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 66,645,476 new shares at a subscription price of DKK 1.60 per new share with pre-emptive rights for the existing shareholders of BioPorto A/S at the ratio of 1:3.

This prospectus (the "**Prospectus**") has been prepared in connection with a capital increase comprising an offering (the "**Offering**") of up to 66,645,476 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 1:3, 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 ("**VP Securities**") on 29 September 2020 at 5:59 p.m. CEST (the "**Allocation Time**") will be allocated one (1) Pre-emptive Right for each Existing Share (as defined below). For three (3) Pre-emptive Rights, the holder is entitled to subscribe for one (1) New Share at a price of DKK 1.60 per New Share (the "**Subscription Price**").

The Offering is directed solely to Existing Shareholders and to Qualified Investors (as defined below). Immediately prior to the Offering, the Company has 199,936,428 shares issued (the "**Existing Shares**"). The Existing Shares are listed on Nasdaq Copenhagen A/S ("**Nasdaq Copenhagen**") under the ISIN code DK0011048619.

On 25 September 2020, the Company's board of directors (the "**Board of Directors**") resolved to issue up to 66,645,476 New Shares with Pre-emptive Rights for Existing Shareholders according to the authorization in section 16a and 16c of the Company's articles of associations by increasing the Company's share capital with between nominally DKK 45,000,000 and nominally DKK 66,645,476. The Pre-emptive Rights have been approved for trading and official listing on Nasdaq Copenhagen under the ISIN code DK0061409208.

The trading period for the Pre-emptive Rights commences on 28 September 2020 at 9:00 a.m. CEST and closes on 9 October 2020 at 5:00 p.m. CEST (the "**Rights Trading Period**"). The subscription period for the New Shares commences on 30 September 2020 at 9:00 a.m. CEST and closes on 13 October 2020 at 5:00 p.m. CEST (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 VP Securities under the temporary ISIN code DK0061409042. 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 VP Securities 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 21 October 2020. 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 22 October 2020.

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.

The Offering is fully underwritten, subject to satisfaction of certain conditions set out in separate advance subscription commitments and guarantee undertakings entered into between the Company and a number of Existing Shareholders and other investors, including Formue Nord Markedsneutral A/S, Aktieselskabet Arbejdernes Landsbank, Media-Invest Danmark A/S and a number of other institutional and Qualified Investors (the "**Guarantors**") prior to publication of this Prospectus (the "**Subscription Commitments**"). On the terms and conditions of 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. Therefore, subject to satisfaction of such terms and conditions, the Company has ensured that all New Shares will be subscribed for corresponding to aggregate gross proceeds of approximately DKK 106.6 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 the 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 May 2020 ("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 and the Global Coordinator (as defined below) may require 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 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"), and are only offered and sold outside the U.S. or 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 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".

Global Coordinator
Nordea

This Prospectus is dated 25 September 2020

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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 DK0061409208. The temporary ISIN code for the New Shares is DK0061409042, which will not be admitted to trading and official listing on Nasdaq Copenhagen.
Competent authority	This Prospectus has been approved on 25 September 2020 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 focusing on developing 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 outcomes for patients, providers and the healthcare ecosystem. The Company's flagship product is a test for NGAL, called The NGAL Test. The test is designed to aid in the risk assessment of AKI, a common clinical syndrome that can have severe consequences, including significant morbidity and mortality. 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 and UOP. 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 and reduce the economic burden of AKI. In addition to developing its NGAL portfolio, the Company has created a new platform technology, called gRAD, that enables rapid development of lateral flow assays. Having tested the platform's ability to generate high quality results, including with NGAL, the Company is now engaged in a series of development efforts that center around flexibility and rapid iteration to create simple assays that can be used in environments without access to sophisticated laboratory personnel and technology.
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 Thomas Magnussen (Chairman), Torben Arnth Nielsen (Deputy Chairman), Kirsten Aarup Drejer, Christopher James Lindop and Michael Scott Singer.
Statutory auditors	The statutory auditors of the Company is PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab. The Company's financial statement for the financial year 1 January 2019 – 31 December 2019 were audited by Torben Jensen and Allan Knudsen. PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab is currently represented by State Authorized Public Accountants Torben Jensen and Allan Knudsen.

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 2019 – 31 December 2019 and 1 January 2018 – 31 December 2018 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 – 30 June 2020 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	**2018**	**2019**
Total revenue	26.0	26.6
Operating profit (EBIT)	(41.8)	(74.3)
Net profit	(38.0)	(69.6)
Total comprehensive income	(38.3)	(70.0)

Statement of financial position		***1 January – 31 December***
DKK million	**2018**	**2019**
Total assets	66.2	42.7
Total equity	56.2	25.3
Total net financial debt	(45.8)	(13.3)

Statement of cash flow		***1 January – 31 December***
DKK million	**2018**	**2019**
Cash from operating activities	(38.0)	(60.2)
Cash from investing activities	(1.5)	(2.1)
Cash from financing activities	39.1	33.6

Income statement		***1 January – 30 June***
DKK million	**2019**	**2020**
Total revenue	13.3	10.9
Operating profit (EBIT)	(33.7)	(33.1)
Net profit	(32.2)	(30.8)
Total comprehensive income	(32.2)	(30.6)

Statement of financial position		***1 January – 30 June***
DKK million	**2019**	**2020**
Total assets	76.4	68.0
Total equity	61.3	34.9
Total net financial debt	(46.8)	(15.9)

Statement of cash flow		***1 January – 30 June***
DKK million	**2019**	**2020**
Cash from operating activities	(29.5)	(23.9)
Cash from investing activities	(0.5)	(0.4)
Cash from financing activities	34.7	36.5

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

Key risks

The key risks that are specific for the Company are:

- Public health epidemics, pandemics or outbreaks, such as COVID-19 could adversely impact the Company's business, future financial position, timeline, results of operations and future growth prospects
- The Company's capital structure may be insufficient to support its business operations and the Company may need to raise additional funding, which may not be available on acceptable terms, or at all, and failure to

obtain such funding when needed may force the Company to delay, limit or terminate its product development efforts or other operations

- A failure to obtain FDA clearance of The NGAL Test for risk assessment of AKI would have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects
- The Company's future success depends in part on its ability to attract and retain its management team and key employees
- A failure to successfully commercialize The NGAL Test for pediatric and adult AKI uses would have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects
- The Company's Products and Future (NGAL) Products are complex to manufacture, and the Company may encounter difficulties in manufacturing that could have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects
- The Company's ability to compete may decline if the Company does not adequately protect its proprietary rights and confidential information
- The Company's Products and Future (NGAL) Products may fail to achieve the degree of market acceptance by physicians, laboratory management, healthcare payors and others in the medical community necessary for commercial success and market penetration may be lengthy and difficult
- The Company may face competition from companies with considerably more resources and experience and/or more novel technology than the Company, which may result in others discovering, developing, receiving clearance for or commercializing products before or more successfully than the Company
- The Company is dependent on third-party partners to sell the Company's Products globally
- The manufacture of the Company's Products is dependent on the supply of raw materials and key components from suppliers, some of which are single source suppliers for the Company
- The pricing of the Company's Products and Future (NGAL) Products will depend in part on the clinical value of the product and delivery technology used in such products
- The Company's ability to retain key licenses could affect its ability to manufacture and sell Products and Future (NGAL) Products
- The Company operates in a highly regulated industry, and changes in regulations or the implementation or enforcement of existing regulations could have a material adverse effect

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 share classes. The ISIN code for the Existing Shares is DK0011048619. The ISIN code for the Pre-emptive Rights is DK0061409208. The temporary ISIN code for the New Shares is DK0061409042, which will not be admitted to trading and official listing on 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, expectedly on 22 October 2020. The temporary ISIN code of the New Shares will be merged with the ISIN code of the Existing Shares, expectedly on 23 October 2020. The Existing Shares are denominated in DKK. At the Prospectus Date, the Company's registered share capital was DKK 199,936,428 divided into 199,936,428 shares (each with a nominal value of DKK 1). Upon completion of a fully-subscribed Offering, the Company's registered share capital will be 266,581,904 divided into 266,581,904 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 VP Securities. 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 and pre-emptive rights. Upon completion of the Offering, all Shares will then carry 1 vote per nominal value of DKK 1. 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. 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 no restrictions under the Company's Articles of Association or Danish law apply to the transferability of the Shares.
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 revenue, if any, for purposes of the Company's current and future business. 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 will be registered with the Danish Business Authority expectedly on 21 October 2020 and issued through VP Securities the same day. The New Shares will not be admitted to trading and official listing on Nasdaq Copenhagen under the temporary ISIN. 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 22 October 2020.

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 and Pre-emptive Rights may be highly volatile

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 66,645,476 New Shares each of which will have a nominal value of DKK 1. The Offering is conditional upon at least 45,000,000 New Shares being subscribed for, corresponding to gross proceeds of DKK 70 million and net proceeds of approximately DKK 60 million.

Shareholders registered with VP Securities on 29 September 2020 at 5:59 p.m. CEST as shareholders of the Company will as Existing Shareholders be entitled to an allocation of Pre-emptive Rights. For every three (3) Pre-emptive Rights, holders of Pre-emptive Rights will be entitled to subscribe for one (1) New Share against payment of the Subscription Price. Pre-emptive Rights will be allocated free of charge.

Shares traded after 25 September 2020 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 VP Securities.

Announcement of Prospectus:	25 September 2020
Last day of trading in Existing Shares including Pre-emptive Rights:	25 September 2020
First day of trading in Existing Shares ex Pre-emptive Rights:	28 September 2020
First day of Rights Trading Period:	28 September 2020
Allocation Time of Pre-emptive Rights:	29 September 2020
First day of Subscription Period:	30 September 2020
Last day of Rights Trading Period:	9 October 2020
Last day of Subscription Period:	13 October 2020
Allocation of Remaining Shares:	15 October 2020
Expected date of publication of the results of the Offering:	15 October 2020
Expected registration of the New Shares with the Danish Business Authority:	21 October 2020
Expected date of admission of the New Shares to trading and official listing under the ISIN code of the Existing Shares:	22 October 2020
Expected merger of ISIN codes:	23 October 2020

Admittance to trading

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 28 September 2020 at 9:00 a.m. CEST to 9 October 2020 at 5:00 p.m. CEST.

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 25%. If the Existing Shareholders exercise their Pre-emptive Rights in full, they will not be diluted.

Estimated expenses

The estimated costs and expenses payable by the Company related to the Offering, assuming completion of a fully subscribed Offering, are approximately DKK 13 million. The fee to the Global Coordinator is variable and, therefore, the total expenses are subject to the results of the Offering.

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 enable the Company to successfully continue its operations and to further develop its Products.

If the Offering is completed and fully subscribed, the Offering will raise gross proceeds to the Company of approximately DKK 106.6 million with net proceeds expected to be approximately DKK 93.6 million after deduction of costs and expenses payable by the Company in relation to the Offering.

The Company expects to apply net proceeds of DKK 60 million to finance of the Company's operations until October 2021, which includes costs of employees, clinical trial costs, sales & marketing costs, production costs, R&D costs not related to employees or clinical trials as well as other operational costs. Any net proceeds from DKK 60 million and DKK 90 million will be applied to finance the NGAL development, which includes developing its U.S. organization to

	prepare for an FDA clearance and commercialization of The NGAL Test and supporting the NGAL development, including costs for a clinical trial and submission to FDA related NGAL for adults. If the Offering is fully subscribed, the net proceeds above DKK 90 million including the Company's current cash position, will be applied to develop the gRAD platform, including developing new indications using the gRAD platform. In case the Offering is not fully subscribed, the Company's activities and future investments will be adjusted accordingly.
Rights issue agreement	The Company and the Global Coordinator have entered into the Rights Issue Agreement. Pursuant to the Rights Issue Agreement, the Global Coordinator is entitled to terminate the Rights Issue Agreement upon occurrence of certain exceptional events and/or unpredictable circumstances. The Rights Issue Agreement also contains completion conditions, which the Company believes to be customary for the Offering, and the completion of the Offering is subject to compliance with all conditions as set out in the Rights Issue Agreement. If one or more conditions for completion are not met, the Global Coordinator may, at its discretion, also terminate the Rights Issue Agreement, which may thereby require that the Company withdraws the Offering.
Subscription and guarantee commitments	The Offering is fully underwritten in accordance with certain advance subscription commitments and guarantee undertakings dated on or about 25 September 2020 and entered into between the Company and 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 thus undertaken to exercise Pre-emptive Rights and/or to subscribe for any Remaining Shares for aggregate gross proceeds of approximately DKK 106.6 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 key employees. In addition, the Company has issued warrants to the Executive Management and selected 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 part of their commitments that do not relate to exercise of Pre-emptive Rights. Some of the Guarantors are shareholders, directly or indirectly, in the Company and therefore have an interest in the Offering. The Global Coordinator and its affiliates have from time to time been engaged in, and may in the future engage in, commercial banking, investment banking and financial advisory transactions and services in the ordinary course of their business with the Company or any of the Company's respective related parties. With respect to other of these transactions and services, the sharing of information is generally restricted for reasons of confidentiality, internal procedures or applicable rules and regulations. The Global Coordinator have received and will receive customary fees and commissions for these transactions and services and may come to have interests that may not be aligned or could potentially conflict with the interests of shareholders, prospective investors and the Company. In particular, the Global Coordinator is party to the Rights Issue Agreement pursuant to which the Global Coordinator is entitled to fees relating to the completion of the Offering. In addition, in the ordinary course of business the Global Coordinator and its respective affiliates may make or hold a broad array of investments including serving as counterparties to certain derivative and hedging arrangements and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the Company. The Global Coordinator and its respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

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 all information in this Prospectus (including any information or material incorporated by reference), including the risks described below, before they decide to subscribe for or to invest in New Shares or Pre-emptive Rights. This section addresses both general risks associated with the industry and market in which the Company operates, and the specific risks associated with its business and its intellectual property rights. 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 and the Pre-emptive Rights and the New Shares, which could also adversely impact the value of the New Shares and/or the Pre-emptive Rights. With respect to forward-looking statements that involve risks and uncertainties, see "*2. Certain information regarding the Prospectus and the Offering – Forward-looking statements*".

The risks and uncertainties discussed below are those that the Company's management 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 its management 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 New Shares and/or the Pre-emptive Rights and a loss of part or all of the prospective investor's investment. The most material risks, as currently assessed by the Company, taking into account the expected magnitude of their negative impact on the Company and the Company's business and the probability of their occurrence are set out first in each category of risk factors below.

1.1 Risks related to the Company's business

1.1.1 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 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 Liaison ("**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 the hospital lab or alternative site, competitive advantages, labeling restrictions or warnings, changes in physicians' diagnostic preferences, changes in the competitive landscape and changes in reimbursement policies. See "*5.7 Business – Markets*".

Changes to the standard of care for the targeted indications may also have an impact on market acceptance of such products. For instance, the current standard for assessing kidney injury is the use of serum creatinine ("**SCR**") and urine output ("**UOP**"). Adding a new product, such as the Company's main product, The NGAL Test, requires substantial clinical evidence as well as getting neutrophil gelatinase-associated lipocalin ("**NGAL**") included in clinical guidance documents. See "*5.7 Business – Markets*".

NGAL has been described extensively in the published literature for its use in detecting acute kidney injury ("**AKI**"), yet physician knowledge of NGAL and its use is not pervasive. 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 and UOP 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 recommended by clinical guidelines. With the availability of The NGAL Test and faster turnaround of results, there is growing interest in the use of the product as it is clear that early identification of AKI is important to optimize care, such as through careful fluid management and attention to the risks of nephrotoxic drugs.

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 guidelines.

The Company may not be successful in all 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 products and establish commercial partnerships with companies the Company is trying to engage with, resulting in a material adverse effect on the Company's business, results of operations, cash flow, financial position and/or prospects.

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

The diagnostic industry is highly competitive and is subject to swift 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.

The Company is currently competing with a large diagnostic company, that has had an U.S. Food and Drug Administration ("**FDA**") cleared acute renal biomarker, on the market for six years, giving it a head start on market penetration. Further, another renal biomarker is commercially available on many automated systems and is complementary to NGAL, as it is a marker of glomerular function, and not of tubular injury. In addition, the Company's license partner Abbott Laboratories ("**Abbott**"), has been granted a license to the proprietary NGAL patents and applications for specific formats (see "*14. Material Contracts*"), enabling Abbott to develop competing NGAL products with a royalty fee.

The NGAL Test could also be surpassed by products from smaller or early-stage companies that develop and commercialize AKI diagnostic products that have advantages over The NGAL Test. For example, the Company is aware of a competitor that is developing a product that is a real time monitoring system to continuously measure UOP to detect fluctuations that may indicate early AKI. Further, a FDA clearance of The NGAL Test may result in competitors seeking separate approvals of competing NGAL tests for the identification of AKI. 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. 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.

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

The Company sells 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 its 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 failure of third-party collaboration partners to perform and satisfy their contractual obligations or establish and comply with applicable laws and regulations, among other things, may 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 versus The NGAL Test, or developing their own NGAL test (in areas with no 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 business, results of operations, cash flows, financial condition, and/or prospects.

1.1.4 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 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.

Products similar to The NGAL Test are set at different prices. The diagnostic test, the SCR test, which has been available for over 50 years and is routinely used for standard assessments of kidney function is substantially less expensive than The NGAL Test. However, this test is non-specific for AKI and predicts the risk of developing AKI at a much later stage than The NGAL Test. In addition, a newer diagnostic test that indirectly predicts AKI by identifying two cell cycle arrest proteins, has a substantially higher price than is expected for The NGAL Test. This newer diagnostic test for AKI runs on a separate point-of-care system not generally used by laboratories, making it more costly compared to The NGAL Test, which runs on central laboratory clinical chemistry instruments that are standard in most hospitals.

As such, the technology used to deliver The NGAL Test may affect its price, as some NGAL products would be delivered through highly automated central laboratory clinical chemistry instruments and other NGAL products might be provided through point-of-care or rapid device formats. The level of automation, user training, technician involvement or interpretation may all play a role in differential pricing. Continued attention to, and pressure on the pricing of diagnostic tests could lead to regulatory reforms and legislative changes that might negatively impact the price of the Products and Future (NGAL) Products.

1.1.5 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. In this context it is noted that the Company has no third party assessments of the market potential for the Company's Product and that 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 which 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.

1.1.6 Global 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 may, for example as the result of COVID-19, paralyze economic activities and reduce the amount of funding for the healthcare sector. Political conditions, 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 or able to establish coverage, and adequate reimbursement levels, as well as pricing policies.

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.

This uncertainty is further heightened in light of the impeding 2020 U.S. presidential elections. 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., payment for laboratory testing is changing as a result of The Protecting Access to Medicare Act of 2014 requiring the Centers for Medicare & Medicaid Services ("**CMS**") to develop a national fee schedule for laboratory tests based on private-payer data, rather than on historical laboratory fees, see *"5.13 Business – Regulatory environment"*. There is uncertainty about how these changes may affect the Company's Products and Future (NGAL) Products, but there is an expectation that many companies will see a reduction in payments due to upcoming changes, but the actual results and how they affect each company are unknown.

In the EU, changes to healthcare systems, including the establishment and operation of health services and the pricing and reimbursement of medicinal products, are almost exclusively a national matter. 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 medicines, 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. As such, global economic uncertainty and other global economic or political or regulatory developments may have material adverse effect on the Company's business, results of operations, cash flows, financial condition, and/or prospects.

1.1.7 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 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. Any of these actions could result in material impairments of assets, material restructuring charges and other adverse impacts on the Company's results of operations. In addition, the reporting of adverse safety events involving the Company's Products or Future (NGAL) Products and public rumors about such events could cause the Company's share price to decline or experience periods of volatility.

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

Clinical trials for medical devices are designed to support a "reasonable assurance of safety and effectiveness"[1] for the marketing application. In the U.S., clinical trials are required for the Company's Products, which must be designed and conducted to follow Good Clinical Practices ("**GCP**") which are implemented by the FDA by law. GCP is defined as a standard for the design, conduct, performance monitoring, auditing, recording, analysis and reporting of clinical trials or studies, and is used in both the U.S. and the EU. The clinical trial design is unique to each device and is highly dependent on the risk, intended use population, and the desired claims of the device. Important trial design considerations include, but are not limited to, the inclusion and exclusion criteria, sample size, number of clinical sites/investigators, and statistical analysis plan.

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 the third parties do not successfully carry out their responsibilities. Third-party performance failure may delay the Company's ability to obtain regulatory clearance and delay or prevent the commercialization of the Company's Products. The Company engages third parties through agreements that specify the obligations and deliverables for the clinical trial. If the 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 trial could mean delays for the product submissions, which would have a material adverse effect on the Company's business, results of operations, cash flows, financial condition, and/or prospects.

[1] Code of Federal Regulations (CFR) Title 21, section 860.7

1.1.9 Timing of clinical trials depend on many factors outside of the Company's control

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 full control and may cause the timing to achieve the milestones to vary considerably from the Company's original estimates. Further, timing of milestones may be affected by strikes, natural disasters, labor disputes, or other disruptions. If the Company fails to achieve announced milestones in the timeframes the Company expects, commercialization may be delayed, which could have a material adverse effect on the Company's business and financial results.

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 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 May 2020, the Company announced that it was unable to begin patient enrollment of the current U.S. pediatric trial due to the global COVID-19 pandemic, which resulted in a pause of all non-critical clinical studies across the U.S.

1.1.10 The Company may not be able to successfully implement its strategies

The Company's future growth and success depend inter alia on the Company's ability to implement its business strategies successfully. 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 production infrastructure to ensure quality and drive increased profitability. There can be no assurance that the Company will be successful in implementing these strategies. In addition, the capital expenditures required to implement the Company's strategies may also be significantly greater than the Company currently anticipates, which could have a negative impact on the Company's financial results. 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. 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 and results of operations or prospects.

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

1.2.1 The NGAL Test for risk assessment of AKI

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

The Company's main product, The NGAL Test, was CE marked for measurement of NGAL in adult population in the ICU in Europe 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 select distributors. However, the Company's business and future success is highly dependent on its ability to obtain a FDA clearance of The NGAL Test for IVD use in order to successfully market and commercialize the product in the U.S. See *"5.13 Business – Regulatory environment"*.

Two main risks relate to the clinical trial and its respective submission: the timeline for the trial and the FDA review. The timeline for the FDA approval has been challenged by COVID-19, which has not been positive for enrollment of patients to the Company's clinical trials. Although the Company's current FDA discussions have been productive, the FDA may request additional information, which could also delay the clearance. A De Novo submission's success (see "*5.13 Business – Regulatory environment*") 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 disappointing results. In September 2015, the Company submitted an application to the FDA for clearance of The NGAL Test for use in the diagnosis of AKI in adults in the U.S. 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 late 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 intensive care unit ("**ICU**"). In October 2018, the FDA responded that they required further data to support the application.

In the meantime, the Company redirected its focus to prioritize its FDA efforts towards a pediatric population (defined as 3-22 years in the Company's pediatric study), which was supported by pediatric nephrologists 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 21 and was granted Breakthrough Designation status, see "*5.13 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 supports 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 way the samples had been collected, and the Company decided to conduct a

prospective study to further support the pediatric application to the FDA. In 2019, the Company hired a Chief Medical Officer and a VP of Regulatory Affairs from Roche Diagnostics to bring the expertise in medical/scientific affairs and regulatory interactions with the FDA from a successful diagnostic organization to the Company prior to its next FDA submission. Following a scheduled pre-submission dialogue with the FDA in the first quarter of FY2020, the Company designed and began to execute the protocol for the new pediatric study just as the COVID-19 pandemic began, which subsequently delayed patient recruitment. The Company announced on 23 June 2020 that the first patient had been recruited for the study and it would focus efforts towards submitting the FDA application within the fourth quarter of 2020.

Whether FDA clearance will be successful 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. In addition, there is a risk that FDA approves The NGAL Test for a narrower use than applied for in the Company's submission.

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

In the event that a FDA clearance is obtained, 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, attracting and retaining experienced sales, marketing, KOLs and MSL resources; entering into key partnerships necessary to effectively expand market access for The NGAL Test and obtaining adoption of The NGAL Test by the medical community.

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 Siemens Healthineers AG ("**Siemens**") and Roche Holding AG and its subsidiaries and affiliates ("**Roche**"), with whom the Company has existing distribution relationships. Although Siemens and Roche have a significant market share, it would be beneficial to engage with additional major diagnostic companies such as Abbott and Beckman Coulter Inc. to have the test available in as many hospital laboratories as possible. These companies have significant sales and marketing organizations with established relationships in all of the major medical centers and could significantly expand access to The NGAL Test. If Siemens or Roche were to terminate their current distribution agreements 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.

1.2.2 Planned expansion of The NGAL Test for use on Third Party Systems and the use of The NGAL Test for new indications ("Future NGAL Products")

1.2.2.1 A failure to successfully complete development, obtain regulatory clearance for IVD use of and commercialize Future NGAL Products would have a material adverse effect on the Company's business, future financial position, results of operations and future growth prospects

The Company's business and future success are highly dependent on its strategy to deliver The NGAL Test on as many clinical chemistry systems as possible to support optimal market penetration. The Company's strategy is to get The NGAL Test cleared with the FDA on the Roche c501 instrument with the intent of expanding The NGAL Test to other third-party clinical chemistry systems in subsequent filings. These would include, for example: Siemens Atellica instruments, Abbott Alinity instruments, Beckman Coulter AU series instruments and Ortho Clinical Diagnostics Vitros instruments.

The expansion of the CE marked The NGAL Test to other third-party chemistry systems is different in the EU and is accomplished through self-certification. The Company is also exploring adaptation of The NGAL Test on other kinds of third-party systems such as point-of-care instruments as well as exploring additional intended uses for The NGAL Test that would provide expanded use and sales of Future NGAL Products.

The ability to obtain U.S. regulatory clearance for Future NGAL Products on additional clinical chemistry systems will depend on several factors such as: obtaining access to the different systems for clinical and analytical studies; managing any technical issues with the instruments when performing analytical and clinical studies; having sufficient clinical specimens to use on the different systems; and entering into agreements

with third parties to conduct the studies, if necessary. Any delays in getting approval on additional instruments will limit access to The NGAL Test in hospital laboratories that do not have the Roche c501. The Company's revenue potential would significantly decrease in the event that The NGAL Test can only be used on limited instrument platforms.

There are several additional uses for The NGAL Test that would expand the market for the Company's Future NGAL Products. As such, the Company expects to conduct clinical studies and FDA submissions for the most clinically relevant and commercially beneficial uses, after the initial FDA clearances are received. The ability to obtain regulatory clearance for new intended uses would depend on the Company's ability to fund, initiate, and complete successful new clinical studies that validate the new intended uses in a timely manner. Failure to expand the applications for Future NGAL Products and achieve commercial success will have a material adverse effect on the Company's future growth prospects.

1.2.3 NGAL gRAD Dipstick ("The NGALds")

1.2.3.1 A failure to obtain regulatory clearance for and commercialize The NGALds would have a material adverse effect on the Company's future financial position, results of operations and future growth prospects

In the U.S., a regulatory submission to the FDA is required before The NGALds can be legally marketed. The Company plans to develop the regulatory strategy for this product in collaboration with the FDA through the pre-submission process. It is anticipated that The NGALds will be a Class II device and require either a De Novo classification or a traditional 510(k) submission. See "*5.13 Business – Regulatory environment*" for a further description of regulatory clearance. The submission will include analytical and clinical data to validate the device and demonstrate safety and effectiveness.

The NGALds is another extension of the Company's NGAL product line. This product is designed to be a semi-qualitative, lateral flow product that could be used in near patient settings, such as the Emergency Department ("**ED**"), physician office clinics, ambulances, combat areas, etc. The test might be used for triaging patients to determine if they need urgent or ICU care, or whether they can be cared for in a less intensive manner. The Company intends to generate data to compare the clinical performance of The NGALds to The NGAL Test to confirm that the clinical results obtained with The NGALds correlate to The NGAL Test for seamless transitions between the two products. A successful clearance of The NGALds depends on the Company's ability to clearly design the clinical trials, execute agreements with clinical sites, recruit sufficient numbers of participants, obtain analytical and clinical data that meet regulatory requirements for the intended use; and manage requests for additional information or data during the regulatory review with experienced medical/regulatory employees and consultants.

The NGALds product will be self-declared in the EU. However, 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 (the "**IVDR**") will come into full effect on 26 May 2022. See *"5.13 Business – Regulatory environment"* for a further description of the IVDR. If The NGALds is CE marked prior to May 2022, the Company will have to decide whether it shall be CE marked under IVDR or Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (the "**IVDD**") and transferred to IVDR by May 2022. The IVDR will have significant impact on The NGALds, which will fall into class C for which the conformity assessment procedure includes the involvement of an independent and neutral institution appointed by a member state of the European Economic Area (a "**Notified Body"**). The IVDR spells out the requirements for clinical evidence for IVDs and describes the requirements for a performance evaluation plan and report. Therefore, if the Company decides to apply the IVDR requirements (annex I) for the CE marking of The NGALds, confirmation of conformity with these requirements must be based on scientific validity, analytical performance and clinical performance data providing a sufficient level of clinical performance studies as part of the design validation, which might not end up being successful. A launch review cannot be passed until these have been successfully completed and concluded in the form of a performance evaluation report. In addition, since the device is intended for use at point-of-care setting the technical documentation must be reviewed by the Notified Body prior to placing the product on the market.

Further, the Company's business and future success is highly dependent on its ability to successfully commercialize The NGALds once cleared for IVD use by the relevant regulatory authority. Commercialization factors for The NGALds will be similar to the other NGAL products above but may have some unique hurdles due to its assay format and intended users. If significant sales are outside of the hospital, such as physician office clinics, ambulances, military arenas, etc., there will be a need for additional direct sales representatives and MSLs and/or specific distribution partners that have existing relationships with decision makers for these segments. The adoption of The NGALds test may also take more time to achieve until acceptance of The NGAL Test has been confirmed and there is a willingness to use a rapid format for outpatient settings. Another important aspect of obtaining commercial traction with The NGALds test would require petitioning for a new Current Procedural Terminology ("**CPT"**) code that would be paid for at a level commensurate with the value of the test. This can be a lengthy process that includes gaining support from clinical organizations, providing evidence of the medical and economic value of the test, and petitioning the CMS for a new code. Without a CPT code that would provide sufficient reimbursement, the Company would not anticipate significant U.S. sales outside of a hospital setting.

1.2.4 COVID-19 gRAD Dipstick Products ("COVID-19ds")

1.2.4.1 A failure to successfully develop, obtain regulatory clearance for and commercialize the COVID-19ds would have a material adverse effect on the Company's future financial position, results of operations and future growth prospects

The COVID-19 pandemic has created worldwide demand for diagnostic products to identify individuals infected with the virus as well as to identify individuals who have been exposed to the virus and now have antibodies that might provide immunity. Accordingly, many companies across the world have an intensive focus on developing new COVID-19 tests. The Company is working on developing lateral flow tests which may detect individuals who are infected with the virus or who have been exposed to the virus and who may have developed antibodies to provide some level of immunity. There is no assurance that the Company may successfully develop a functioning product for COVID-19 testing. The Company's success of commercialization is further dependent on its ability to obtain regulatory clearance for the COVID-19ds worldwide.

As the FDA has granted Emergency Use Authorizations ("**EUAs"**) for over 100 molecular, antigen, serology and lab developed COVID-19ds, the Company could be in a unique position to get a similar authorization after development of this product. To date, only a few lateral flow COVID-19 antibody and antigen tests have achieved EUA.

Obtaining clearance for COVID-19 products is currently highly competitive and the FDA has updated the performance requirements for serology tests, which has resulted in some EUAs being revoked for tests that do not meet FDA performance expectations. In addition, there are many tests that meet the updated performance expectations and hundreds of others that have been submitted to FDA for review, straining FDA resources. Therefore, it may be challenging and time consuming for new COVID-19 products to get through the EUA process. Following the first submission through the De Novo classification process, the FDA expects all following submissions to be through the 510(k) pathway as opposed to EUA. See "*5.13 Business – Regulatory environment*".

As for a potential EU clearance, the COVID-19 products will follow the same approval process as described above for The NGALds, and similar risks apply. Whether commercialization is successful will depend on factors such as the Company's ability to successfully obtain regulatory clearances in a timely manner, and to distribute the product through distributors and government agencies in an expedited manner for broad access outside of the Company's usual customer base.

In addition to regulatory risks, the Company may run into manufacturing issues wherein the Company, or its manufacturing partners, are unable to scale up manufacturing or provide a consistent flow of products to meet the medical need. Any lengthy disruption to the supply chain could result in end users moving to other available products, thereby diminishing the Company's financial goals for this product line.

Globally, significant efforts are underway to develop a vaccine for COVID-19. The Company estimates that there are over 100 vaccines in development with over 30 vaccines in clinical trials.[2] In a best-case scenario, at least one vaccine may be available in the U.S. and EU in early 2021. A potential vaccine may have different degrees of efficiency and as such, COVID-19 testing for virus, antigen and antibodies will still be required in order for patients to establish if they have contracted COVID-19 or the regular flu. It is expected that testing for COVID-19 antibodies will also be required, in to order enable individuals with immunity to donate plasma to treat other COVID-19 patients. Over time, a decline in cases and the successful production of effective vaccines could result in a decline in the number of diagnostic tests needed or reduce the need for these products to a seasonal basis, similar to flu diagnostics and therefore the Company's revenue potential for COVID-19 products may decline.

1.2.5 Development of New Diagnostic Products (on gRAD or other platforms) ("Future Products")

1.2.5.1 A failure to successfully develop, obtain regulatory clearance for and commercialize Future Products would have a material adverse effect on the Company's future financial position, results of operations and future growth prospects

The Company is constantly exploring and identifying possible new or existing biomarkers and technologies in the area of kidney health and critical care, with the aim of developing new diagnostic products to complement and expand its product portfolio. This is done through in-house R&D, through participation in grant funded research projects or in collaboration with academic or commercial partners.

The Company's business and future success is dependent on its ability to obtain regulatory clearance and successfully commercialize the Future 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.

As with The NGALds, these Future Products will be self-declared in the EU. However, the IVDR will come into full effect on 26 May 2022. If Future Products are CE marked prior to 26 May 2022, the Company will have to decide whether they shall be CE marked under IVDR or IVDD and transferred to IVDR by 26 May 2022.

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

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

In December 2019, a novel strain of COVID-19 emerged in Wuhan, Hubei Province, China. While initially the outbreak was largely concentrated in China and caused significant disruptions to its economy, it has now spread across the world and infections have been reported globally, including the countries where the Company has operations and is conducting clinical trials. The outbreak has led governments across the world to impose measures intended to control its spread, including restrictions on freedom of movement and business operations such as travel bans, border closings, business closures and quarantines.

[2] WHO, Draft landscape of COVID-19 candidate vaccines as of 9 September 2020, https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

To seek to mitigate the risks related to the COVID-19 outbreak at the Company premises, a plan was implemented to allow for continued production and sales efforts by increasing sanitary and disinfecting activities and limiting the number of employees working on site by staggering work hours, as well as providing work from home options.

The COVID-19 outbreak affected the Company's pediatric clinical trials for The NGAL Test in the U.S. where the Company announced that it was unable to begin patient enrollment due to the global COVID-19 pandemic, which halted all non-critical clinical studies across the U.S.

The extent to which COVID-19 and other potential public health epidemics or outbreaks impact the Company's operations in the future, future financial position, results of operations and future growth prospects will depend on future developments, which are highly uncertain and inherently unpredictable, including the duration and severity of the outbreak, and the actions to contain COVID-19 or other outbreaks or address its impact, among others.

In particular, the continued spread of COVID-19 or other potential public health epidemics or outbreaks could adversely impact the Company in the future, including further delays of the timing of the Company's clinical trials. For example, if the Company's key suppliers in Japan and Norway that manufacture key components for The NGAL Test or other Products are affected by COVID-19 or other health epidemics/outbreaks, disruption of the supply chain may happen and the Company's Products would not be able to be manufactured. The Company is currently investigating alternative suppliers. If the Company's sales and marketing organization or distributor organizations are impacted by these health concerns, it could result in the disruption of a continuous supply of Products and customer support to end users. In the midst of an epidemic, surgeries and other procedures could 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.

These and other factors may negatively affect the Company's business 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 Company's future success depends in part on its ability to attract and retain its management team and key employees

The Company currently has a relatively small organization and is highly dependent on its key employees in R&D, clinical, operations, financial, marketing, sales and business development along with the expertise of its senior management team. As the Company only has a limited number of key employees and a lean management structure, the loss of any one of these key employees or management members may have a significant impact on the Company's development, commercialization and business strategy. As the Company has limited resources, a large part of its compensation package may be incentive-based and it may be difficult to retain key employees long term if the Company cannot get Products cleared for sale or if the Company cannot achieve its sales goals. In addition, former employees may be hired to or carry out business which is in direct competition with the Company.

The Company will need to generate sales and/or secure financing to assure that it can significantly grow its organization, especially in the commercial area, in order to sell and support its Products and Future (NGAL) Products. Attracting and replacing management and key employees may be difficult and would take time because of competition for the 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 be unable to hire, train, retain or motivate the members of its management team or key employees on acceptable terms given the competition among numerous life science companies for similar personnel. 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.

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

The Company's 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 business and financial results.

In addition, the Company 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. 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 business and financial results. To meet commercial commitments to deliver its Products, the Company builds up inventory, however, from time to time such inventories may be low or non-existing, in particular following delivery of larger orders. 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.

1.3.4 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 only 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 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.

The Company's Japanese supplier manufactures key components, as well as buffer, calibrator and controls, which are all incorporated in The NGAL Test kit and related calibrator and control kits. The manufacturer is the Company's sole partner for these components meaning early termination or any disruption at this facility would adversely affect the Company's business and results of operations. Further, the Company entered into an agreement with Diatec Monoclonals AS for the manufacture of the Company's NGAL antibodies, which are used in the production of NGAL products sold by the Company. The manufacturer is the Company's sole partner for these antibodies meaning early termination or any disruption at this facility would adversely affect the Company's business and results of operations. Further, some suppliers 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. This limits the Company's control over the process or timing of finalization of certain Products, and limits its ability to prepare a robust disaster recovery plan.

1.3.5 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 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. Even if the Company can secure appropriate alternative suppliers in a timely manner, its costs could increase significantly. Any of these events could adversely affect the Company's business, results of operations, cash flows, financial condition, and/or prospects.

Specifically, 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 regulation when conducting the clinical trials. Failure of such external parties to establish and comply with required producers and regulation, 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.

1.3.6 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, 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. Japan 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. Currently, 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 Japanese supplier cannot meet its commitments and obligations, this could have a material adverse effect on the Company's business, results of operations, cash flows, financial condition, and/or prospects.

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 business, financial condition and results of operations, and/or prospects.

1.3.7 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, corruption of data, unauthorized access or leaks, natural disasters, attacks, terrorism, war and telecommunication and electrical failures.

The Company has not experienced any such material system failure, or security breach to date, however, if such an event were to occur it 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.

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.

To the extent that any disruption or security breach were to result in a loss of the Company's data, technology, confidential information, relating to its technology, Products or Future (NGAL) Products, the Company could incur costs, losses, liabilities, regulatory exposure, its competitive position could be harmed, and the further development and commercialization of its 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 and could have a material adverse effect on the Company's business, financial condition or results of operations. 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.

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

The Company's business is exposed to potential product liability and warranty or guarantee claims. 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 which 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. In addition, human and other errors or accidents may occur during the operation of the Company's Products. 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 financial position, results of operations and cash flows could be materially and adversely affected.

1.3.9 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

It is generally necessary for the Company to secure certain levels of insurance as a condition for any sale or use of its diagnostic tests and in the conduct of trials. Over time, the Company may be unable to obtain insurance or other protection against e.g. business interruption or potential product liability claims, and the Company could be exposed to significant liabilities, which could materially and adversely affect its business and financial position. These liabilities could prevent or interfere with the Company's product development and commercialization efforts. If the Company becomes subject to business interruption or is sued for any injury caused by its products, the Company's liability could exceed its product liability insurance coverage and the Company's own financial resources, and consequently could have a material adverse effect on its business, financial position, results of operations, and/or prospects.

The Company has taken out product liability insurance with respect to the IVD use of The NGAL Test for approved indications for the cleared territories, the clinical trials and ongoing trials performed to date for which the Company is responsible. The insurance coverage is subject to commercially agreed terms and conditions, which includes various exemptions and limitations, including exemptions for crime, intellectual property right infringement, product recalls and business interruption. There can be no assurance that the Company's insurance is adequate to cover product liability and other material liability risk and any related losses not covered by insurance could significantly affect the Company's operating results and financial position.

1.3.10 To manage its growth the Company must continually improve existing reporting systems and procedures

The Company has a very lean organization with few employees. As such, the employees focus on the Company's core business, and internal processes and reporting procedures are not as sophisticated as in more developed companies. To manage its growth and improve its performance, the Company must maintain and continuously improve its operational systems and processes, including its IT systems. Some of these improvements and areas of expansion will take time as the Company is still in the early stages of growth and has many areas to prioritize. The Company is currently planning to establish its own sales organization, 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 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 and financial systems as the Company grows. The Company's successful commercialization will furthermore depend on its ability to manage its expanding operations.

1.3.11 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 collaborators. 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, including the imposition of significant fines or other sanctions.

1.3.12 The Company's operations involve hazardous materials and the Company and third parties with whom the Company contracts must comply with environmental laws and regulations, which can be expensive and restrict how the Company does business

As a diagnostic company, the Company's business activities involve the controlled use of hazardous materials, and the Company is thus subject to environmental and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with health and safety regulations is substantial. The Company's R&D activities involve the controlled storage, use and disposal of hazardous 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 hazardous materials. In some cases, these hazardous 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 business, results of operations and/or prospects.

1.4 Risks related to the Company's intellectual property

1.4.1 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 on obtaining and maintaining proprietary 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 related to its product Products and Future (NGAL) Products. See *"5.10 Business – Intellectual Property Rights"*. The Company is only able to protect its Products and Future (NGAL) Products technologies from use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, are in place.

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: (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 diminish the patents; or (v) the Company may not be able to license third party patents to have freedom to operate in commercially relevant territories. In addition, since the ruling in the Prometheus vs. Mayo case in 2012, the issuance of U.S. diagnostic patents with broad claims, and the uncertainty of already issued U.S. diagnostic patents, has been more difficult to achieve and maintain. Diagnostic patent applications now need to include claims that are strengthened by adding transformative and novel determining steps. Accordingly, the Company may experience difficulties in obtaining and maintaining diagnostic patents in the U.S.

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 only way that the Company may extend patent term coverage is to submit a new application based on information contained in the original patent to cover additional claims that were not covered in the approved patents. Although this is possible, 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 in 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.

1.4.2 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/applications. 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 contracts*". 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 those products, which would adversely affect its business, results of operations and financial condition.

In some circumstances, the Company has to rely on the licensor to obtain and maintain the in-licensed patents and the Company may not have any control over the quality of the decisions that are made regarding these patents. In other circumstances, 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; (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 diminish the patents; or (v) the Company may not be able to license third-party patents to have freedom to operate in commercially relevant territories.

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.

1.4.3 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 not as strong as 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 partes review and equivalent proceedings, and opposition proceedings. Such proceedings could result in revocation or amendment of the Company's patents in such a way that they no longer cover the Company's 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 European patent, EP 2128625B1 filed in South Korea is currently undergoing litigation proceedings in South Korea regarding its validity. Possible outcomes include that the patent will be upheld; upheld in part; or that the patent will be revoked in South Korea. The European patent, EP 2064553A1 has been revoked in opposition proceedings and an appeal was filed in 2017. Oral arguments will be heard in the appeal on 13 October 2020. Possible outcomes include that the patent will be upheld, that the patent will be upheld in part or that the patent will be revoked. See *"5.10 Business – Intellectual Property Rights".*

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. If the Company fails to protect or to enforce its intellectual property rights successfully, its competitive position could suffer, which could harm the Company's results of operations.

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 business, results of operations and financial condition.

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 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.

1.4.4 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 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 business.

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

Third parties may claim that the Company is infringing their intellectual property rights. The Company may 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 prior art.

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.

From time to time, the Company has received notices from third parties asserting infringement and the Company has been subject to lawsuits alleging infringement of third party intellectual property rights. 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.

1.4.6 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.

1.4.7 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 who were previously employed at universities or other life science companies, including its competitors or potential competitors. 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, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. 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. Even if the Company is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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 "*5.13 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 "*5.13 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 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.

1.5.3 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 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.

1.5.4 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.

1.5.5 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 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.

1.5.6 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. 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.

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

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. The Company expects its research and development investments to continue in connection with ongoing activities, and to increase in connection with label expanding regulatory clinical studies once The NGAL Test has obtained regulatory clearance in the U.S.

As of 30 June 2020, the Company's cash and cash equivalents were DKK 30.3 million. The net proceeds from the Offering are estimated to be approximately DKK 93.6 million. The Company expects that the net proceeds from the Offering, the Company's existing cash and cash equivalents and revenue from diagnostic tests and antibody sales will be sufficient to allow the Company to fund the anticipated operating expenses including clinical studies and capital expenditures for the 12 months following the Prospectus Date. However, the Company's operating plans 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. Further, the Company may seek additional capital if market conditions are favorable or if the Company has specific strategic considerations. If additional capital is not available on acceptable terms, or at all, failure to obtain such funding when needed may force the Company to delay, limit or terminate its product development efforts or other operations.

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

The Company recognized net losses of DKK 69.6 million in 2019 and DKK 38.0 million in 2018. The Company considers that its ability to generate revenue and reach profitability depends primarily on obtaining the regulatory clearance of The NGAL Test in the U.S. for both the pediatric and adult populations, and the successful commercialization of The NGAL Test through the Company's own sales force as well as through its distribution partners.

If the uptake of The NGAL Test is not significant, the intended use approved by regulatory authorities is narrower, or if The NGAL Test adoption is reduced because of competing products or, 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 business and financial results.

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. For example, 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. If the Company is unable to meet its capital expenditure requirements, the Company may not be able to maintain its product development and commercialization plans, which may materially adversely impact the Company's business, financial condition and results of operations, reputation or prospects.

1.6.4 The Company is facing risks related to sales and production contracts being denominated in currencies other than DKK

Currency risks include the risk arising from sales and production contracts being denominated in currencies other than DKK. Contracts are primarily made in USD and EUR, meaning that other currencies do not represent significant currency risks. As long as the DKK is linked to the EUR the Company's revenue and costs in EUR are not being hedged.

Revenues and contracts are still relatively modest and thus the Company is not hedging its USD exposure. However, the Company is monitoring its currency exposure and will consider using financial instruments to hedge this exposure once the revenue generated in currencies other than the EUR increases.

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. This can affect the Company's margins, as its operating revenue in any one currency is not matched by expenses in the same currency. There is no guarantee that the Company's financial results will not be materially adversely affected by currency exchange rate fluctuations or that any efforts by the Company to engage in currency hedging will be effective.

1.6.5 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 2019, the Company's largest customer amounted to less than 5% of revenue.

The Company monitors its credit risk through a simplified credit loss model. Based upon this model the Company is recognizing its bad debt provision. In 2019 the bad debt provision amounted to DKK 0.3 million and in 2018 to DKK 0.4 million. In both years the actual losses on trade receivables were less than the provision.

There can be no assurance that the Company will not suffer losses from trade receivables in the future. This could have a material adverse effect on the Company's business, results of operations, cash flows, its financial position and prospects.

1.7 Risks related to the Offering and the Shares

1.7.1 The market price of the Company's Shares and Pre-emptive Rights may be highly volatile

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.

In addition, 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, which 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 other similar companies, additions or departures of key employees and further sales of Shares by the Company or the Company's major shareholders may also affect the price of the Company's 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.

1.7.2 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 28 September 2020 at 9:00 a.m. CEST and closes on 9 October 2020 at 5:00 p.m. CEST. 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.

1.7.3 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 other 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 other jurisdictions outside Denmark with respect to any such rights in the future.

1.7.4 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 in line with 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.

1.7.5 Failure to exercise Pre-emptive Rights by the end of the Subscription Period (13 October 2020 at 5:00 p.m. CEST) 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 13 October 2020 at 5:00 p.m. CEST, the Pre-emptive Rights will lapse with no value.

1.7.6 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.

1.7.7 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*".

1.7.8 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.

1.7.9 It may be difficult or impossible for the Company's shareholders and investors outside Denmark to enforce judgments from their home jurisdictions against the Company

The Company is incorporated, and a majority of the Company's assets and operations are held and conducted in Denmark. As such, it may be difficult or impossible for shareholders and investors outside of Denmark to enforce judgments obtained in courts of such shareholder's and investor's home jurisdictions against the Company.

1.7.10 The Offering may be withdrawn, and shareholders and investors having exercised and/or purchased Pre-emptive Rights or New Shares may incur a loss if the Offering is not completed

The Offering may be withdrawn during the period leading up to registration with the Danish Business Authority of the capital increase pertaining to the New Shares. If the Offering is not completed, 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).

Shareholders and 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.

1.7.11 Following the Offering, certain Existing Shareholders may increase their shareholdings and may be able to influence important actions the Company take

Following the Offering, certain Existing Shareholders may increase their shareholdings and may be able to influence the outcome of decisions at general meetings, which may influence important actions the Company takes. These Existing Shareholders concentration of share ownership could have the effect of delaying, postponing, preventing or accelerating a change of control in the Company, and could impact any potential mergers, consolidations, acquisitions or other forms of combinations, which may or may not be desired by other shareholders. No assurances can be given that the interests of these Existing Shareholders participating in the Offering, or investors directly or indirectly controlling the Existing Shareholders participating in the Offering, will not differ from the interests of other shareholders. The interests of these Existing Shareholders participating in the Offering may not be aligned with the interests of minority shareholders or new shareholders with respect to such voting decisions.

1.7.12 The Subscription Commitments might not be honored

A number of Guarantors has, subject to the satisfaction of certain terms and conditions in the Subscription Commitments, made binding undertakings to subscribe for all 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 their individual commitments. If any Subscription Commitments is not honored, this may cause the termination of the Offering and may materially adversely impact the Company's business, financial condition and results of operations, reputation or prospects.

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. Neither the Company nor the Global Coordinator accepts 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, unless such distribution, offering, sale or exercise is permitted under applicable legislation in the relevant jurisdiction, and the Company and the Global Coordinator receive satisfactory documentation to that effect. This Prospectus may not be distributed or otherwise 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 any jurisdiction outside Denmark, unless such distribution, offering, sale or exercise is permitted under applicable legislation in the relevant jurisdiction, and the Company and the Global Coordinator receive 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 state securities legislation in the U.S. Accordingly, the Pre-emptive Rights may not be offered, sold, acquired or exercised within the U.S., and the New Shares may not be subscribed for, offered or sold within the U.S. The New Shares are not, and will not be, registered under the U.S. Securities Act and are solely offered and sold outside the U.S. for the account or benefit of, persons who are not U.S. Persons (as defined in Regulation S) in accordance with Regulation S or pursuant to another exemption from 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. For certain restrictions on transfer of the Pre-emptive Rights and the New Shares, see "*20.17 Terms and conditions of the offer of securities to the public – Transfer restrictions*".

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 and the Global Coordinator; 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 and the Global Coordinator receive satisfactory documentation to that effect.

2.6 Information to distributors

Solely for the purposes of the product governance requirements contained within: (a) EU 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. Furthermore, it is noted that, notwithstanding the Target Market Assessment, the Global Coordinator will only procure investors who meet the criteria of professional clients and eligible counterparties (except for a public offering to shareholders and investors in Denmark conducted pursuant to a separate prospectus that has been approved by and registered with the Danish Financial Supervisory Authority).

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.

Nordea Danmark, filial af Nordea Bank Abp, Finland is Global Coordinator and Bookrunner (the "**Global Coordinator**") in connection with the Offering and will receive remuneration from the Company for its services. In the course of its usual business activities, the Global Coordinator or certain companies affiliated with it may have provided and may in the future provide investment banking advice and carry on normal banking business with the Company and any subsidiaries and affiliates. The Global Coordinator acts exclusively for the Company and no one else in connection with the Offering, and it will not regard any other person as its respective clients in relation to the Offering.

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 or the Global Coordinator 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. The Global Coordinator makes no representation or warranty, whether expressed or implied, as to the accuracy or completeness of the information contained in the Prospectus. Nothing contained in this Prospectus is or may be relied upon as a promise or representation by the Global Coordinator in this respect, whether as to the past or the future. The Global Coordinator assumes no responsibility for the accuracy or completeness of the Prospectus and accordingly disclaims, to the fullest extent permitted by applicable law, any and all liability whether arising in tort, contract or otherwise which the Global Coordinator may otherwise be found to have in respect of this Prospectus or any such statement.

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 two (2) business days after the publication of such supplement.

Further, investors acknowledge that they have not relied on the Global Coordinator or any person affiliated with the Global Coordinator in connection with an investigation of the accuracy of any information contained in this Prospectus or their investment decision. Investors also 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 or the Global Coordinator.

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 Global Coordinator and 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 neither the Company, nor the Global Coordinator, have taken or 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, neither the Company nor the Global Coordinator, nor any of their respective representatives, will 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 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 and the Global Coordinator to inform themselves about such restrictions and to observe such restrictions. Neither the Company, the Company's auditors nor the Global Coordinator 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.

In connection with the Offering, the Global Coordinator and any of its respective group enterprises, acting as an investor for their own account, may take up New Shares in the Offering and, in that capacity, may retain, purchase or sell for its own account such securities and New Shares or other investments, except in connection with the Offering. Accordingly, any reference in the Prospectus to New Shares being offered or placed should be read as including any offering or placement of New Shares to the Global Coordinator or any of its group enterprises acting in such capacity. The Global Coordinator does not intend to disclose the extent of any such investment or transaction otherwise than in accordance with any legal or regulatory obligation to do so.

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*", "*11.6 Information on assets and liabilities, financial position, results and dividend policy–Dividend policy*", "*11.1 Information on assets and liabilities, financial position, results and dividend policy–Financial statements*", "*5. Business*" and "*7. Consolidated Prospective Financial Information*" are based on views of Management, as well as on assumptions made by and information currently available to Management, and such statements may constitute 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 can generally be identified by terminology such as "targets", "believes", "estimates", "expects", "aims", "intends", "plans", "seeks", "will", "may", "anticipates", "would", "could", "continues" or similar expressions or the negative forms thereof. 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 "*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, 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 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 2018 – 31 December 2018 ("**FY2018 Financial Statements**"), the audited consolidated financial statements of the Company for the period 1 January 2019 – 31 December 2019 ("**FY2019 Financial Statements**") and the unaudited consolidated financial statements for the period 1 January 2020 – 30 June 2020 (the "**Half Year Financial Statements**") are included in the Prospectus by reference. FY2018 Financial Statements and FY2019 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 Financial Statements has 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. 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.

Neither the Company nor the Global Coordinator makes 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 and the Global Coordinator do 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, 25 September 2020

BioPorto A/S

Board of Directors

Thomas Magnussen
Chairman

Torben Arnth Nielsen
Vice Chairman

Kirsten Aarup Drejer
Board Member

Christopher James Lindop
Board Member

Michael Scott Singer
Board Member

Thomas Magnussen: Member of the executive management of Therazone ApS and Thera Property ApS
Torben Arnth Nielsen: Chief executive officer of Arnth Advice ApS
Kirsten Aarup Drejer: Member of the executive management of KD Invest ApS
Christopher James Lindop: Professional board member
Michael Scott Singer: Chief scientific officer of Cartesian Therapeutics, Inc.

Executive Management

Peter Mørch Eriksen
CEO

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. 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 Torben Jensen, State Authorized Public Accountant and Allan Knudsen, State Authorized Public Accountant.

The independent auditor's report included in the Company's published annual report for the financial year 1 January 2018 – 31 December 2018 and the annual report for the financial year 1 January 2019 – 31 December 2019 were signed by Torben Jensen and Allan Knudsen.

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 Business

Certain statements in the Business section constitute forward-looking statements. These forward-looking statements are not guarantees of future events, achievements or financial performance, and the Company's actual achievements or results could differ materially from those expressed or implied by these forward-looking statements as a result of many factors, including but not limited to those described under "*2.9 Certain information regarding the Prospectus and the Offering – Forward-looking statements*" and "*1. Risk Factors*". Investors are urged not to place undue reliance on any of the statements.

5.2 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 2013, the Company has transitioned into an IVD company focused on developing 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 may help improve 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 is valued at USD 69.2 billion (2019), with expected growth of 4% annually.[3] 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 of AKI, a common clinical syndrome that can have severe consequences, including significant morbidity and mortality.[4] 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 and UOP. 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 and reduce the economic burden of AKI.

The NGAL Test, which addresses a potential global market estimated of up to USD 5 billion annually, is currently CE marked for sale in Europe and several other geographies. The CE mark claim for The NGAL Test is intended to measure NGAL in adult population in the ICU. In addition, the Company is in the process of completing studies to submit a renewed application in the fourth quarter of 2020 for FDA clearance for use in pediatrics through the De Novo classification process (see "*5.13 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.

In addition to developing its NGAL portfolio, the Company has created a new platform technology, called gRAD, that enables rapid development of lateral flow assays. Having tested the platform's ability to generate high quality results, including with NGAL, the Company is now engaged in a series of development efforts that center around flexibility and rapid iteration to create simple assays that can be used in environments without access to sophisticated laboratory personnel and technology.

The Company has a small, dedicated team of 27 employees (as per 30 June 2020), of whom 21 are situated in Denmark and six are situated in the U.S.

Headquarters in Denmark houses all corporate functions, R&D, Manufacturing, Customer Service and Quality, while the U.S. organization currently consists of Clinical/Regulatory and Commercial personnel.

5.3 Key Strengths

The Company has several key competitive advantages in developing, sourcing and commercializing tests in the healthcare market.

5.3.1 Diversified Pipeline

The NGAL biomarker is being developed for risk assessment of AKI, but has several other potential applications, which are part of the Company's long-term development strategy. The gRAD platform also expands the Company's pipeline of potential products, as it is used to develop rapid assays for any application for which the Company can create a matched antibody pair (see "*5.6 Business – Products and Product Pipeline*").

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[3] Kalorama Information, The In Vitro Diagnostics Market, https://kaloramainformation.com/the-in-vitro-diagnostics-market/

[4] 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

5.3.2 Breadth of Partnerships

To support the Company's efforts in bringing The NGAL Test to market and in raising awareness of AKI, the Company has engaged in collaborations with key players in the diagnostics industry and in critical care nephrology. For example, the Company has negotiated agreements with Roche and Siemens, two of the top five global IVD companies, for distribution of The NGAL Test for use on their laboratory instruments. The Company has also had the opportunity to work with several kidney-focused advocacy organizations (e.g., National Kidney Foundation, KDIGO and ADQI) with the common goal of improving the lives of people with AKI. Throughout the development of The NGAL Test, the Company has also built strong relationships with thought-leaders in academic medical centers around the world, particularly in the U.S. where the Company has been conducting studies and helping to advance research through the use of The NGAL Test for research use only ("**RUO**"). The Company has recently attracted experienced commercial talent to its U.S. team to help plan for and execute the U.S. launch of The NGAL Test following a potential FDA clearance.

5.3.3 Development Expertise

In 2019, the Company added to its development team by hiring an experienced Chief Medical Officer and a VP of Regulatory Affairs. Together with a talented R&D team, this group has established strong relationships with key authorities, international partners and research universities to pursue compelling new areas for assay development.

5.3.4 Broad Intellectual Property Portfolio

Since 2014, the Company has worked to establish a broader intellectual property base for NGAL and gRAD, both by filing its own patents as well as through in-licensing patents. The Company's goal is to continue on this path by establishing, or in-licensing, patents for potential new biomarkers. For a description of the Company's intellectual property rights, see "*5.10 Business – Intellectual Property Rights*".

5.4 Strategy and Objectives

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.

5.4.1 Establish Commercial Capabilities to Drive Growth

Through the Company's own commercial team, as well as through partnerships, the Company seeks to introduce and expand use of novel assays by communicating the clinical and economic value of its Products and Future (NGAL) Products in a clear, efficient and compelling manner.

5.4.2 Expand Product Pipeline and Clinical Knowledge

The Company will focus on expanding its pipeline vertically through development of new indications for The NGAL Test as well as horizontally by leveraging the gRAD platform to develop new rapid assays for emerging conditions, such as COVID-19.

5.4.3 Strengthen Production Infrastructure to Ensure Quality and Drive Profitability

The Company will seek to secure strong suppliers to support its chemistry assays and will also build in-house expertise in product logistics and supply chain in both Denmark and the U.S.

5.5 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 a novel platform for the rapid development of lateral flow tests, gRAD.

Within the portfolio of clinically actionable biomarkers, the biomarker NGAL has been developed across each of these product formats. NGAL is a small 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.[5] Development of NGAL is expected by the Company to create significant commercial opportunity, based on its numerous potential clinical applications and has served to demonstrate the feasibility of the Company's product development approach.

[5] 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

5.6 Products and Product Pipeline

5.6.1 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 which uses an analytical method that can be run on most clinical chemistry systems that are used in hospital laboratories known to the Company, making adoption of the test easy for laboratories, thereby maximizing the available opportunity.

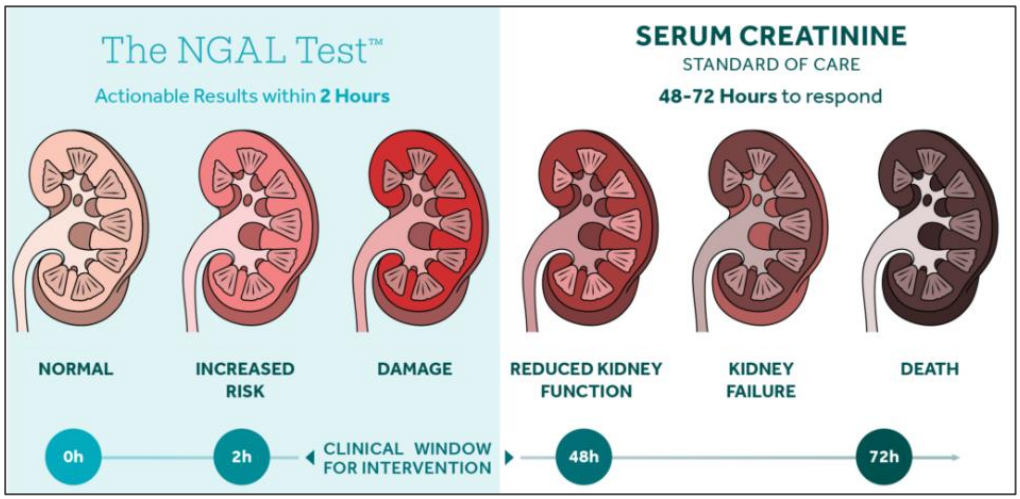

Figure 1: Progression of kidney damage in AKI as illustrated by the Company

As described in Figure 1, 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 kidney dysfunction after 48 to 72 hours. This difference is important for patient management as the early detection of kidney damage can allow earlier and more tailored approaches. For example, the close control of fluid levels and the heightened attention to nephrotoxic drugs, 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.[6]

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.

5.6.1.1 About AKI

AKI is a rapid loss of kidney function which 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.[7] Factors influencing the increase in AKI include growing rates of underlying clinical conditions such as diabetes, hypertension 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[8] affected with AKI during a hospital setting of care and one in four children[9] affected with AKI during their admissions to the ICU. Among the patients most at risk of developing AKI during a hospital setting of care are those who undergo cardiac surgery (up to 30%)[10], are receiving mechanical ventilation for respiratory support (29%)[11], are being treated for sepsis (26-50%)[12], or who are receiving nephrotoxic medications (14-26%).[13]

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.

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[6] 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

[7] Pavkov ME. (2018) 'Trends in Hospitalizations for Acute Kidney Injury — United States, 2000–2014', MMWR Morb Mortal Wkly Rep. 2018;67.

[8] Susantitaphong P. (2014) Correction, Clin J Am Soc Nephrol, CJASN. 2014;9(6)

[9] Kaddourah A. (2017) 'Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults', N Engl J Med. 2017;376(1)

[10] O'Neal JB. (2016) 'Acute kidney injury following cardiac surgery: Current understanding and future directions', Crit Care. 2016;20(1)

[11] 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)

[12] Alobaidi R. et al. (2015) 'Sepsis-associated acute kidney injury', Semin Nephrol. 2015;35(1)

[13] Perazella MA. (2018) 'Pharmacology behind Common Drug Nephrotoxicities', Clin J Am Soc Nephrol. 2018;13(12)

The burden of AKI is significant, as it is associated with numerous negative hospital outcomes including: longer length of hospital stay (7-29 days);[14] increased use of renal replacement therapy (12% higher);[15] prolonged time on mechanical ventilation;[16] and a 25% increase in overall mortality rate.[14] 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 readmission;[17]
- be 38% more likely to have a major cardiac event;[18] and
- progress to chronic kidney disease (25% of patients).[19]

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.[20] Of those who survive, 59% have one or more kidney abnormalities.[21]

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., it has been estimated that AKI is associated with an increase in hospitalization cost of USD 7,933 to USD 1,795 (unadjusted vs. adjusted for hospital and patient characteristics) per episode, driving the total cost to the American healthcare system up by USD 5.4 to USD 24 billion annually (range for adjusted vs. unadjusted costs).[22] 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.

5.6.1.2 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 chronic kidney disease ("**CKD**") with the risk of end-stage kidney disease ("**ESKD**") and need of renal replacement therapy (dialysis or kidney transplantation).[23] 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.[24] In addition, more than half of an individual's kidney function can be lost due to acute insult before creatinine levels rise.[25] As a result, SCR often fails to identify AKI.

5.6.1.3 Regulatory Approval of The NGAL Test

The NGAL Test is currently CE marked for measurement of NGAL in adult population in the ICU and is available for IVD use in Europe and other geographies, and 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, which became a distinct opportunity as the first application for The NGAL Test. As part of the Company's discussions with the FDA, the Company has achieved a breakthrough designation status for this application, demonstrating that the clinical application and population that the Company seeks to address represent a significant unmet medical need. See "*5.13 Business – Regulatory environment*" for further information on the process for regulatory approval of The NGAL Test in the U.S.

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 AKI in children, called the AWARE study, published in The New England Journal of Medicine in 2016.[26] 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.

In the first quarter of 2020, study planning and contracting was conducted. However, enrollment of patients was delayed until June 2020 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 leading U.S. children's hospitals, including Cincinnati Children's Hospital, Children's Hospital of Colorado, Children's Healthcare of Atlanta and Texas Children's Hospital. The Company's expectation is to complete the study and submit a De Novo application to the FDA in the fourth quarter of 2020.

Immediately following the potential FDA clearance of The NGAL Test for risk assessment of moderate to severe AKI in children, the Company intends to initiate an application process for use of the test in adult populations. The Company intends to file a 510(k) submission for use of

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[14] 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)
[15] 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)
[16] Kaddourah A. (2017) 'Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults', N Engl J Med. 2017;376(1)
[17] 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)
[18] Odutayo A. et al (2017) 'AKI and Long-Term Risk for Cardiovascular Events and Mortality', JASN. 2017;28(1)
[19] 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)
[20] 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 statistics for death and mortality in the U.S., https://www.cdc.gov/nchs/fastats/deaths.htm
[21] Askenazi DJ et al. (2006) Kidney Int: 69(1), https://pubmed.ncbi.nlm.nih.gov/16374442/
[22] Silver SA. et al. (2017) 'The Economic Consequences of Acute Kidney Injury', Nephron. 2017;137
[23] Van Duijl TT. et al. (2019) 'Kidney Injury Biomarkers in an Academic Hospital Setting: Where Are We Now?', Clin Biochem Rev. 2019;40(2)
[24] Devarajan P. (2010) ' Neutrophil gelatinase-associated lipocalin: a promising biomarker for human acute kidney injury', Biomark Med. 2010;4(2)
[25] Desanti De Oliveira B. et al. (2019) 'Molecular nephrology: types of acute tubular injury', Nature Reviews Nephrology 2019:15
[26] Kaddourah A. (2017) 'Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults', N Engl J Med. 2017;376

The NGAL Test in adults, using the pediatric test as its predicate. See "*5.13 Business – Regulatory environment*" for further information on De Novo requests in relation to 510(k) applications to the FDA.

5.6.1.4 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.[27] 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.[28] 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.[29]

5.6.1.4.1 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 identified late in the development programs, with only 2% of drug attritions happening in preclinical studies but 19% during phase 3 studies.[30] 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.[31] These biomarkers are not yet required by the FDA in renal safety testing, but the BQP represents an established pathway to work to gain acceptance of NGAL, and other renal biomarkers, for drug-induced renal safety and toxicity testing.

Because clinical practice guidelines, along with regulatory guidance and new drug application ("**NDA**") submission requirements, provide the foundation for pharma 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 it could aid in the translation 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.[32]

5.6.1.4.2 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
- Kidney damage in connection with COVID-19

5.6.2 The Generic Rapid Assay Device (gRAD) Platform

The Company's patented gRAD platform was created in 2016 to enable rapid development of lateral flow assays. The features of gRAD include optimization with two printed lines: a test line for 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 no specific antibodies need to be immobilized on the strip. 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 developing, in conjunction with expert academic partners, four emerging applications:

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[27] 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

[28] 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

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

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

[32] 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

- **NGALds for point-of-care applications:** A near-patient test for NGAL levels
- **Two COVID-19 assays:** 1) A diagnostic test for the identification of the active virus (antigen test); and 2) a serology-based test for the identification of immunity (antibody test)
- **Sepsis:** A blood test using antibodies to thrombomodulin for the early identification of septic shock
- **Stratification of snakebites:** Rapid tests to allow for earlier intervention with appropriate anti-venoms

5.6.2.1 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 outside of 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[33] between the two methods. This early study provides a strong indication of the potential clinical accuracy that this novel near-patient test option may offer. The Company is currently pursuing a CE mark for The NGALds, which it expects to obtain in the fourth quarter of 2020. After this, the Company intends to market the test in select countries.

5.6.2.2 COVID-19 Diagnostics

SARS-CoV-2 is the virus that causes the COVID-19 disease. Since COVID-19 became a pandemic, two rapidly emerging diagnostic needs have developed: the initial need for a broad scale diagnosis of viral infections, and the second need to identify those who may have acquired some degree of immunity to the virus. A viral COVID-19 test could be used to rapidly screen individuals in non-laboratory settings, offering a simple and immediate result, while an antibody response test could be used post-infection to help identify individuals who may have some degree of immunity to SARS-CoV-2.

Current molecular diagnostic tests for viral infection by SARS-CoV-2 are typically expensive, require instrumentation and skilled personnel, and many have long (over one hour) turnaround times. By contrast, a gRAD-based test would require no instrumentation or skilled laboratory personnel, could provide a result in under 10 minutes, and could also be offered at a lower price. A gRAD test for immunity, using both IgM and IgG antibodies on the same test strip, could provide similar speed and economic benefits. The Company believes that these tests, potentially available for launch by late 2020 following an FDA EUA and EU CE mark approval, could be developed to offer high sensitivity and specificity, competitive with existing tests that have been granted EUA by the FDA. See "*5.13 Business – Regulatory environment*" for further information.

5.6.2.3 Rapid Test for Sepsis

The Company has partnered with Rigshospitalet, one of the largest hospitals in Denmark, to create a gRAD-based test for the quantitative determination of thrombomodulin in human plasma or whole blood samples. The test is being evaluated for use in patients with septic shock induced endotheliopathy. Results of the test will be used to randomize patients into a trial of low-dose prostacyclin, to evaluate its ability to help prevent multiorgan failure in the ICU.

5.6.2.4 Stratification of Snakebites

The gRAD platform is currently being developed to be used in a partnership between BioPorto Diagnostics A/S and VenomAid Diagnostics ApS. According to VenomAid Diagnostics ApS, annually over five million people are affected by snakebites, particularly in rural and poverty-stricken areas of the world, where access to medical care is limited. Rapid, low-cost methods to diagnose snakebite using a lateral flow test based on gRAD could lead to treatment with specific, rather than broad-spectrum antivenoms, potentially helping to improve care and reduce costs in these under-resourced environments.

5.6.3 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.

5.6.3.1 ELISA Kits

Primarily for research applications, the Company offers NGAL ELISA kits for human use (CE marked) as well as for six additional species, ranging from mouse to monkey. The NGAL ELISA kits target different forms of NGAL and allow scientists to 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, as well as to investigate new potential applications of NGAL. The Company does not intend to actively develop new ELISA kits as a driver of its business strategy, nor to 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 might evolve into future products in the form of FDA cleared or approved actionable biomarkers.

[33] 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

5.6.3.2 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 is also able to provide in-house scaled up production of custom antibodies in bulk volumes to meet specific program needs, such as for diagnostic kit manufacturers.

5.7 Markets

5.7.1 The NGAL Test

The Company's assessment of the global opportunity for The NGAL Test is 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 drug development applications, as described above. The Company estimates an initial opportunity of approximately 100 million tests annually, of which 5-10 million are in pediatrics. Based on expanded indications, the global addressable market for The NGAL Test could increase to a total of 250 million tests with an annual value of USD 5 billion, assuming a sales price per test of USD 20.

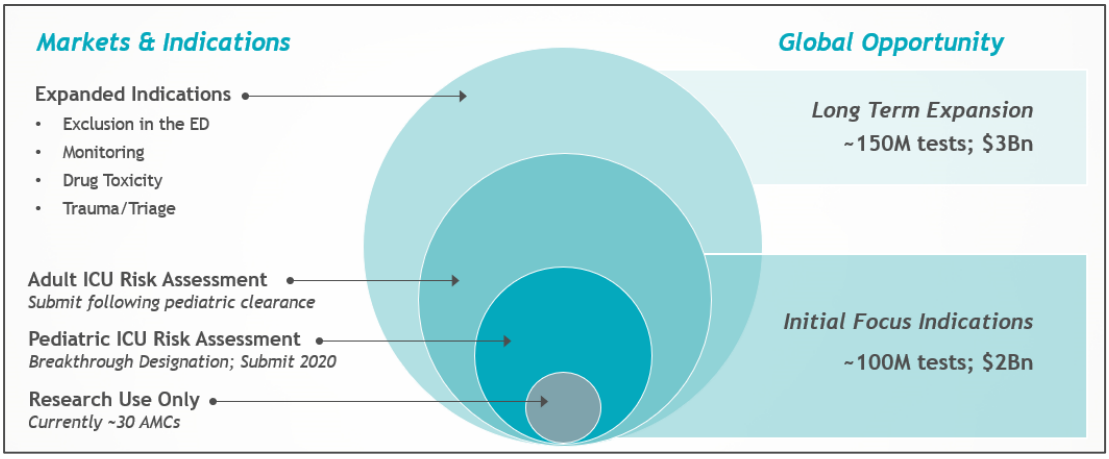

Figure 2: Management estimated market opportunity for The NGAL Test. Circles are not to scale.

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.

5.7.1.1 The U.S. Market Opportunity

Based on an expectation of submitting an application to the FDA for approval of The NGAL Test for pediatric use in the fourth quarter of 2020, the Company is preparing for an expected commercial launch of The NGAL Test for pediatrics upon an expected FDA clearance in 2021. Subsequently, the Company expects to launch The NGAL Test for adults in 2022, which assumes a separate FDA approval prior to launch. 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,[34] and another separate study in pediatrics revealed 26.9% developed AKI.[35] 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.*"[36]

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.[37] With the first expected FDA clearance in pediatrics, the Company will focus on hospitals with a pediatric ICU ("**PICU**"). 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.[38] 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 increase 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.[39]

[34] 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)
[35] Kaddourah A. (2017) 'Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults', N Engl J Med. 2017;376(1)
[36] Halpern NA., SCCM., https://www.sccm.org/Communications/Critical-Care-Statistics
[37] 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
[38] Horak RV. et al. 'Growth and Changing Characteristics of Pediatric Intensive Care 2001-2016', Crit Care Med. 2019;47(8)
[39] 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

5.7.1.1.1 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.[40] Accordingly, the U.S. and 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.

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

- **Peer-to-peer education:** Leveraging KOLs 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 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 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 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 distribution agreements with Roche and Siemens, who represent the two largest players in the chemistry/immunoassay 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 related disorders.

5.7.1.2 Rest of World: The NGAL Test

5.7.1.2.1 CE Mark & History in Europe

In 2012, The NGAL Test received a CE mark and was cleared for market launch in the EU as an IVD biomarker for AKI in adult population in the ICU. Following clearance, the Company launched The NGAL Test in the EU with a combination of direct and distribution sales leveraging the knowledge of select local distributors. Following the EU launch, the Company has received regulatory approval for IVD use in Canada, South Korea and Israel, and has launched the test in these markets through distribution.

5.7.1.2.2 Market Sizes: Targeted Geographies[41,42]

Global epidemiology of AKI shows that high-income countries have a lower incidence of AKI than low-to-middle-income countries, where the burden of AKI is highly influenced by contaminated water and endemic diseases. As access to expensive clinical chemistry analyzers is extremely limited in low-income countries, in the rest of the world ("**ROW**"), which represents 56% of the global market, the Company expects

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[40] 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

[41] 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)

[42] Hoste EA. et al. (2018) 'Global epidemiology and outcomes of acute kidney injury', Nat Rev Nephrol, 2018;14(10)

it will focus on expanding penetration of The NGAL Test primarily in the EU, UK, Asia and the Middle East, which represent the majority of the market outside U.S.

In these areas, AKI occurs at rates similar to those in the U.S. population of adults and children.[43] 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.

5.7.1.2.3 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 BNP 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 product launches in Europe and in ROW.

In markets inside the EU and in the UK, the Company's sales approach is a combination of direct sales and leveraging local distribution networks, while 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, efforts are focused on NGAL measurements in connection with cardiac surgery. The Company has recently initiated a focused pediatric commercial plan, based on direct sales in the UK, Germany and the Scandinavian countries, combined with intensified collaboration with key distributors in the EU and South Korea.

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 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.

5.7.1.3 Customers for The NGAL Test

5.7.1.3.1 Direct Customers

The Company has ongoing partnerships with both Roche and Siemens (see "*14. Material Contracts*"). These relationships help to provide access to new markets, key hospitals and institutions and are 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.

5.7.1.3.2 End-users and Decision Makers, Global

5.7.1.3.2.1 Clinicians

The physicians who are involved in the care of critically ill patients are the clinical customers for The NGAL Test. They are the originators of demand for the test, and include four primary specialties:

- **Intensivists:** Doctors who 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 who 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 will 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 inter-operatively (though this requires further study).
- **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.

5.7.1.3.2.2 Laboratory Medicine

Pathologists or laboratory medicine physicians 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 doctors need to be persuaded of the clinical and economic value of The NGAL Test, and then would be responsible for the process of approving, purchasing and validating the test. They must also interface with the hospital's IT-team to make The NGAL Test available to be ordered in the hospital's ordering system, with results available in the electronic medical record.

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[43] 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

5.7.1.3.2.3 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 length of stay, 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.

5.7.1.3.2.4 Payors

In the U.S. market, hospital coding impacts hospital payments, which are accomplished primarily through diagnosis (ICD-10) codes and diagnosis related groups ("**DRGs**"), codes that are primarily driven by the procedures related to each patient. The cost of performing The NGAL Test, because it is used in the ICU, does 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. Presence or absence of AKI may or may not impact DRG assignments, which 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 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.

5.7.1.4 Competitive Landscape for The NGAL Test

Standard assessments of kidney function, particularly the SCR tests, but also blood urea nitrogen tests and UOP tests, are the main competitors to The NGAL Test. While the limitations of the SCR tests are widely published, it is a test that 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 help improve management of patients at risk of AKI.

Of the novel renal biomarkers that have been studied, only two have been made available for commercial IVD use: the protein Cystatin C, and NephroCheck which is a combination of the two markers TIMP-2 and IGFBP-7. Cystatin C is complementary to NGAL, as it is a marker of glomerular function, and not of tubular injury. It is a blood test available from many IVD companies and is run in the core laboratory on chemistry analyzers.

NephroCheck received FDA clearance in September 2014 and is a urine-based test that 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 performed using single-use cartridges and a stand-alone meter. The Company considers that the NephroCheck product differs from The NGAL Test, as NephroCheck needs separate equipment, has a longer turnaround time (no batching), higher sales price per test (reported to be between USD 55-100[44]) and can be impacted by the presence of certain common interfering substances.

5.7.2 gRAD: Rapid Lateral Flow Test Market

Lateral flow assays are simple, cellulose-based devices that are used in many settings and for many indications to detect the presence of a targeted compound in a liquid sample, e.g., blood, urine, saliva, without the need for expensive laboratory equipment. In 2018, the global addressable market for lateral flow tests was estimated to be USD 5.2 billion, with anticipated annual growth of 4.0%, and increasing demand for point-of-care testing, and for infectious disease testing, is expected to drive growth in this diagnostic category.[45]

In addition to offering tests used in hospital and other clinical laboratories, the Company seeks to capture a very small share of this broad marketplace through the deployment of its proprietary gRAD platform. There are several opportunities to develop assays using gRAD, of which The NGALds and testing for COVID-19 hold the earliest commercial potential.

5.7.2.1 Market Potential: NGALds

The Company has used gRAD to create The NGALds, a lateral flow test for semi-quantitative determination of NGAL levels, expanding the potential applications for this biomarker into several novel areas. One of the initial targets for this product could be to aid in the follow up of patients who have had an episode of AKI in the hospital, as it has been shown that 59% of AKI survivors have one or more kidney abnormalities,[46] and up to 25% progress to CKD.[47] For these individuals, avoiding nephrotoxic medications such as nonsteroidal anti-inflammatory agents (NSAIDS) which are common pain medications, can be important. The NGALds could be developed to be used in nephrology offices to check for kidney injury in these patients. According to the American Society of Nephrology, in the U.S. there are over 10,000 nephrologists involved in direct patient care in the U.S. (2016 data), with the majority working in nephrology practices.[48]

An important aspect of obtaining commercial traction in the U.S. with The NGALds will be ensuring market access through coverage, coding and payment. It is anticipated that The NGALds would need a new CPT code that would be paid for at a level commensurate with the value of

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[44] Hall. et al. (2018) 'The future for diagnostic tests of acute kidney injury in critical care: evidence synthesis, care pathway analysis and research prioritisation.', Chapter 5, which has 2015 data and Berdugo MA. et al. (2019) 'Economic and clinical benefits of early identification of acute kidney injury using a urinary biomarker', Journal of Medical Economics, 22:12

[45] Grand View Reasearch (2019) 'Lateral Flow Assay Market Size, Share & Trends Analysis Report By Product (Kits & Reagents, Lateral Flow Readers), By End Use, By Application (Clinical Testing, Veterinary Diagnostics), By Technique, By Region, And Segment Forecasts, 2019–2026', https://www.grandviewresearch.com/industry-analysis/lateral-flow-assay-market

[46] Askenazi DJ. et al. (2006) '3–5 year longitudinal follow-up of pediatric patients after acute renal failure', Kidney International. 2006;69(1)

[47] 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)

[48] Salsberg E. et al. 'The US Nephrology Workforce 2016: Developments and Trends.' Washington, DC: American Society of Nephrology; 2016

the test. This can be a lengthy process that includes gaining support from clinical organizations, providing evidence of the medical and economic value of the test, and petitioning CMS for a new code.

NGAL may also be useful to aid in risk prediction in military applications, which represents another future market. Triage during combat operations, where resources are limited, is critical as medics must make a field assessment of what level of care is needed for each wounded individual. The NGALds could potentially be deployed in combat zones to offer a simple, rapid tool that could identify patients with differing levels of kidney injury to help with triage decisions.[49]

5.7.2.2 Market Potential: COVID-19ds

Due to the global urgency to contain the spread of the SARS-CoV-2 virus, the market for testing has developed rapidly. As it has become clear that asymptomatic individuals can transmit the virus, the importance of broad-based diagnostic testing has gained prominence. As of early August 2020, the FDA had authorized 168 molecular tests, 37 antibody tests and two antigen tests[50] through the EUA process.

In addition to testing broad populations of individuals who are at risk, it is expected that regular screening of healthcare workers will be a priority until a vaccine or cure is achieved. The Company's gRAD-based test for COVID-19 would be designed to be easy to deploy broadly to settings where access to molecular diagnostics may be limited. For example, healthcare providers could be screened quickly at their workplaces, with positive results reflexing to molecular testing for confirmation. The Company estimates that if these U.S. healthcare providers, including nurses, doctors and physicians assistants, each needed to be screened daily, the market could reach 1.1 billion tests per year.[51]

During the development of the COVID-19ds, the Company will determine the optimal partnerships for deployment. It is expected that novel, accurate and proprietary assays will be highly sought-after. Potential commercial approaches include:

- Licensing to global IVD players
- Partnering with medical distribution companies
- Supplying directly to international organizations providing healthcare in developing countries.

The sequence of events for the commercialization of the SARS-CoV-2 antigen test commences with continued optimization of the antibodies for optimal detection of inactivated virus (see "*14.1.8 – Material Contracts – Co-financed Research Agreement with the University of Southern Denmark*"). This is followed by the development of a prototype test utilizing either lateral flow or gRAD technology. The prototype will be used to assess detection of the inactive virus and then optimized for human samples (active virus). Once the assay has been optimized and clinically validated, the Company expects to file an EUA with the FDA and expects begin commercializing the product. Simultaneously, the Company will initiate clinical trials for a regulated pathway with the FDA. The Company expects to begin testing in human mammals approximately 3-4 weeks after the Prospectus Date. The timeline for obtaining an EUA is expected to be approximately 10 weeks thereafter.

5.7.3 Markets for ELISA Kits and Antibodies

The overall research antibodies market is expected to grow from USD 9.33 billion in 2017 to USD 12.60 billion by 2022, at a CAGR of 6.2% from 2017 to 2022, as these are critical components in life sciences research.[52] 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 highly 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.

5.8 Suppliers and Production

The Company sources antibodies for The NGAL Test from a subcontractor that supplies the antibodies to a third-party that then completes assay manufacturing. The manufactured 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 assembly 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.

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[49] Beyer CA. et al. (2019) 'Point-of-Care Urinary Biomarker Testing for Risk Prediction in Critically Injured Combat Casualties', JACS 2019. 229(5)

[50] FDA (2020) 'Coronavirus (COVID-19) Update: Daily Roundup August 7, 2020', https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-august-7-2020?utm_campaign=080720_PR_Coronavirus%20%28COVID-19%29%20Update%3A%20Daily%20Roundup%20August%207%2C%202020&utm_medium=email&utm_source=Eloqua

[51] Management estimates, based on the following sources: AACN (2019) 'Nursing Fact Sheet', www.aacnnursing.org/News-Information/Fact-Sheets/Nursing-Fact-Sheet; Young A. et al. (2016) 'A Census of Actively Licensed Physicians in the United States, 2016', Journal of Medical Regulation 101(2);; U.S. Bureau of Labor Statistics (2020) 'Physician Assistant', www.bls.gov/ooh/healthcare/physician-assistants.htm

[52] 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 2022', https://www.marketsandmarkets.com/Market-Reports/research-antibodies-reagents-market-94212793.html

5.9 Organization

The Company is located in Copenhagen, Denmark with its primary address at Tuborg Havnevej 15, ground floor, DK-2900 Hellerup. As of 30 June 2020, the Company had a total of 27 employees, including employees in the U.S.. Of these, 21 were based 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. The Company intends to retain a relatively limited staff to manage its diagnostics business. An overview of the Company's staff is presented below.

- Management: Five persons comprising the Executive Management and Key Employees, see "*8. Board of Directors, Executive Management and Key Employees*"
- R&D, Clinical and Regulatory: Nine persons
- Sales, Marketing and Support: Six persons
- Production: Four persons
- Administration: Three persons

Period	FY2019	FY2018	FY2017
Total no. of FTE (average over the-period)	34	28	25

The Company also has a newly-established 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. It is anticipated that the office will ultimately have between 25-40 employees, consisting of a commercial team (Sales, MSLs, Marketing), Customer Service, Production Facilities as well as warehouse and administrative personnel to support the growth of product sales and distribution in the U.S. Any expanding activities are subject to future funding.

5.10 Intellectual Property Rights

Through R&D efforts, the Company has developed expertise in the development of research and diagnostic assays to detect analytes present in various disease states. The Company seeks to protect some of the Company's methods and materials as trade secrets while the diagnostic tests and their uses are primarily sought to be protected through patents.

5.10.1 Patent Strategy

The Company's patent strategy involves an evaluation of its R&D projects, its Products and their uses, methods and technologies in order for the Company to develop a strategy for the respective products that is closely linked to the Company's business strategy and objectives. The Company aims to file patent applications as early as possible to secure patent protection for developing or commercial products. The patent applications are prioritized and managed by the Company's in-house R&D team and patent steering group and prepared by the Company's outside patent counsel.

For most of the Company's patent families, a single priority founding application is initially filed to secure priority, and is then followed by filings through the International Patent Cooperation Treaty ("**PCT**") system. Patent applications are then entered nationally/regionally in the U.S. and Europe and further jurisdictions around the world when considered commercially relevant. Divisional/continuing applications are filed to secure additional claims and further national patent rights.

As the Company considers intellectual property one of its competitive advantages, significant resources are devoted to develop, protect and defend intellectual property assets. The Company's patent prosecution is generally handled by the Company's outside patent counsel and regional legal consultants. The Company proactively evaluates third-party patents and patent applications to investigate if there are any third-party patent rights potentially relevant for its freedom to operate or to license and retain as strategic assets where the Company can control sublicensing rights. The Company's success depends in part on the Company's ability to obtain and maintain a patent portfolio for the Company's Products in order to secure a prominent market position and create value that may result in favorable licensing deals and revenue.

While intellectual property protection forms an important part of the Company's marketing strategy, 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*".

5.10.2 Patents

5.10.2.1 NGAL and Technology Patents

The Company has generated a number of patents related to NGAL (the "**NGAL Patents**") and has together with its in-licensed patents developed a portfolio that the Company believes optimizes its position with The NGAL Test and provides value to key partners that collaborate with the Company.

5.10.2.2 The Company's Owned NGAL Patents

The Company's NGAL Patents consist of five patent families, which in 2014 were licensed to Abbott as part of a cross-license where the Company was able to access patents owned by Abbott, Phadia and Columbia University. For further information, see "*14. Material contracts*". The Company evaluates its patent portfolio against other commercial products to determine if there is infringement of its patent claims. If the Company finds a product that it believes infringes the Company's patents, the Company will have to consider a number of factors including, the commercial threat to the Company, the financial strength of the infringing party, the use of the product (i.e. research purposes), etc. Litigation is very expensive, varies from country to country, is time consuming, and would consume resources of the Company that would be better used for its research and operations. Therefore, actions against potential infringers must be carefully considered and can range from sending a notice informing the infringer of the Company's patents, entering into licensing discussions or initiating litigation proceedings.

1. **The NGAL Cut-off patent family** - Determination of Neutrophil Gelatinase-Associated Lipocalin (NGAL) as a Diagnostic Marker for Renal Disorders.

European patent **EP 2128625B1** was granted on 25 January 2017 and is validated in Germany, Denmark, UK, France, Italy, Spain and Sweden. The patent is directed to a method for determining the likelihood of a renal disorder and for discriminating a condition not affecting the kidney, by determining the NGAL concentration in a sample (urine, serum or plasma) and comparing the concentration to a predetermined cut-off value between the range of 250-525 ng/ml, where an NGAL concentration above that cut-off is indicative of a renal disorder. The patent expires on 20 December 2025. Patents with a similar scope are also granted in Australia, Canada, China, Hong Kong, India, Japan and South Korea. Litigation proceedings are ongoing in South Korea regarding the validity of the South Korean patent. See "*5.10.3 Business – Intellectual Property Rights – Patents – Litigation regarding the Company's patents*".

European patent **EP 3208616B1** was granted on 26 September 2018 and validated in Germany, Spain, UK, France and Italy. The patent is directed to monitoring the onset of a renal disorder by determining the concentration of NGAL in a bodily fluid and repeating this step on another sample from the same person after 24 hours or less and if there is a rise in NGAL of 50 ng/ml or more it is indicative that the person is developing or has developed a renal condition. The patent expires on 20 December 2025.

European patent **EP 3489689B1** was granted on 17 June 2020 and expected to be validated in Germany, Italy, Spain, France, UK, Switzerland/Liechtenstein, Denmark, Poland and Sweden. The patent is directed to a method for discriminating between a condition that does not affect the kidney and one that is a renal disorder by determining the concentration of NGAL in a bodily fluid and comparing to a predetermined cut-off that has been chosen to exclude conditions that do not affect the kidney, and wherein an NGAL concentration above the cut-off is indicative of a renal disorder. The patent expires on 20 December 2025.

2. **The NGAL Exclusion patent family –** Diagnostic Test to Exclude Significant Renal Injury.

European patent **EP 2064553A1** was granted on 3 September 2014 and validated in France, Germany, Italy and UK. The European patent has been revoked in opposition proceedings and an appeal was filed in 2017. Oral proceedings are scheduled for 13 October 2020. The possible outcome is that the patent will be upheld; that the patent will be upheld in part; or that the patent will be revoked. See "*5.10.3 Business – Intellectual Property Rights – Patents – Litigation regarding the Company's patents*". The patent is directed to a method of diagnosing, monitoring, or determining the risk of developing acute renal failure, by measuring the concentration of NGAL in urine, serum or plasma and comparing to a predetermined cut-off that has been chosen so that an NGAL concentration below the cut-off categorizes a subject as not having acute renal failure, where the cut-off is 150 ng/ml or lower for urine and 200 ng/ml or lower for plasma or serum. The patent expires on 3 August 2027.

U.S. Application **16/270,379** is pending, and is directed to a method of treating a subject, having an NGAL concentration above a cut-off selected between 150-200 ng/ml for plasma or between 100-150mg/ml for urine and belonging to an unselected group of adults admitted to the ICU, by improving blood circulation to the kidneys or removing urinary obstructions.

3. **The NGAL Forms patent family –** Diagnostic Use of Individual Molecular Forms of a Biomarker.

European patent **EP 2215481B2** was granted on 2 April 2014 and validated in Finland, France, Germany, Italy, Netherlands, Poland, Spain, Sweden and UK. The patent is directed to a method of diagnosing, monitoring or assessing the severity of renal injury by measuring free NGAL monomer by a method that is specific or selective for the free monomer in a bodily fluid from an individual and comparing the concentration with a range of NGAL monomer concentrations that exist in individuals not affected by a renal disorder/injury, where the deviation from said range determines the presence of renal disorder or injury. The patent expires on 14 November 2028.

4. **The NGAL Ratio patent family –** Diagnostic Test for Renal Injury.

European patent **EP 2137538B1** was granted on 9 April 2014 and validated in Germany, France, Italy and UK. The patent is directed to a method of diagnosing or monitoring for the presence of renal injury in a mammal by determining the concentration of NGAL in urine and plasma or serum and calculating the ratio of urine to plasma/serum NGAL and comparing the ratio to a cut-off value from a range of ratios in mammals without evidence of renal injury, where a greater value indicates an injury has occurred. The patent expires on 18 March 2028.

U.S. patent **US 8,313,919** was granted on 20 November 2012. The patent is similar to the EP 2137538B1E patent above, but the diagnosis of renal injury is determined when the ratio value is greater than 0.3 or higher when urine to plasma/serum is calculated and lower than 3.33 when plasma/serum to urine is calculated. The patent expires on 29 January 2029.

5. The NGAL Trauma patent family – Methods for Rapid Assessment of Severity of a Trauma.
European patent **EP 2035835B1** was granted on 28 December 2011 and validated in France, Germany, Italy and UK. The patent is directed to a method for assessing severity of an injury that is due to physical causes in a human by measuring NGAL within 6 hours after the injury has occurred. The patent expires on 30 May 2027.

U.S. patent **US 9,927,446** was granted on 27 March 2018. The patent is directed to a method for diagnosing and treating a human who was exposed to radiation by obtaining an NGAL value on plasma within 12 hours of exposure, comparing the value to a cut-off, making a diagnosis of radiation injury when the NGAL value is above the cut-off, and a further step of treating the patient by administering radiation protection drugs. The patent expires on 21 January 2028.

U.S. Patent **Application 15/889,311** is pending and has additional claims for assessing the severity of physical causes.

5.10.2.3 NGAL patents in-licensed from The Trustees of Columbia University

On 28 December 2016, the Company entered into an exclusive license agreement with The Trustees of Columbia University regarding NGAL patent families assigned to The Trustees of Columbia University and one of its partners. The license agreement was amended on 24 May 2017 to expand access to additional patents. See "*14. Material contracts*".

The license agreement with The Trustees of Columbia University covers the following patent families:

1. Serum NGAL Patent Family – Method for the Early Detection of Renal Disease and Injury.
European patent **EP 1766395B2** was granted on 17 November 2010 and validated in France, Germany and UK. The patent is directed to a method for early detection of a renal tubular injury in a mammal by determining the level of NGAL in blood serum within the first 24 hours of onset by contacting the blood serum with an antibody to NGAL to form a complex of antibody and NGAL. The patent expires on 7 June 2025. Patents with a similar scope are also granted in Australia, Canada, China and Japan.

European patent **EP 2264459B1** was granted on 2 January 2019 and validated in France, Germany, Italy, Spain and the UK. This patent is directed to a method for early detection of renal tubular cell injury by detecting a rise in NGAL levels in blood serum samples taken from a patient at selected intervals prior to an increase in SCR levels. This patent expires on 7 June 2025.

2. Urine NGAL Patent Family – Method and Kit for Detecting the Early Onset of Renal Tubular Cell Injury.
European patent **EP 1616184B2** was granted on 22 July 2009 and validated in France, Germany, Italy, Spain, Denmark, Sweden and UK. The patent is directed to a method for detection of an ischemic renal tubular cell injury in a human within 24 hours of the onset of the ischemic renal injury by contacting a urine specimen with an antibody to NGAL and detecting the complex. Other claims relate to monitoring the effectiveness of treatment and the use of a kit. The patent expires on 26 March 2024. Patents with a similar scope are also granted in Australia, Brazil, China, Japan, Mexico, New Zealand and Hong Kong.

European patent **EP 2083270B1** was granted on 12 June 2019 and validated in France, Germany, Italy, Spain and UK. The patent is directed to a method of detecting renal tubular cell injury in a human caused by certain events, where a urine sample is contacted with an antibody to NGAL to form a complex and the complex is detected. The patent also includes kit claims. The patent expires on 26 March 2024.

European patent **EP 2360475A1** was granted on 2 October 2019 and validated in Belgium, Switzerland/Liechtenstein, Germany, Denmark, Spain, Italy, France, UK, Ireland, Netherlands and Sweden. The patent is directed to a method of assessing the extent of renal injury in a subject by analyzing the level of NGAL in a urine sample and a method of monitoring the progress of treatment by analyzing a urine sample for the presence and level of NGAL. The patent expires on 26 March 2024.

3. Acute Renal vs Chronic Renal – Method for Diagnosing Acute Renal Failure or Chronic Renal Failure.
European patent **EP 2661963B1** was granted on 16 September 2015 and validated in France, Germany and UK. The patent is directed to a method of diagnosing whether a subject is experiencing acute renal failure or chronic renal failure by measuring both NGAL and SCR in blood and assigning a diagnosis of acute renal failure when there is a high correlation between NGAL and creatinine and a diagnosis of chronic renal when there is no correlation between NGAL and creatinine. Other claims for assigning a diagnosis of acute tubular necrosis in blood samples, and a kit are included. The patent expires on 6 May 2025.

4. Chronic Patent – Diagnosis and Monitoring of Chronic Renal Disease Using NGAL.
European patent **EP 1946107** was granted on 25 February 2015 and validated in France, Germany, Netherlands and UK. The patent is directed to a method for evaluating a change in chronic renal injury status in a human by determining the level of NGAL in serum/plasma and obtaining another NGAL level in a subsequent sample from the same patient and evaluating the change in NGAL levels to determine any changes in chronic renal status. The patent expires on 13 October 2026.

European patent **EP 2469284B1** was granted on 7 December 2016 and validated in France, Germany, Italy, Spain and UK. The patent is directed to a method for evaluating chronic renal injury status in a mammal by obtaining a serum/plasma sample, determining the NGAL level and evaluating chronic renal injury status according to the NGAL level. Another claim provides cut-off levels for NGAL to determine stable or worsening chronic renal failure. This expires on 13 October 2026.

5. Kidney Dysfunction – Method for Distinguishing Between Kidney Dysfunctions.
U.S. patent **US 7,977,110B2** was granted on 12 July 2011 and is directed to a method for distinguishing between kidney dysfunctions in a patient having an unknown renal injury upon admission where creatinine is determined in a serum or plasma sample and NGAL is determined in a urine sample and where the NGAL level is above the NGAL cut-off the patient has acute renal injury and when the urine NGAL is below the NGAL cut-off and creatinine is above the creatinine cut-off, the patient has chronic kidney disease. There is another claim for using serum or plasma to measure NGAL. The patent expires on 21 June 2028.

5.10.2.4 gRAD Patents
As a part of the Company's strategy to expand its product portfolio, the Company entered into a license agreement with Rapid Assays ApS on 1 January 2018 (superseding previous agreements signed in 2015) whereby the Company obtained an exclusive license to the gRAD patent family and related technologies). See "*14. Material contracts*".

The license agreement with Rapid Assays ApS covers the following patents:

US 8,507,295 Methods of Quantifications of Lateral Flow Devices.

The patent was granted on 13 August 2013 and is directed to a lateral flow technology where a sample with the analyte of interest is mixed with a quantification agent (a "**QA**") that can simultaneously bind to the analyte in the sample and to an immobilized binding surface. The solution is applied to a lateral flow device with a test band where the QA bound to the analyte is captured and the amount of complexed QA-analyte is compared to calibration samples with known amounts of the analyte to determine the analyte concentration. The patent expires on 10 November 2028.

EP 2212698B1 Methods and Quantification of Lateral Flow Devices.

The patent was granted on 8 January 2014 and validated in Germany, France, UK and Ireland. The patent is directed to a method to quantify an analyte using a lateral flow device similar to the U.S. patent above. The patent expires on 10 November 2028.

5.10.3 Litigation regarding the Company's patents
There is significant litigation in the life science industry regarding patents and other intellectual property rights. The Company may be exposed to future litigation by third parties based on claims that its Products or Future (NGAL) Products, technologies or activities infringe the intellectual property rights of others, or that the Company's patents are considered invalid. If the Company's activities are found to infringe any such patents, the Company may be prevented in performing its commercial activities, have to pay significant damages or seek licenses to such patents. Further, if any of the Company's patents are deemed invalid, significant rising competition may occur, leaving the Company with a lesser market share.

As of the Prospectus Date, the Company is involved in the following patent litigation proceedings:

The South Korean counterpart of PCT application PCT/DK2005/000806, South Korea patent no. 10-0971305 is undergoing litigation proceedings brought on by IVD Lab, Co., Ltd in 2016 regarding its validity. The Company has appealed the decision by the court to invalidate the patent and has on-going actions in South Korea consisting of a Correction Trial to clarify the claims in the patent and an appeal at the South Korean Supreme Court. Possible outcomes include that the patent will be upheld as granted; upheld in amended form; or that the decision to revoke the patent is upheld by the Supreme Court.

The European patent, EP 2064553A1 was revoked in opposition proceedings at the European Patent Office following an opposition filed by Gentian Diagnostics from Norway in 2015. The decision was appealed by the Company and oral proceedings are scheduled for 13 October 2020. Possible outcomes include that the patent will be upheld as granted; that the patent will be upheld in amended form; or that the decision to revoke the patent is upheld by the Board of Appeal.

5.10.4 Trademarks
The Company trademarks are part of its intellectual property assets. By protecting certain trademarks, brand names and logos that define the Company's Products, the Company can provide consumers with confidence that the Company's Products bearing the Company's trademark, are in line with the Company's reputation and commitment to providing quality products. Trademark protection gives the Company legal protection for anyone trying to use the registered trademarks.

5.10.4.1 The NGAL Test
The Company owns the registered trademark "The NGAL Test" in the European Union, in trademark classes 1 and 10. The trademark class 1 protects chemicals for use in industry, science and photography, as well as in agriculture, horticulture and forestry; unprocessed artificial resins, unprocessed plastics; fire extinguishing and fire prevention compositions; tempering and soldering preparations; substances for tanning animal skins and hides; adhesives for use in industry; putties and other paste fillers; compost, manures, fertilizers; biological preparations for use in industry and science. The trademark class 10 protects surgical, medical, dental and veterinary apparatus and instruments; artificial limbs, eyes and teeth; orthopaedic articles; suture materials; therapeutic and assistive devices adapted for persons with disabilities; massage apparatus; apparatus, devices and articles for nursing infants; sexual activity apparatus, devices and articles. The trademark will be renewed before its expiration on 14 January 2021.

5.10.4.2 NGALds

The Company owns the registered trademark "NGAL^{ds}" in the European Union, which is registered in trademark classes 1 and 5. The trademark will be renewed before its expiration on 8 August 2029. The trademark "NGAL^{ds}" is pending for the International Protocol in trademark classes 1 and 5 with designations in Japan, South Korea and the U.S. The trademark class 5 protects pharmaceuticals, medical and veterinary preparations; sanitary preparations for medical purposes; dietetic food and substances adapted for medical or veterinary use, food for babies; dietary supplements for human beings and animals; plasters, materials for dressings; material for stopping teeth, dental wax; disinfectants; preparations for destroying vermin; fungicides, herbicides.

5.10.4.3 BioPorto

The Company owns the registered trademark for "BioPorto" in the EU, International Protocol, China, the U.S. and South Korea in trademark classes 1, 5, 10 and 42. The next renewal for the EU is on 31 December 2026. The next renewal for The International Protocol is on 11 March 2026, which includes the U.S., China and South Korea. The due dates for filing a declaration of use in the U.S. are on 3 April 2024 and on 3 April 2028. The trademark is registered in classes 1, 5, 10 and 42. The trademark class 42 protects scientific and technological services and research and design relating thereto; industrial analysis, industrial research and industrial design services; quality control and authentication services; design and development of computer hardware and software.

5.10.5 Proprietary antibodies owned or controlled by the Company

In addition to patents, the Company has developed or in-licensed key monoclonal antibodies to use in its product portfolio. The Company developed proprietary monoclonal antibodies that are used in the current NGAL products (for IVD and RUO), which have been used to generate numerous clinical and research publications. The Company estimates that it would take a competitor significant investment and time to replicate similar antibodies used in an assay to generate, if possible, a similar body of evidence. Even though other NGAL antibodies are available, the Company estimates that its developed antibodies have been studied more extensively than other NGAL antibodies.

5.11 Changes in the Company's regulatory environment

See "*5.13 Business – Regulatory environment*".

5.12 Investments

As of the Prospectus Date, a regulatory clinical study for NGAL in pediatrics is the Company's only significant investment in progress for FY2020. The total investment by the Company is currently expected to amount to DKK 17 million, of which DKK 11 has been invested as of the Prospectus Date. A total of DKK 8 million of the investment is committed to a clinical research organization assisting the Company performing the study. The remaining part of the investment is planned to take place during the last quarter of 2020.

The Company expects to finance the investment with the Company's current cash holdings and with proceeds from the Offering. 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.

5.13 Regulatory environment

5.13.1 The European Economic Area

5.13.1.1 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 as 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.

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 to provide more legal certainty for market stakeholders as compared to EU member states having to transpose EU directives into national law.

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 (providing certain grace periods) 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 will 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 may continue to be placed on the market until 27 May 2024 (i.e. following application of the new IVDR) and made available until 27 May 2025.

5.13.1.2 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 GCP. 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.

5.13.1.3 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.

5.13.1.4 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.

5.13.1.5 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;
- IVD Directives, 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;
- IVD Directives, 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.

5.13.1.6 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.

5.13.2 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.

5.13.2.1 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)**"), 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 (QSR), 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. Based on the 510(k), the FDA may permit to commercially distribute a device (a "**510(k) Clearance**"). Devices deemed by FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have certain new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring FDA approval of a PMA.

5.13.2.2 510(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.

5.13.2.3 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. Under FDASIA, FDA is required to classify the device within 150 days following receipt of the De Novo application.

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.

5.13.2.4 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 requests for De Novo designation 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.

5.13.2.5 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.

5.13.2.6 The Investigational Device Exemption 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.

5.13.2.7 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.

5.13.2.8 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.

5.13.2.9 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. Following a potential FDA clearance of The NGAL Test for pediatric use, the Company plans to initiate further trials/studies with a view to submit a new 510(k) application for the clearance of The NGAL Test for adult use.

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 21 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.

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, or costs and selling prices since the end of the period covered by the FY2019 Financial Statements.

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 FY2019 Financial Statements.

6.3 Other trends

6.3.1 COVID-19

As per the Prospectus Date, the Company has not yet seen any significant changes to the financial performance or to trends in production, sales and inventory, or costs and selling prices since the period covered by the FY2019 Financial Statements due to the COVID-19 pandemic.

As a result of the COVID-19 pandemic, both ongoing and new clinical studies were halted across the globe and patient enrollment was postponed until hospitals were able to evaluate and understand their capacity to manage non-critical activities, such as clinical trials.

As the Company announced in its interim report for the first quarter of FY2020, the Company's original expectation was to begin patient enrollment for its NGAL clinical trial in pediatrics in the first quarter of FY2020 following a pre-submission dialogue with the FDA, leading to a 510(k) application in the second quarter of FY2020. The COVID-19 pandemic hampered this schedule and as a result, patient enrollment in the Company's pediatric NGAL clinical trial was temporary put on hold.

On 23 June 2020, the Company announced enrolment of the first patient in its pediatric NGAL clinical trial. Costs related to the clinical trial, as well as the application to the FDA, will be postponed to the second half of FY2020, which the Company announced in its interim report for the first quarter of FY2020.

7 Consolidated Prospective Financial Information

7.1 Statement by management

Management's prospective consolidated financial information for FY2020 is presented below (the "**Consolidated Prospective Financial Information**").

We have prepared and presented the Consolidated Prospective Financial Information, including the key assumptions set out in "*7.2.3 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 2019 and consistent with the accounting policies as those applied in the FY2019 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 "*7.2.3 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, 25 September 2020

Board of Directors

Thomas Magnussen
Chairman

Torben Arnth Nielsen
Vice Chairman

Kirsten Aarup Drejer
Board Member

Christopher James Lindop
Board Member

Michael Scott Singer
Board Member

Executive Management

Peter Mørch Eriksen
CEO

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.

The Consolidated Prospective Financial Information was not prepared with a view to ensure compliance with published guidelines of the U.S. Securities and Exchange Commission and the American Institute of Certified Public Accountants (the "**AICPA**"), for preparation and presentation of prospective financial information. Accordingly, this information does not include disclosure of all information required by the AICPA guidelines on prospective financial information.

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 Management's Responsibility

The Company's Board of Directors and Executive Management are responsible for the proper compilation of the Consolidated Prospective Financial Information on the basis stated and for the basis of accounting used for the Consolidated Prospective Financial Information being consistent with the accounting policies of the Company and for such internal control as the Company's Board of Directors and Executive Management determine is necessary to enable the preparation of the Consolidated Prospective Financial Information on the basis stated.

Furthermore, the Company's Board of Directors and Executive Management are responsible for the assumptions underlying the Consolidated Prospective Financial Information.

7.2.3 Methodology and assumptions

The Consolidated Prospective Financial Information has been prepared in accordance with the accounting policies presented in the FY2019 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 updated budget for FY2020 prepared in accordance with the Company's forecasting and budgeting procedures and on a basis comparable to the FY2019 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 until 31 December 2020, 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 60 million. Other key assumptions in relation to the Consolidated Prospective Financial Information are the following:

7.3.1 Assumptions relating to revenue

The Company's estimates concerning revenue for FY2020 are principally based upon and assume the following:

- Revenue will be supported by an increase in NGAL product sales across regions compared to FY2019 (partly outside the Company's control).
- Sales of antibodies and ELISA kits are assumed to decline due to the Company's narrower focus on its own antibody library compared to FY2019 (within the Company's control).
- Revenue does not include any launch of The NGAL Test for pediatrics in 2020 (within the Company's control).
- Revenue is assumed to be back-end loaded. As per 30 June 2020, revenue amounted to DKK 10.9 million. Revenue for the fourth quarter of FY2020 is assumed to be in the same range as first half of FY2020, mainly due to increased NGAL ROW revenue (partly outside the Company's control).
- Revenue from NGAL ROW in the fourth quarter of FY2020 is dependent upon timing of delivery of a few larger orders (outside the Company's control).
- Currency exchange rates assumed to be USD/DKK: 6.70 and EUR/DKK: 7.45 (outside the Company's control).

7.3.2 Assumptions relating to EBIT

In addition to the Company's assumptions as to revenue, the Company's estimates regarding EBIT for FY2020 are principally based on the following assumptions:

- EBIT assumed to be affected negatively by full year impact of 2019 hires primarily within Corporate Management and R&D (within the Company's control).
- Costs related to clinical studies are assumed to increase significantly compared to FY2019 (within the Company's control).
- The regulatory clinical trial of NGAL in pediatrics can enroll 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 decrease compared to FY2019 (within the Company's control).
- Costs related to Production, Administration and Depreciation are assumed at FY2019 levels (within the Company's control).

7.4 Consolidated Prospective Financial Information

Based principally on the assumptions and methodology as set out above, the Company provides the following estimates for FY2020:

- Revenue of approximately DKK 30 million.
- Operating loss (EBIT) of approximately 73 million.

8 Board of directors, executive management and key employees

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 employees (the "**Key Employees**" and together with the Executive Management, the "**Corporate Management**"). The business address of the Board of Directors, Executive Management and the Key Employees is Tuborg Havnevej 15, ground floor, DK-2900 Hellerup, Denmark, however, the business address of Amy Winslow and Christopher Bird is 117 Fourth Avenue, Suite 202, Needham, MA 02494, the United States of America.

For a description of the remuneration of the Board of Directors, Executive Management and Key Employees, including ownership of Shares and holding of Share related instruments granted under the Company's current incentive schemes, see the FY2019 Financial Statements.

In addition to statutory governance boards, the Company has established an advisory board consisting of a number of KOLs. From time to time, the Company also hires individual KOLs on an ad hoc basis to conduct studies etc. for the Company. The KOLs are independent from the Company but receives 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 five members elected by the general meeting including the Chairman, the Deputy Chairman and three 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
Thomas Magnussen	Chairman	Independent	2013	2021
Torben Arnth Nielsen	Deputy Chairman	Independent	2013	2021
Kirsten Aarup Drejer	Member	Independent	2017	2021
Christopher James Lindop	Member	Independent	2019	2021
Michael Scott Singer	Member	Independent	2019	2021

[1] The Company has based its assessment of independence on the basis of the criteria set out in the current Corporate Governance Recommendations.

All members of the Board of Directors are considered by the Company to be independent under the current Corporate Governance Recommendations.

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.

Thomas Magnussen (born 1953, Danish nationality) has been a member of the Board of Directors of the Company since 2013 and is Chairman of the Board of Directors. Thomas Magnussen is chief executive officer of Therazone ApS and Thera Property ApS. Thomas Magnussen is a serial entrepreneur within high-tech, focusing on start-up companies with a global business potential. Thomas Magnussen has experience in commercialization strategies within nanotechnology, ICT and MedTech industries and has previously been chairman of the board of directors of QuantumWise ApS and Zylinc A/S. Thomas Magnussen holds an MBA from INSEAD as well as a Ph.D. and MSc from the Technical University of Denmark.

Current directorships in other companies: Thomas Magnussen is chairman of the board of directors of UserTribe A/S, BioPorto Diagnostics A/S and Veterinary Diagnostics A/S and BioPorto Inc. and a member of the executive management of Therazone ApS and Thera Property ApS.

Previous directorships in other companies: In the past five years, Thomas Magnussen has previously been chairman of the board of directors of QuantumWise A/S and Zylinc A/S.

Torben Arnth Nielsen (born 1960, Danish nationality) has been a member of the Board of Directors of the Company since 2013 and is Deputy Chairman of the Board of Directors. Torben Arnth Nielsen has over the past 25 years held senior positions in the financial sector, most recently as a member of the executive management of Sydbank A/S, being responsible for asset management and capital markets, and as chairman of the board of directors of BankInvest Private Equity A/S. Concurrently, he has held several national and international board directorships. Over the last 30 years, of which 5 years were in New York and London, Torben Arnth Nielsen has built and managed businesses in Denmark and abroad in all relevant commercial business areas in the financial sector and has been involved in and responsible for several mergers and acquisitions. Torben Arnth Nielsen holds DIEU's top management education VL (2006) as well as a degree in banking.

Current directorships in other companies**:** Torben Arnth Nielsen is chairman of the board of directors and partner of Linde & Partners Kapitalrådgivning A/S, chairman of the board of directors of Nordic Firefly A/S, deputy chairman of the board of directors of Safe Online ApS, member of the board of directors of Wavepiston A/S, BioPorto Diagnostics A/S and Veterinary Diagnostics A/S and chief executive officer of Arnth Advice ApS.

Previous directorships in other companies: In the past five years, Torben Arnth Nielsen has previously been chairman of the board of directors of Safe Online ApS and a member of the executive management of LP Dividende Fond A/S and LP Value Fond A/S.

Kirsten Aarup Drejer (born 1956, Danish nationality) has been a member of the Board of Directors of the Company since 2017. Kirsten Aarup Drejer is co-founder of Symphogen A/S, a biopharmaceutical company focused on the innovative therapeutic utilization of antibody mixtures. In the period 2000-2016, Kirsten Aarup Drejer was chief executive officer of Symphogen A/S and in the period 2016-2018 she was a member of the board of directors of Symphogen A/S. Prior to this, Kirsten Aarup Drejer has held a number of scientific and managerial positions within Novo Nordisk A/S as well as directorships of, among others, Danisco A/S. Kirsten Aarup Drejer is a member of numerous advisory boards at the University of Copenhagen, Danish Technical University and the Copenhagen Business School. Kirsten Aarup Drejer won the prize of "BiotechBuilder of the Year" in 2003 and "Entrepreneur of the Year, Biotech" in 2007. Kirsten Aarup Drejer holds a MSc (pharm) and Ph.D. in pharmacology from the University of Copenhagen.

Current directorships in other companies: Kirsten Aarup Drejer is chairman of the board of directors of Antag Therapeutics ApS, ResoTher Pharma ApS and Bioneer A/S, deputy chairman of the board of directors of Zealand Pharma A/S as well as a member of the board of directors of Lyhne & Company A/S, Malin Plc and Alligator Bioscience AB. Kirsten Aarup Drejer is also member of the executive management of KD Invest ApS.

Previous directorships in other companies: In the past five years, Kirsten Aarup Drejer has previously been chief executive officer and member of the board of directors of Symphogen A/S and member of the board of directors of the Danish Growth Fund (Vækstfonden) and Bionor Pharma ASA.

Christopher James Lindop (born 1957, British and American nationality) has been a member of the Board of Directors of the Company since 2019. 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. In 2003, Christopher James Lindop took the position as chief financial officer of Inverness Medical Ltd., before he became chief financial officer and EVP Business Development at Haemonetics Corporation Ltd. (HAE) in 2007. Since 2017, Christopher James Lindop has been chief financial officer of Quotient Limited (QTNT) until his retirement in May 2020. From 2007 until 2018 Christopher James Lindop was a member of the board of directors of Parexel International (PRXL) where he served as chairman of the audit committee and member of the nominating and governance Committee. Christopher James Lindop has considerable experience in management of U.S. listed health care and diagnostic companies and within finance and reporting, corporate governance, mergers & acquisitions, funding and strategy development and execution.

Previous directorships in other companies: In the past five years, Christopher James Lindop has previously been chief financial officer and EVP Business Development at Haemonetics Corporation Ltd., chief financial officer of Quotient Limited and a member of the board of directors of Parexel International Corporation, where Christopher James Lindop served as chairman of the audit committee and member of the nominating and corporate governance committee.

Michael Scott Singer (born 1973, American nationality) has been a member of the Board of Directors of the Company since 2019. Michael Scott Singer has served since 2016 as chief scientific officer and co-founder of Cartesian Therapeutics, Inc., a U.S. clinical-stage cell and gene therapy company. Prior to this, he was co-founder and chief scientific officer of Topokine Therapeutics, Inc., where he was responsible for pre-clinical and clinical development of the company's adipomodulatory products. Topokine Therapeutics, Inc. was acquired by Allergan in 2016. Michael Scott Singer was also co-founder and chief scientific officer of HealthHonors Corporation, acquired by Healthways in 2009. He also served as director of translational medicine at Novartis and a physician at Harvard and the U.S. Veterans Affairs Medical Center. Michael Scott Singer serves on the clinical faculty and as an entrepreneur in residency at Yale University. He volunteers on the board of museum advisors at the Museum of Science, Boston. He holds an M.D. cum laude and a Ph.D. in neuroscience from Yale University, CT.

Current directorships in other companies: Michael Scott Singer is a director at Cartesian Therapeutics, Inc., Pykus Therapeutics, Inc. and Anodyne Nanotech, Inc. He serves on the advisory board of IvexSol, Inc.

Previous directorships in other companies: In the past five years, Michael Scott Singer has previously been chief scientific officer of Topokine Therapeutics, Inc. and chief medical officer of Neutrolis Inc.

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 Employees.

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
Peter Mørch Eriksen	Chief Executive Officer	2013	2013

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.

Peter Mørch Eriksen (born 1960, Danish nationality) has served as Chief Executive Officer of the Company since July 2013 and has spent more than 20 years in the medtech/life science industries, including as chief executive officer of Sense A/S and VP of Medtronic. From these positions, Peter Mørch Eriksen brings extensive experience in creating growth, restructuring and funding in technology-intensive and complex companies. He is an experienced leader with a record of business success 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.

Current directorships in other companies: Member of the board of directors and chief executive officer of BioPorto Diagnostics A/S, member of the board of directors of BioPorto Inc., BioPorto Diagnostic Inc., Veterinary Diagnostics A/S, FluoGuide A/S and member of the executive management of PME Holding ApS. Peter Mørch Eriksen is also a member of the advisory board at Lund University Diabetes Centre and a member of the Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Center in Cincinnati, Ohio (US).

Previous directorships in other companies: In the past five years, Peter Mørch Eriksen has previously been chairman of the board of directors of Ocumove ApS, JGN 1 3-12-2018 ApS, JGN 2 3-12-2018 ApS, JGN 3 Glamsbjerg ApS and Fonden Mtic, Medtech Innovation Center and member of the board of directors of Online Grænsehandel Group A/S, Nervex A/S and ON Line Group.

8.6 Key Employees

The Key Employees are employed by the Company with responsibility for their functional areas.

The following table presents an overview of the Company's current Key Employees:

Name	Position	Year of first appointment	Year of appointment to current position
Ole Larsen	Chief Financial Officer	2018	2018
Jan Kuhlmann Andersen	Chief Operating Officer	2016	2016
Christopher Bird	Chief Medical Officer	2019	2019
Amy Winslow	President, BioPorto Diagnostics, Inc.	2019	2019

8.7 Key Employees – Biographies

Other than as presented below, none of the Key Employees have 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.

Ole Larsen (born 1965, Danish nationality) was appointed Chief Financial Officer of the Company in June 2018. Ole Larsen brings comprehensive industrial and financial knowledge to the Company as an experienced executive in international health care and media companies. Most recently from Bavarian Nordic A/S, a listed Danish biotechnology company focused on cancer immunotherapies and vaccines for infectious diseases. Since 2008, Ole served as executive vice president and chief financial officer and was responsible for Finance, IR and IT. Prior to this, he held chief financial officer positions at two of the largest Danish and Nordic media groups, Nordisk Film and Berlingske Tidende. Ole Larsen holds a MSc in Economics from Copenhagen Business School.

Current directorships in other companies: Ole Larsen is a member of the board of directors of BioPorto Diagnostics A/S, BioPorto Inc., BioPorto Diagnostic Inc. and Veterinary Diagnostics A/S and chairman of the board of directors of Rikke Gravengaard - Copenhagen A/S.

Previous directorships in other companies: In the past five years, Ole Larsen has previously been executive vice president and chief financial officer of Bavarian Nordic A/S and member of the board of directors and member of the executive management of Aktieselskabet af 1. juni 2011 I and Aktieselskabet af 1. juni 2011 II.

Jan Kuhlmann Andersen (born 1961, Danish nationality) was appointed Chief Operating Officer of the Company in August 2016. Jan Kuhlmann Andersen is an experienced executive having worked in sales and business development in the life science industry since 1995, primarily in US-owned companies such as FMC, Cambrex, Fisher Scientific (now Thermo Fisher). From 2007 and until joining the Company, Jan Kuhlmann Andersen was vice president, sales & marketing, in the Animal Health & Nutrition division in Chr. Hansen A/S. Jan Kuhlmann Andersen holds a Ph.D. in immunology and a MSc in Biology from the University of Copenhagen.

Current directorships in other companies: Jan Kuhlmann Andersen is chief executive officer of Veterinary Diagnostics A/S and chairman of the board of directors of Cytovac A/S.

Previous directorships in other companies: In the past five years, Jan Kuhlmann Andersen has previously been a member of the Board of Directors of the Company, member of the board of directors of CellMade Laboratories and vice president, sales & marketing of Chr. Hansen A/S.

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 Ph.D. in Molecular Immunology from Oxford University, where he was an Abraham Scholar.

Previous directorships in other companies: In the past five years, Christopher Bird has previously been a member of the Charter Schools USA board as vice president, a member of the scientific advisory board of Conner Prairie and head of North American medical and scientific affairs in Roche Diagnostics Corp.

Amy Winslow (born 1971, American nationality) was appointed President of BioPorto Diagnostics, Inc. in April 2019. Amy Winslow is an experienced diagnostics executive, who most recently served as President and CEO of Magellan Diagnostics, Inc., a Boston-based point-of-care diagnostics company. While at Magellan Diagnostics, Inc., Amy Winslow lead the company's restructuring for growth, increased profitability, built a dedicated commercial team, and ultimately ran a successful sale of the company to Meridian Bioscience, Inc. Prior to this, among other roles, Amy Winslow served as vice president of marketing for Athena Diagnostics, Inc., a neurodiagnostic specialty laboratory testing business that was later acquired by Quest Diagnostics and as marketing manager at Genyzme Transgenics. Amy Winslow holds an MBA from Harvard Business School and a BA in Biology from Brown University. Amy Winslow serves on several non-profit boards, including the Museum of Science, Boston and the Brigham and Women's Physician's Organization.

Previous directorships in other companies: In the past five years, Amy Winslow has previously been president and chief executive officer of Magellan Diagnostics, Inc. and EVP of Meridian Bioscience.

8.8 Statement of kinship

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

8.9 Statement on past records

During the past five years, none of the members of the Board of Directors, the Executive Management or any of the Key Employees 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, except for as set out immediately below, 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.

Thomas Arnth Nielsen was a member of the executive management of LP Dividende Fond A/S until 2015, when the company went into voluntary liquidation and a member of the executive management of LP Value Fond A/S until 2015, when the company went into voluntary liquidation.

Peter Mørch Eriksen was a member of the board of directors of Nervex A/S until 2015, when the company went into voluntary liquidation.

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 Employees and their private interests or other duties.

None of the members of the Board of Directors, or the Executive Management or any other Key Employees have conflicts of interest with respect to their duties as members of the Board of Directors, or the Executive Management or as Key Employees.

None of the members of the Board of Directors, the Executive Management or the Key Employees have positions in other companies which could result in a conflict of interest vis-à-vis such companies, either because the Company has an equity interest in such company or because the Company and the company concerned have an ongoing business relationship. However, the Company may do business in the ordinary

course with companies in which members of the Board of Directors, or the Executive Management, or the Key Employees may hold positions as directors or officers.

The Company is not aware of any member of the Board of Directors, or the Executive Management or any of the Key Employees having been appointed to their current position pursuant to an agreement or understanding with Major Shareholders, customers, suppliers or others.

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 different voting rights. 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.

Certain members of the Board of Directors and the Management participated in the Company's rights issue completed on 15 April 2020. In total they acquired 285,486 new shares at a price of DKK 1.60 per share totaling DKK 456,778 as specified in company announcement no. 11 dated 15 April 2020.

10 Related party transactions

See the FY2019 Financial Statements and the Half Year Financial Statements for related party transactions incorporated into this Prospectus by reference. The Company has not entered into any related party transactions (within the meaning of IFRS) since the FY2019 Financial Statements and the Half Year Financial Statements, except for compensation and benefits received by the Board of Directors and Executive Management because of their membership of the Board of Directors, employment with the Company or shareholdings in the Company and except for the advance commitment and guarantee undertakings from the Board of Directors and Executive Management described under "*20.16.4 Terms and conditions of the offer of securities to the public – Placing and underwriting – Advance undertakings and underwriting*".

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/.

Document/information:
FY2018 Financial Statements
Published on 22 February 2019
Management statement, page 71
Independent auditor's report, pages 72-73
Consolidated financial statement including notes, pages 34-70
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
Half Year Financial Statements
Published on 19 August 2020
Management statement, page 9
Consolidated financial statement including notes, pages 10-15
Articles of Association
Dated 19 August 2020

11.2 Auditing of financial statement

The audit report for the FY2018 Financial Statements is included in this Prospectus by reference.

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

The Half Year Financial Statements are unaudited.

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

11.3 Legal and arbitration proceedings

As of the Prospectus Date, the Company is involved in litigation regarding the Company's patents. See "*5.10.3 Business – Intellectual Property Rights – Patents – Litigation regarding the Company's patents*".

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 has been no significant change to the operations and principal activities of the Company since the end of the period covered by the Half Year Financial Statements.

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 revenue, 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*".

The Board of Directors is not authorized to distribute extraordinary dividends.

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 199,936,428 divided into 199,936,428 Existing Shares with a nominal value of DKK 1. No shares carries special rights. The Company has no share classes and 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 266,581,904 divided into 266,581,904 Shares with a nominal value of DKK 1.

12.2 Incentive program

12.2.1 Warrants

The Company has a long-term share-based incentive warrant program for members of management and certain key employees (the "**Warrant Program**"). A total of 18,682,500 warrants are outstanding from the various grants. As set out in the Company's remuneration policy, most recently amended at the Company's annual general meeting in April 2020, 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. Members of the Board of Directors do not participate in any incentive-based remuneration.

Grants of warrants under the program are made at the discretion of the Board of Directors. The warrants generally vest between two and three years after the time of grant and are generally subject to customary good/bad leaver and claw back provisions. Vesting may be subject to KPIs defined by the Board of Directors in accordance with the Company's short and long-term targets.

Vested warrants may be exercised at the earliest two years and at the latest five years after the date of grant. Warrants not exercised on or before the last day in the exercise period will lapse without compensation or other consideration.

The warrants may be subject to adjustment in certain extraordinary events, such as a (voluntary or mandatory) takeover bid, 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. Warrants may also be adjusted in case of certain changes in the company's share capital structure affecting the value of the warrants.

The terms governing the Company's Warrant Program are attached to the Articles of Association which are included in the Prospectus 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 9.34% of the Company's share capital on a fully diluted basis are outstanding. Annex 1.3 to Appendix 1 of the Articles of Association (which are incorporated by reference in this Prospectus) sets out the individual warrants grants, including vesting requirements, exercise prices and applicable vesting and exercise periods. 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**
April 2016 grant	2,432,500	4.58	April 2018 – April 2021
June 2018 grant	900,000	3.11	June 2021 – June 2023
August 2018 grant	4,100,000	3.44	August 2021 – August 2023
December 2018 grant	2,500,000	3.75	December 2021 – December 2023
April 2019 grant	5,100,000	3.92	April 2021 – April 2024
August 2019 grant	1,250,000	2.88	August 2021 – August 2024
December 2019 grant	250,000	2.90	December 2021 – December 2024
May 2020 grant	2,150,000	2.72	May 2022 – May 2025
	18,682,500	N/A	N/A

13 Regulatory disclosures

During the last 12 months, the Company has announced the following inside information in accordance with Regulation (EU) No 596/2014 on market abuse ("**Market Abuse Regulation**"):

- Publication of prospectus in connection with a rights issue with pre-emptive subscription rights for existing shareholders (See company announcement no. 17, dated 25 September 2020);
- Plans of clinical evaluation of gRAD-based test for rapid detection of COVID-19 virus (See company announcement no. 16, dated 17 September 2020);
- Initiation of rights issue with pre-emptive rights for existing shareholders (See company announcement no. 6, dated 16 March 2020);
- Progress update on its activities to strengthen its financial position (See company announcement no. 5, dated 16 March 2020);
- Progress update on its activities to strengthen its financial position (See company announcement no. 4, dated 11 March 2020);
- Preliminary financial result for 2019, guidance for 2020 and postponement of the publication of audited annual report for 2019 to 11 March 2020 and the pursuit of a private placement of new shares (See company announcement no. 1, dated 26 February 2020);
- Additional patient information in support of its US application for regulatory clearance of The NGAL Test™ for pediatric risk assessment of Acute Kidney Injury (See company announcement no. 20, dated 18 November 2019); and
- Submission of answers to the FDA regarding The NGAL Test™ for risk assessment for AKI in pediatric patients (See company announcement no. 19, dated 17 October 2019).

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 contracts

14.1 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.

14.1.1 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 the last to expire licensed patents under the agreement.

14.1.2 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 and urine patents and 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 expiration of the last valid claim under the licensed patents and is subject to commercially agreed termination provisions.

14.1.3 Exclusive License Agreement with Rapid Assays ApS

In January 2018, BioPorto Diagnostics obtained an exclusive, worldwide, royalty-bearing license from Rapid Assays ApS for patents related to gRAD, granting BioPorto Diagnostics 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.

14.1.4 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 an NGAL product specifically for use with the Siemens' proprietary BN series instrument systems (BN II and BN ProSpec). Pursuant to the agreement, BioPorto Diagnostics shall manufacture and supply 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 instruments. The agreement is subject to commercially agreed termination provisions.

14.1.5 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 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.

14.1.6 Agreement for Manufacturing and Supply of components for The NGAL Test

BioPorto Diagnostics has entered into an agreement with a foreign manufacturing company for the manufacturing and supply of components for The NGAL Test. The agreement is subject to commercially agreed termination provisions.

14.1.7 Purchase Agreement with Diatec Monoclonals AS

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

14.1.8 Co-financed Research Agreement with the University of Southern Denmark

The Company has entered into an agreement on co-financed research with the University of Southern Denmark ("**SDU**") for the development of a COVID-19 test for early detection of infected patients. The agreement provides inter alia that the Company can require SDU to grant the Company a royalty-bearing, worldwide, exclusive sub-licensable license to all of SDU's rights to commercially exploit two selected antibodies raised against SARS-CoV-2 virus for diagnostic purposes.

14.1.9 Rights Issue Agreement

The Company and the Global Coordinator have as of the Prospectus Date entered into the Rights Issue Agreement. Pursuant to the Rights Issue Agreement, the Company has given customary representations and warranties to the Global Coordinator and has also undertaken to indemnify the Global Coordinator for certain potential liability obligations related to the Offering.

The Global Coordinator may, at its own discretion, terminate the Rights Issue Agreement, which may thereby require the Company to withdraw the Offering, if any of the closing conditions are not met. The Rights Issue Agreement contains closing conditions which the Company believes

are customary for offerings such as the Offering and the closing of the Offering is dependent on compliance with all of the conditions set forth in the Rights Issue Agreement.

The Company has undertaken that for a period of 180 days counted from the date of admission to trading and official listing of the New Shares under the existing ISIN code it will not without the prior written consent of the Global Coordinator, (i) issue, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of (or publicly announce such action), directly or indirectly, any Shares or any securities convertible into or exercisable or exchangeable for Shares, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of Shares, or (iii) submit to its shareholders a proposal to effect any of the foregoing. Certain exemptions apply. See "*22.2.1 Selling securities holders – Lock-up agreements – Lock-up agreement with the Company*" for a description of the exemptions to the lock-up agreement with the Company.

Further, the members of the Board of Directors and of the Executive Management have each agreed that for a period of 180 days counted from the date of official listing of and trading of the New Shares under the existing ISIN code they will not without the prior written consent of the Global Coordinator, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly any Shares or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Shares, whether any such transaction described in (i) or (ii) above is to be settled by delivery of such Shares or such other securities, in cash or otherwise. Certain exemptions apply. See "*22.2.2 Selling securities holders – Lock-up agreements – Lock-up agreements with individual board members and executive management members*" for a description of the exemptions to the lock-up agreements with the members of the Board of Directors and of the Executive Management.

14.1.10 Subscription Commitments

See "*20.16.4 Terms and conditions of the offer of securities to the public – Placing and underwriting – Advance undertakings and underwriting*" 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 FY2018 Financial Statements.
- The FY2019 Financial Statements.
- The Half Year Financial Statements.
- The Prospectus related to the Offering.

Any request for copies of the Prospectus may be made to: Ole Larsen, CFO, ol@bioporto.com.

Subject to certain exceptions, the Memorandum of Association, Articles of Association, the FY2018 Financial Statements, the FY2019 Financial Statements and the Half Year Financial Statements and the Prospectus can also be downloaded from the Company's website: https://bioporto.com/investor-relations/. Except for the information incorporated herein by reference, the contents of the website do not from part of the Prospectus.

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. 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 key 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 Global Coordinator and its respective affiliates have from time to time been engaged in, and may in the future engage in, commercial banking, investment banking and financial advisory transactions and services in the ordinary course of their business with the Company or any of the Company's respective related parties. The Global Coordinator has received and will receive customary fees and commissions for these transactions and services and may come to have interests that may not be aligned or could potentially conflict with the interests of shareholders, prospective investors and the Company. In particular, the Global Coordinator is a party to the Rights Issue Agreement pursuant to which the Global Coordinator is entitled to fees relating to the completion of the Offering. For further information see "*20.16.2 Terms and conditions of the offer of securities to the public – Placing and underwriting – Rights Issue Agreement*".

In addition, in the ordinary course of business the Global Coordinator and its respective affiliates may make or hold a broad array of investments including serving as counterparties to certain derivative and hedging arrangements and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the Company. The Global Coordinator and its respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

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 enable the Company to successfully continue its operations and to further develop its Products.

If the Offering is fully subscribed, the gross proceeds from the Offering will amount to approximately DKK 106.6 million. The net proceeds to the Company from the issue of the New Shares are expected to be approximately DKK 93.6 million after deduction of costs and expenses payable by the Company in relation to the Offering.

If the minimum amount of New Shares offered is subscribed for, corresponding to 45,000,000 New Shares and net proceeds of DKK 60 million, the Company expects to apply the proceeds to finance the Company's current operations for 12 months. This includes costs of employees, clinical trial costs, sales & marketing costs, production costs, R&D costs not related to employees or clinical trials as well as other operational costs (leases, auditors, lawyers, consultants etc.).

Any net proceeds from DKK 60 million to DKK 90 million will be applied to finance the NGAL development:

- Developing the Company's U.S. organization to prepare for a FDA clearance and commercialization of NGAL for pediatrics. This includes hiring approximately 15 FTEs (sales staff, medical liaisons, product management, tech support and partner/distributor support) – approximately DKK 15 million
- Supporting the NGAL development, including costs for a clinical trial and the submission to FDA related to NGAL for adults as well as research projects to expand the label or usage of NGAL – approximately DKK 15 million

If the Offering is fully subscribed, the net proceeds above DKK 90 million including the Company's current cash position, will be applied to develop the gRAD platform:

- Developing new indication using the gRAD including a regulatory clinical trial as well as research projects, expectedly within the areas of COVID-19, Sepsis and Inflammation – approximately DKK 15 million

In case the Offering is not fully subscribed, the Company's activities and future investments will be adjusted accordingly.

18.3 Working capital statement

The Company's present working capital, including 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.

If the Offering is completed with net proceeds of DKK 60 million, the Company considers based on given current knowledge, including the assumptions related to 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*"), that 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. This assessment relies on a number of assumptions, inter alia regarding a positive development in the Company's FDA application process and subsequent commercialization of The NGAL Test, each of which remains difficult to predict. Further, the operations of the Company remain subject to the risk factors applicable to the Company. In the event the FDA application process from The NGAL Test does not progress as planned or that any of the other risk factors relating to the Company materializes, including if the adverse market conditions following 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 for a twelve months' period after the Prospectus Date or periods thereafter. In such a case or in the event the Offering is not completed, the Company will take mitigating actions to seek to protect or further strengthen its financial position, including potentially by raising further capital, although there can be no assurance any such future efforts will be successful.

In case the Company's ongoing R&D, approval process and/or commercialization efforts are more positive than anticipated, the Company may also 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 months' period after the Prospectus Date.

18.4 Capitalization and indebtedness

The following tables set forth the consolidated capitalization, indebtedness (distinguishing between guaranteed and unguaranteed, secured and unsecured) and cash, cash equivalents, and securities of the Company as of 30 June 2020 on an actual basis reflecting the carrying amounts on the internal bookkeeping of the Company. This table should be read in conjunction with the FY2019 Financial Statements and the Half Year Financial Statements.

Capitalization

DKK million	**As of 30 June 2020 Not reviewed and not audited**
Current debt	
Guaranteed	-
Secured	0.9
Unguaranteed / unsecured	2.5
Total current debt	**3.4**
Non-current debt	
Guaranteed	-
Secured	-
Unguaranteed / unsecured	11.0
Total non-current debt	**11.0**
Share capital and reserves	
Share capital	199.9
Exchange-rate adjustments	(0.4)
Retained earnings	(164.6)
Total share capital and reserves	**34.9**
Total capitalization	**49.3**

Indebtedness

DKK million	As of 30 June 2020 Not reviewed and not audited
Cash	
Cash	30.3
Liquidity	**30.3**
Total financial assets	**30.3**
Current financial liabilities	
Current portion of non current debt	3.4
Total current financial liabilities	**3.4**
Non-current financial liabilities	
Other non-current loans	11.0
Total non-current financial liabilities	**11.0**
Total financial indebtedness	**14.4**
Total net financial indebtedness	**(15.9)**

It is the Company's assessment that there has not been any material change to its capitalization or its total net financial indebtedness since 30 June 2020, other than changes resulting from the ordinary course of business.

During 2019, a governmental funding of DKK 0.6 million was received by BioPorto Diagnostics from Innovationsfonden. The funding is covering part of the costs relating to a Ph.D student completing her Ph.D thesis. The funding is recognized in the profit and loss as the cost occur. BioPorto Diagnostics has a repayment obligation if the costs which the grant covers do not materialize.

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 66,645,476 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 1:3, 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 three (3) 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 VP Securities on 29 September 2020. Shares traded after 25 September 2020 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: DK0061409208. 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 28 September 2020 to 9 October 2020.

19.1.2 The New Shares

The Subscription Period for the New Shares will commence on 30 September 2020 and will close on 13 October 2020. 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 1.60 per New Share.

After payment of the Subscription Price, the New Shares will be issued under the temporary ISIN code DK0061409042. The New Shares under the temporary ISIN code will be registered with VP Securities but will not be admitted to trading and official listing on Nasdaq Copenhagen.

As soon as possible after registration of the New Shares with the Danish Business Authority, expectedly on 21 October 2020, 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 22 October 2020, and the temporary ISIN code of the New Shares will be merged with the ISIN code of the Existing Shares, expectedly on 23 October 2020.

19.2 Currency

The Offering will be carried out and trading in the Pre-emptive Rights will 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 in 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 75,007,947 with pre-emptive rights for the Company's shareholders.

The Board of Directors adopted a resolution on 25 September 2020 to exercise the authorization and increase the Company's share capital by between nominally DKK 45,000,000 and nominally DKK 66,645,476 by issue of up to 66,645,476 New Shares with a nominal value of DKK 1 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 nor 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

Three (3) 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 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 21 October 2020 and in any event before listing of the New Shares.

Any dividends will be paid in DKK to the shareholder's account with VP Securities. 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 which 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.

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 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. 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 who have a permanent place of residence in Denmark and companies registered in Denmark, or foreign registered companies whose effective seat of management is in Denmark, 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 2020, a tax rate of 27% must be paid on the annual share income up to DKK 55,300 (DKK 110,600 for married couples cohabiting at the end of the income year) and 42% of the annual share income exceeding DKK 55,300 (DKK 110,600 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*" for a description of the tax treatment of investment of pension savings.

Individuals, dividends in respect of investment 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*".

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*" 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 2020, 27% tax must be paid on the annual share income up to DKK 55,300 (DKK 110,600 for married couples cohabiting at the end of the income year) and 42% of the annual share income exceeding DKK 55,300 (DKK 110,600 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 percent taxation, and any loss will be deferrable. In 2020, the account is limited to a deposit of DKK 100,000.

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

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 2020, the account is limited to a deposit of DKK 100,000.

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.

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). It is expected that the proposal shall have legal effect from 1 July 2021.

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 announced that it is contemplating to increase the tax rate for share income for annual share income in excess of DKK 55,300 (DKK 110,600 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 VP Securities on 29 September 2020 at 5:59 p.m. CEST 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 three (3) 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 25 September 2020 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 VP Securities.

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 28 September 2020 at 9:00 a.m. CEST to 9 October at 5:00 p.m. CEST.

The New Shares will be issued under the temporary ISIN code DK0061409042.

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 DK0061409042. 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 VP Securities.

As soon as possible after registration of the New Shares with the Danish Business Authority, expectedly on 21 October 2020, the New Shares will, expectedly on 22 October 2020, 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 23 October 2020.

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 30 September 2020 and will close on 13 October 2020. 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 three (3) 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.

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 Nordea Danmark, filial af Nordea Bank Abp,

Finland, so that the application form is received by Nordea Danmark, filial af Nordea Bank Abp, Finland, no later than on 13 October 2020 at 5:00 p.m. CEST.

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 1.60 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 20 October 2020, against registration of the New Shares in the investor's account with VP Securities under the temporary ISIN code DK0061409042. 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 15 October 2020).

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 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 and the Global Coordinator reserve 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 13 October 2020 at 5:00 p.m. CEST.

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.

The Global Coordinator may, from time to time, acquire and sell Pre-emptive Rights, exercise Pre-emptive Rights and acquire and sell New Shares.

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 66,645,476 New Shares. Upon full subscription of the Offering, the gross proceeds will be approximately DKK 106.6 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 93.6 million.

The Offering is conditional upon at least 45,000,000 New Shares being subscribed for, corresponding to gross proceeds of DKK 70 million and net proceeds of approximately DKK 60 million.

20.10 Withdrawal or suspension of the Offering

The Offering may be withdrawn by the Company subject to certain conditions before 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 and the Global Coordinator have entered into the Rights Issue Agreement. Pursuant to the Rights Issue Agreement, the Global Coordinator is entitled to terminate the Rights Issue Agreement upon occurrence of certain exceptional events and/or unpredictable circumstances. The Rights Issue Agreement also contains completion conditions, which the Company believes to be customary for the Offering, and the completion of the Offering is subject to compliance with all conditions as set out in the Rights Issue Agreement. If one or more conditions for completion are not met, the Global Coordinator may, at its discretion, also terminate the Rights Issue Agreement, which may thereby require that the Company withdraws the Offering.

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 Shares*".

20.10.1 Withdrawal of applications for subscription

Instructions to exercise Pre-emptive Rights related to the New Shares are irrevocable, except that in the event of 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, 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 two (2) business days after the publication of such supplement.

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.

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 an agreement with one 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 12.6 million (see "*20.16.4 Terms and conditions of the offer of securities to the public – Placing and underwriting – Advance undertakings and underwriting*").

20.13 Subscription price

The New Shares are offered at the Subscription Price of DKK 1.60 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 21 October 2020 before listing of the New Shares. A company announcement concerning the results of the Offering is expected to be disclosed on 15 October 2020.

20.15 Expected timetable of the offering

The following table presents the expected timetable of principal events:

Announcement of Prospectus:	25 September 2020
Last day of trading in Existing Shares including Pre-emptive Rights:	25 September 2020
First day of trading in Existing Shares ex Pre-emptive Rights:	28 September 2020
First day of Rights Trading Period:	28 September 2020
Allocation Time of Pre-emptive Rights:	29 September 2020 at 5:59 p.m. CEST
First day of Subscription Period:	30 September 2020
Last day of Rights Trading Period:	9 October 2020
Last day of Subscription Period:	13 October 2020
Allocation of Remaining Shares:	15 October 2020
Expected date of publication of the results of the Offering:	15 October 2020
Expected registration of the New Shares with the Danish Business Authority:	21 October 2020
Expected date of admission of the New Shares to trading and official listing under the ISIN code of the Existing Shares:	22 October 2020
Expected merger of ISIN codes:	23 October 2020

20.16 Placing and underwriting

20.16.1 Global Coordinator

The Offering is coordinated by Nordea Danmark, filial af Nordea Bank Abp, Finland, which acts as the Global Coordinator of the Offering.

20.16.2 Rights Issue Agreement

In connection with the Offering, the Company and the Global Coordinator have signed the Rights Issue Agreement.

The Company and the Global Coordinator have entered into the Rights Issue Agreement. Pursuant to the Rights Issue Agreement, the Global Coordinator is entitled to terminate the Rights Issue Agreement upon occurrence of certain exceptional events and/or unpredictable circumstances. The Rights Issue Agreement also contains completion conditions, which the Company believes to be customary for the Offering, and the completion of the Offering is subject to compliance with all conditions as set out in the Rights Issue Agreement. If one or more conditions for completion are not met, the Global Coordinator may, at its discretion, also terminate the Rights Issue Agreement, which may thereby require that the Company withdraws the Offering. See "*20.10 Terms and conditions of the offer of securities to the public – Withdrawal or suspension of the Offering*".

See "*14.1.9 Material Contracts – Rights Issue Agreement*" for further description of the Rights Issue Agreement.

20.16.3 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

20.16.4 Advance undertakings and underwriting

The Offering is fully underwritten, subject to the satisfaction of certain conditions set out in separate advance subscription commitments and guarantee undertakings dated on or about 25 September 2020 and entered into between the Company and 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 thus undertaken to exercise Pre-emptive Rights and/or to subscribe for any Remaining Shares for aggregate gross proceeds of approximately DKK 106.6 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	Commitment amounts (DKK million)
Formue Nord Markedsneutral A/S	25
Aktieselskabet Arbejdernes Landsbank	20
Media-Invest Danmark A/S	12.6
Modelio Equity AB and management (Modelio Equity AB, Oscar Molse and Oliver Molse)	11.2
Artha (Investeringsselskabet Artha Max A/S, Investeringsselskabet Optimum A/S and Investeringsselskabet Safe A/S)	10.4
Gerhard Dal	10
Other institutional investors and Qualified Investors (aggregate)	17.4

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 Rights.

20.17 Transfer restrictions

The Offering consists of a public offering in Denmark with Pre-emptive Rights for the Company's Existing Shareholders and private placements in certain other jurisdictions.

20.17.1 General restrictions

The Offering is made pursuant to Danish law, and neither the Company nor the Global Coordinator have 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. Neither the Company nor the Global Coordinator accepts 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 and the Global Coordinator to inform themselves 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 and the Global Coordinator 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, all 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.

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 state securities legislation in the U.S. Accordingly, the Pre-emptive Rights may not be offered, sold, acquired or exercised within the U.S., and the New Shares

may not be subscribed for, offered or sold within the U.S., absent an applicable exemption from such laws. The Pre-emptive Rights and the New Shares have not been, and will not be, registered under the U.S. Securities Act and are only offered and sold outside the U.S. or to, or for the account or benefit of, non-U.S. Persons (as defined in Regulation S) in accordance with Regulation S or in transactions otherwise exempt from, or not subject to, the registration requirements of the U.S. Securities Act. 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.

Any offering of the Pre-emptive Rights and the New Shares made in the U.S. will only be made by the Company pursuant to an exemption from, the registration requirements of the U.S. Securities Act to a limited number of investors that (i) are qualified institutional buyers as defined in Rule 144A under the U.S. Securities Act ("**QIBs**") and (ii) 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 cannot exercise Pre-emptive Rights or subscribe for New Shares. In connection with the rights issue, the Global Coordinator 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. Any person in the U.S. that obtains a copy of the Prospectus or any pre-printed issue statement or application form and that is not a QIB is required to disregard them.

Each investor in the U.S. or who is a U.S. person will be deemed to have represented and agreed as follows:

1. The investor (a) is a QIB or a broker-dealer acting for the account of a QIB, (b) is acquiring such Pre-emptive Rights and/or New Shares for its own account or for the account of a QIB, and (c) is aware that the Pre-emptive Rights and New Shares are restricted within the meaning of the U.S. Securities Act and may not be deposited into any unrestricted depositary facility, unless at the time of such deposit the Pre-emptive Rights and New Shares are no longer restricted.
2. The investor is aware that the Pre-emptive Rights and New Shares have not been and will not be registered under the U.S. Securities Act, and are being offered in the U.S. only to QIBs in a transaction not involving any public offering in the U.S. within the meaning of the U.S. Securities Act.
3. The investor understands and agrees that the Pre-emptive Rights and New Shares may not be offered, sold, pledged or otherwise transferred, except (a) to a person that the seller and any person acting on its behalf reasonably believes is a QIB purchasing for his, her or its own account or for the account of another QIB or (b) outside the U.S. in accordance with Regulation S under the U.S. Securities Act of 1933, as amended, or (c) pursuant to another exemption from registration under the U.S. Securities Act, or (d) pursuant to an effective registration statement under the U.S. Securities Act.

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 and the Global Coordinator; 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 and the Global Coordinator receive 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 28 September 2020 at 9:00 a.m. CEST to 9 October 2020 at 5:00 p.m. CEST.

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 30 September 2020 at 9:00 a.m. CEST to 13 October at 5:00 p.m. CEST. As soon as possible after registration of the New Shares with the Danish Business Authority, expectedly on 21 October 2020, 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 22 October 2020, and the temporary ISIN code of the New Shares will be merged with the ISIN code of the Existing Shares, expectedly on 23 October 2020.

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
Weidekampsgade 14
DK-2300 Copenhagen S
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.

22.2 Lock-up agreements

22.2.1 Lock-up agreement with the Company

The Company has undertaken that for a period of 180 days counted from the date of admission to trading and official listing of the New Shares that it will not without the prior written consent of the Global Coordinator, (i) issue, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of (or publicly announce such action), directly or indirectly, any Shares or any securities convertible into or exercisable or exchangeable for Shares, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of Shares, whether any such transaction described in clause (i), or (ii) above is to be settled by delivery of Shares or such other securities, in cash or otherwise, or (iii) submit to its shareholders a proposal to effect any of the foregoing. The abovementioned obligation shall not apply to (a) transfers or issues of Shares, warrants or any other securities convertible into or exercisable or exchangeable for Shares or having a similar effect to the Company's and its subsidiaries' employees, the members of the Executive Management or the Board of Directors and the Key Employees in relation to granting, allocation or issue of Shares, warrants or securities convertible into or exercisable or exchangeable for Shares as part of or in accordance with the existing or future general or individual incentive programmes, (b) the exercise by such persons mentioned in (a) of their rights in accordance with the existing or future general or individual employee shareholding and/or warrant programmes, (c) amendment, reissue or cancellation of existing warrants, (d) the transactions contemplated in connection with the Offering, as set out herein, including the sale of the Pre-Emotive Rights received on connection with the Offering in respect of treasury shares, (e) submission to its shareholders of a proposal to adopt, increase and/or extend authorizations of the Board of Directors to increase the share capital of the Company, (f) submission to its shareholders of a proposal to increase and/or extend authorizations of the Board of Directors to issue warrants which will entitle the holders to subscribe for shares in the Company, (g) submit to its shareholders a proposal to authorize the Board of Directors to purchase treasury shares and (h) actions in connection with any takeover offer for the shares in the Company made in accordance with Danish take-over regulation and/or any corporate law merger involving the Company and/or any acquisition by the Company against consideration in Shares or any securities convertible into or exercisable or exchangeable for Shares of Company.

22.2.2 Lock-up agreements with individual board members and executive management members

Further, the members of the Board of Directors and of the Executive Management have each agreed that for a period of 180 days counted from the date of admission to trading and official listing of the New Shares they will not without the prior written consent of the Global Coordinator, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any Shares, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Shares, (iii) announce the intention to make any such acts as described above or (iv) propose any general meeting of the Company, or convene or take action to convene any general meeting for the purpose of proposing a resolution to effect any of the foregoing. The abovementioned obligations shall not apply to (i) transfer of Shares to a related person and to the direct or indirect shareholders of any person holding Shares through a company, subject to certain conditions, (ii) dispose of Shares in accordance with a court order or as required by law or regulation, (iii) dispose of Shares as a result of the death or permanent disability of such person or an interruption in employment for a continuous period of not less than 16 weeks due to disability or illness, (iv) disposal of Shares occurring after termination of employment or appointment, (v) disposal of Shares pursuant to a takeover offer for the Shares in the Company or in connection with any corporate law merger involving the Company or an entity within the Company's group, (vi) exercise of the Pre-emptive Rights allocated/granted or acquired in the Offering, provided that the shares acquired by way of exercise of such Pre-emptive Rights shall be subject to the lock-up, (vii) propose (and/or vote in favor of) resolutions to the general meeting to adopt, increase and/or extend authorizations of the Board of Directors to increase the share capital of the Company, (viii) propose (and/or vote in favor of) resolutions to the general meeting to adopt, increase and/or extend authorizations of the Board of Directors to issue warrants or restricted stock units, shares for matching share programs, performance share units or similar, which will entitle the holders to subscribe for or otherwise receive shares in the Company, (ix) propose (and/or vote in favor of) resolutions at the general meeting to authorize the Board of Directors to purchase treasury shares, (x) exercise of warrants, and other securities convertible into Shares in the Company, subject to certain conditions, (xi) accept to cancel existing Shares granted under incentive programs, subject to certain conditions and (xii) disposal of Shares made with a view to settle, directly or indirectly, any tax liabilities related to incentive programs.

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 66,645,476 New Shares), are approximately DKK 13 million. The fee to the Global Coordinator is variable and, therefore, the total expenses are subject to the results of the Offering.

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.

Neither the Company nor the Global Coordinator will 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 25%.

25 Additional information

25.1 Advisers

Global Coordinator:

Nordea Danmark, filial af Nordea Bank Abp, Finland
Grønjordsvej 10
DK-2300 Copenhagen S
Denmark

Legal adviser to the Company in connection with the Offering:

Gorrissen Federspiel Advokatpartnerselskab
Axeltorv 2
DK-1609 Copenhagen V
Denmark

Legal adviser to the Global Coordinator in connection with the Offering:

Kromann Reumert
Sundkrogsgade 5
DK-2100 Copenhagen Ø
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.

510(k)	A 510(K) is a premarket submission made to 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) FD&C Act) that is not subject to premarket approval. .
510(k) Clearance	The U.S. Food and Drug Administration's written authorization to market a medical device pursuant to a premarket notification submitted under section 510 of the Federal Food, Drug, and Cosmetic Act.
Abbott	Abbott Laboratories.
AICPA	The American Institute of Certified Public Accountants.
AKI	Acute kidney injury.
AMC	Academic Medical Center.
Allocation Time	On 29 September 2020 at 5:59 p.m. CEST. The time at which any person registered with VP Securities as a shareholder of the Company will be entitled to be allocated one (1) Pre-emptive Right for each Existing Share held.
Articles of Association	The Company's Articles of Association of 19 August 2020.
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.
cCMP	Current good manufacturing practice.
CBRN	Chemical, biological, radiological and nuclear.
CDER	FDA's Center for Drug Evaluation and Research.
CEST	Central European Summer Time.
CKD	Chronic kidney disease
Chairman	The chairman of the Board of Directors.
Clearstream	Clearstream Banking S.A.
CMS	Centers for Medicare & Medicaid Services.
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 2020.
Corporate Governance Recommendations	The recommendations on corporate governance published by the Committee on Corporate Governance in November 2017 (as updated in August 2019).

Corporate Management	The Executive Management and the Key Employees.
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.
COVID-19ds	The Company's COVID-19 gRAD dipstick products.
CPB	Cardiopulmonary bypass.
CPT	Current Procedural Terminology.
CVR no.	The Danish Central Business Register number.
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.
Danish Business Authority	The Danish Business Authority (in Danish: "Erhvervsstyrelsen").
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.
DKK	The official currency of the Kingdom of Denmark.
DRG	Diagnosis related groups.
EEA	The European Economic Area.
ELISA	Enzyme-linked immunosorbent assay.
ESKD	End-stage kidney disease.
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 Shares	The 199,936,428 issued shares of the Company, comprising the Company's entire share capital.

Existing Shareholders	Any person registered with VP Securities as a shareholder of the Company as at the Allocation Time.
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.
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 (NGAL) Products	Covering both Future NGAL Products and Future Products.
Future Products	The Company's new diagnostic products, e.g. on gRAD or other platforms.
FY2018	The Company's financial year from 1 January 2018 to 31 December 2018.
FY2019	The Company's financial year from 1 January 2019 to 31 December 2019.
FY2020	The Company's financial year from 1 January 2020 to 31 December 2020.
FY2018 Financial Statements	The consolidated financial statements of the Company for the financial year ended 31 December 2018.
FY2019 Financial Statements	The consolidated financial statements of the Company for the financial year ended 31 December 2019.
FY2020 Financial Statements	The consolidated financial statements of the Company for the financial year ended 31 December 2020.
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).
Global Coordinator	Nordea.
gRAD	The Company's in-licensed generic rapid assay device.
Guarantors	Formue Nord Markedsneutral A/S, Aktieselskabet Arbejdernes Landsbank, Media-Invest Danmark A/S, Modelio Equity AB and management (Modelio Equity AB, Oscar Molse and Oliver Molse), Investeringsselskabet Optimum A/S, Investeringsselskabet Max A/S, Investeringsselskabet Safe A/S, Gerhard Dal and a number of other institutional and Qualified Investors.
Guidance for FY2020	The Company's consolidated prospective financial information for FY2020.
HHS	The U.S. Department of Health and Human Services.
Half Year Financial Statements	The consolidated financial statements of the Company for the period 1 January 2020 – 30 June 2020.

ICU	Intensive care unit.
IDE	An investigational device exemption.
IgG	Immunoglobulin G.
IgM	Immunoglobulin M
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 Employees	Ole Larsen, Jan Kuhlmann Andersen, Christopher Bird and Amy Winslow.
KOL	Key opinion leaders.
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 Employees.
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	MiFID II, Articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II and local implementing measures.
Nasdaq Copenhagen	Nasdaq Copenhagen A/S, company reg. (CVR) no. 19 04 26 77, Nikolajs Plads 6, DK-1067 Copenhagen K, Denmark.

Nasdaq Issuer Rules	Nordic Main Market Rulebook for Issuers of Shares effective from 1 May 2020, including supplements relating to Nasdaq Copenhagen.
New Shares	The Shares issued in connection with the Offering.
NGAL	Neutrophil gelatinase-associated lipocalin.
NGAL Patents	Patents relating to NGAL.
Nordea	Nordea Danmark, filial af Nordea Bank Abp, Finland, company reg. (CVR) no. 25 99 21 80, Grønjordsvej 10, DK-2300 Copenhagen S, Denmark
Notified Body	An independent and neutral institution appointed by a member state of the European Economic Area to conduct a conformity assessment.
NSE Determination	A determination from the FDA that a device is not substantially equivalent.
Offering	The offering of up to 66,645,476 New Shares at a price of DKK 1.60 per New Share with Pre-emptive Rights for the Company's Existing Shareholders at the ratio of 1:3 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 three (3) 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	The 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.
Products	The Company's current products, including The NGAL Test, The NGALds and the COVID-19ds.
Prospectus	This prospectus covering the offer of up to 66,645,476 New Shares at a price of DKK 1.60 per New Share with Pre-emptive Rights for Existing Shareholders dated 25 September 2020.
Prospectus Date	25 September 2020.
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/ECText with EEA relevance.
QA	A quantification agent.
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 apply.
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.
Rights Trading Period	The period beginning on 28 September 2020 and ending on 9 October 2020.
Roche	Roche Holding AG and its subsidiaries and affiliates.
Roche GmbH	Roche Diagnostics GmbH.
ROW	Rest of the world.
Shares	Existing Shares and the New Shares.
SCR	Serum creatinine.
Siemens	Siemens Healthineers AG.
SCCM	Society for Critical Care Medicine.
Subscription Commitments	Certain subscription commitments and guarantee undertakings dated on or about 25 September 2020 entered into between the Company and the respective Guarantors.
Subscription Period	The subscription period for the New Shares from 30 September 2020 to 13 October 2020.
Subscription Price	DKK 1.60 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 NGALds	The Company's NGAL gRAD dipstick.
The NGAL Test	The NGAL Test is a quantitative particle-enhanced turbidimetric immunoassay designed to run on automated chemistry analyzers.
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.
VP Securities	VP Securities A/S, company reg. (CVR) no. 21 59 93 36, Weidekampsgade 14, DK-2300 Copenhagen S, Denmark.
Warrant Program	The Company's warrant program introduced in April 2016.

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	DK0061409042	Subscription price:	DKK 1.6
			Global Coordinator:	Nordea
Subscription Period:	30 September 2020 – 13 October 2020		Date of official listing of New Shares:	22 October 2020
Date of payment:	20 October 2020			

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 Nordea Danmark, filial af Nordea Bank Abp, Finland, no later than on 13 October 2020 at 5:00 p.m. CEST.

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.

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 25 September 2020.

I/we undertake to pay the countervalue of the shares allocated at the Subscription Price. Payment will be effected on 20 October 2020 pursuant to the contract note submitted to me/us against shares under the temporary ISIN code DK0061409042. 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 Nordea Danmark, filial af Nordea Bank Abp, Finland, please tick:

The Remaining Shares will be registered in the relevant Existing Shareholder's/Qualified Investor's VP account with VP Securities A/S.

Registration no.:	CD identification:
Stamp and signature:	

GDPR notice

Those who participate in the Offering will provide personal data to Nordea. Personal data provided to Nordea will be processed in data systems to the extent required to provide services and administer matters in Nordea. 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 Nordea cooperate. Information regarding the processing of personal data is provided by Nordea's branch offices, which also accept requests for correction of personal data. Personal data may be obtained by Nordea in connection with settlement of the Offering in the systems of VP Securities A/S. For detailed information about Nordea's handling of personal information, see https://www.nordea.dk/privat/politik-om-databehandling.html.