allocation Time, and that four (4) Pre-emptive Rights will be required to subscribe for one (1) New Share.
Parent-Subsidiary Directive	Council Directive 2011/96/EU of 30 November 2011 on the common system of taxation applicable in the case of parent companies and subsidiaries of different Member States.
PCT	International Patent Cooperation Treaty.
PICU	Pediatric ICU.
PMA	A premarket approval application.
Pre-emptive Rights	One (1) Pre-emptive Right allocated for one (1) Existing Share.
Preliminary Guidance for FY2022	The Company's preliminary consolidated prospective financial information for FY2022.
Products	The Company's current commercially available products in certain jurisdictions, i.e. The NGAL Test, antibodies, ELISA Kits.
Prospectus	This prospectus covering the offer of up to 66,938,601 New Shares at a price of DKK 1.5 per New Share with Pre-emptive Rights for Existing Shareholders dated 7 March 2022.
Prospectus Date	7 March 2022.
Prospectus Regulation	Regulation (EU) No. 2017/1129 of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC.
PS-AKI	Persistent severe AKI.
QIBs	Qualified institutional buyers as defined in Rule 144A under the U.S. Securities Act.
Qualified Investors	As defined in the Prospectus Regulation.
Regulation S	Regulation S under the U.S. Securities Act.
Relevant Member State	Each member state of the European Economic Area, where the Prospectus Regulation applies.
Relevant Persons	Persons who: (i) are investment professionals falling within Article 19(5); or (ii) fall within Article 49(2)(a) to (d) ("high net worth companies; unincorporated associations, etc."), of the UK Financial

	Services and Markets Act 2000 (Financial Promotion) Order 2005 or other persons to whom such investment or investment activity may lawfully be made available.
Remaining Shares	New Shares which have not been subscribed for by the Existing Shareholders before the expiry of the Subscription Period.
RH	Rigshospitalet.
Rights Trading Period	The period beginning on 9 March 2022 and ending on 22 March 2022.
Roche	Roche Holding AG and its subsidiaries and affiliates.
Roche GmbH	Roche Diagnostics GmbH.
SCCM	Society for Critical Care Medicine.
sCr	Serum creatinine.
Shares	Existing Shares and the New Shares.
Siemens	Healthcare Diagnostics Products GmbH.
Subscription Commitments	Certain subscription commitments and guarantee undertakings dated on or about 7 March 2022 entered into between the Company and the respective Guarantors.
Subscription Period	The subscription period for the New Shares from 11 March 2022 to 24 March 2022.
Subscription Price	DKK 1.5 per New Share.
Target Market Assessment	Product approval process as defined in "*2.6 Certain information regarding the Prospectus and the Offering – Information to distributors*".
The NGAL Test	A quantitative particle-enhanced turbidimetric immunoassay designed to run on automated chemistry analyzers.
The NGALds	The Company's NGAL gRAD dipstick.
Trading Day	A weekday when Nasdaq Copenhagen is open for trading.
U.S.	The United States of America.
U.S. Securities Act	Securities Act of 1933, enacted by the 73rd United States Congress, as amended.
UK	The United Kingdom.
UOP	Urine output.
Euronext Securities Copenhagen	VP Securities A/S, company reg. (CVR) no. 21 59 93 36, Nicolai Eigtveds Gade 8, DK-1402 Copenhagen, Denmark.

ANNEX A - APPLICATION FORM

Only one subscription form per shareholding in the Company or per Qualified Investor (as defined in the Prospectus).

The defined wording in this application form is used in accordance with the definitions in the Prospectus. The restrictions related to the Offering set out in the Prospectus also applies to this application form.

Subscription of Remaining Shares in the Company

Instructions on the use of Pre-emptive Rights must not be given by using this form, but by contacting the Existing Shareholder's/Qualified Investor's custodian institution or financial intermediary in the usual manner.

This application form is for the sole use of:

1. Existing Shareholders wishing to subscribe for more New Shares than their Pre-emptive Rights entitle them to.
2. Qualified Investors wishing to subscribe for Remaining Shares.

To be submitted to the Existing Shareholder's or the Qualified Investors' own custodian bank for endorsement and processing.

Securities code:	New Shares	DK0061685906	Subscription Price:	DKK 1.5
Subscription Period:	11 March 2022 – 24 March 2022		Date of official listing of New Shares:	4 April 2022
Date of payment:	30 March 2022			

Existing Shareholders and Qualified Investors wishing to subscribe for Remaining Shares must submit this application form to their own custodian institution or financial intermediary. The application form must be submitted within an appropriate amount of time for the custodian institution or the financial intermediary to process and forward the application form, so that the application form is received by Arbejdernes Landsbank, no later than on 24 March 2022 at 5:00 p.m. CET.

In case of oversubscription of Remaining Shares in connection with binding undertakings, such Remaining Shares will be allocated according to apportionment keys determined by the Board of Directors in its sole and absolute discretion. If the subscription orders from Existing Shareholders and Qualified Investors do not exceed the number of Remaining Shares, the Company will issue the number of Remaining Shares subscribed for.

For Existing Shareholders

I/we hereby confirm that I am/we are holders of Existing Shares.

I/we hereby submit a binding order to subscribe for _____ (whole number) Remaining Shares in the Company.

Statement Qualified Investors

I/we hereby confirm that I/we are a Qualified Investor.

I/we submit a binding order for subscription of _____ (whole number) Remaining Shares in the Company.

Statement by Existing Shareholders and Qualified Investors

This application form is submitted on the terms and conditions set out in this Prospectus dated 7 March 2022.

I/we undertake to pay the counter value of the shares allocated at the Subscription Price. Payment will be effected on 30 March 2022 pursuant to the contract note submitted to me/us against shares under the temporary ISIN code DK0061685906. If the number of subscription orders exceeds/does not exceed the number of shares offered, the Remaining Shares will be allocated on the terms set out in this Prospectus.

Information and signature

Name:	VP account:
Address:	Account used for settlement:
Post code and city:	Custodian bank:
Date:	I/we wish not to be listed in the Company's register of shareholders, please tick: ☐
Telephone:	My custodian bank or financial intermediary is entitled to forward this application form to Arbejdernes Landsbank, please tick: ☐

The Remaining Shares will be registered in the relevant Existing Shareholder's/Qualified Investor's account with Euronext Securities Copenhagen (VP Securities A/S):

Registration no.:	CD identification:
Stamp and signature:	

GDPR notice*: Those who participate in the Offering will provide personal data to their respective credit institution. Personal data provided to the credit institution will be processed in data systems to the extent required to provide services and administer matters in the credit institution and may be shares with the Company for the purpose of the Offering. Personal data obtained from a party other than the customer to whom the processing relates may also be processed. Personal data may also be processed in data systems at companies and organizations with which the respective credit institution cooperates. Information regarding the processing of personal data is provided by the respective credit institution, which also accept requests for correction of personal data in accordance with applicable law. Personal data may be obtained by the credit institution in connection with settlement of the Offering in the systems of VP Securities A/*