Bioretec Ltd

Press release

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Bioretec intends to launch an initial public offering and listing on Nasdaq First North Growth Market Finland

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Bioretec Ltd ("Bioretec" or the "Company"), a medical device company focusing on the development and manufacturing of strong, safe and reliable bioresorbable implants for pediatric and adult orthopedics, announces that it is planning an initial public offering ("IPO") and a listing of its shares on Nasdaq First North Growth Market Finland ("First North").

Bioretec in brief

Bioretec is a medical device company focusing on the development and manufacturing of strong and safe bioresorbable implants for the treatment of bone and soft tissue injuries. The advantage of Bioretec's implants compared to traditional metal implants is that bioresorbable implants eliminate the need for implant removal operations that result in significant costs and may involve complications.

Bioretec is targeting to achieve strong growth with its next generation RemeOs[™] product family. The new RemeOs[™] product family consists of unique bioresorbable metal based orthopedic implants for load bearing applications – implants that can be used to fix bone fractures, which will not need to be removed, since they naturally resorb into the human body. With RemeOs[™] product family Bioretec expects to tap into a large global USD 7 billion addressable market as one of the first producers who combine the benefits of strong load bearing metal implants and bioresorbability. In the company's view, with its bioresorbable orthopedic implants the following benefits can be achieved:

- They aid the body to use its own systems to heal naturally without introducing any foreign materials
- By gradually resorbing, they improve the formation and strengthening of new bone better than traditional implants
- They eliminate need for implant removal operations, that generate costs and may involve complications

The material used in the new generation RemeOs[™] product family is an all-natural elements based magnesium alloy that is free of rare earth elements ("**REE**"), has optimized mechanical properties and is biomechanically closer to bone than traditional metals, biopolymers or biocomposites. The material is initially more rigid and stronger than an intact bone, which is required to provide immediate load-bearing capabilities. Over time, the implant resorbs gradually transferring load to the bone, which is needed for the bone to recover its natural state. Furthermore, the bioresorbable RemeOs[™] material, made of Magnesium, Zinc and Calcium, promotes new bone formation and incorporation to host bone and ultimately enables the bone to regain its natural strength.

RemeOs[™] product family's proof of concept product, cannulated screws, have passed clinical trial with successful results and has been granted with Breakthrough Device Designation from the U.S. Food and

Drug Administration (FDA) in March 2021. The Company expects the sales of the RemeOs[™] cannulated screws to start in the United States during the first half of 2022, provided that the market authorization has been obtained within target time.

Bioretec's current product portfolio consists of various non-load-bearing products that are used to promote healing in pediatric and adult orthopedics. The existing products are sold in approximately 40 countries globally and generated revenue of EUR 1.5 million in 2020.

Bioretec's strengths

Bioretec believes that the following factors are the Company's key strengths:

- The RemeOs[™] alloy is proven and excellent solution for patient healing magnesium based bioresorbable implants would promote bone healing and eliminate need for implant removal
- Attractive market Bioretec is estimated to tap on a global total addressable market of \$7bn with RemeOs[™] product family by 2027 market characterized by stability and strong growth drivers
- RemeOs[™] cannulated screws clinical studies completed, Breakthrough Device Designation received, providing clear steps to expected FDA approval in the USA and commercialization during H1 2022 pipeline for launching additional products in coming years
- Aim to be the first bioresorbable REE-free metal product family to be launched in the USA
- High sales margin enables scalability with volumes management forecasts RemeOs™ cannulated screws cost of goods sold to be ~3% of the US selling price
- Experienced management team in charge of executing commercialization plan

Bioretec's strategy

In order to achieve its business targets, Bioretec has developed a strategy whose cornerstones are the following:

- Expanding into new high potential market areas
 - Market launch of RemeOs[™] cannulated screws in the USA through own sales force beginning in H1 2022 (target)
 - Market launch of RemeOs[™] cannulated screws in Europe via selected partners beginning in H2 2022 (target)
 - Development and commercialization of further RemeOs[™] products: K-wires, IM-nails and spinal cages
- Maintain world-class talent and capabilities by nurturing a winning culture to secure commitment and attract talent
- Focus on attaining strong profitability by working towards meaningful margin expansion through operational efficiency and lean organizational approach

Bioretec's financial targets

• Revenue of more than EUR 100 million by 2027 in a global USD 7 billion addressable market

• Cash flow positive operations by the end of 2025

Bioretec's business targets

Bioretec's business targets are, among others:

- Achieve Breakthrough Device Designation for RemeOs[™] cannulated screws and initiate the process for sales approval for the cannulated screws (achieved in March 2021)
- Apply for market authorization in Europe (Q3/2021)
- Apply for market authorization in the United States (Q4/2021)
- Start clinical trials of the RemeOs[™] K-wires (H2/2021)
- Receive market approval for the RemeOs[™] cannulated screw and start commercialization in the United States (H1/2022)
- Receive market approval for the RemeOs[™] cannulated screw and start commercialization in Europe (H2/2022)
- Start clinical trials of the RemeOs[™] intramedullary nail (2023)
- Receive market approval for the RemeOs[™] K-wires and start commercialization (2024)
- Receive market approval for the RemeOs[™] intramedullary nail and start commercialization (2026)

Timo Lehtonen, Bioretec's CEO comments:

"Throughout the history of Bioretec, we have aimed at bringing innovative medical implants to the market, to enable better healing, safety and cost efficiency in clinical care. We are extremely proud of our products being able to provide significant advantages to patients, healthcare and societies in general, globally. With our RemeOs[™] cannulated screws taking important leaps in commercialization with a recent Breakthrough Device Designation from the U.S. Food and Drug Administration, the IPO is a natural next step for us in enabling an efficient market launch and further development of our innovative products."

Tomi Numminen, Chairman of the Board of Directors of Bioretec comments:

"Bioretec, with its experienced management, expert team and international top level scientific advisory board, has proven its capability in developing innovative solutions and commercializing them successfully. Trends, such as the aging population, increased trauma, as well as a growing demand and awareness in regard to more advanced and customer-centric medical solutions, are clear growth drivers for Bioretec. We believe in Bioretec's capabilities in answering to this demand, supported by the company's clear strategy. Listing the company is a logical step in unlocking growth."

Information on the IPO

The objective of the contemplated IPO is to enable further investments to the commercialization of the Company's RemeOs[™] cannulated screws and the development and commercialization of further RemeOs[™] orthopedic implants, and thereby to support Bioretec's growth strategy. The IPO is also expected to increase the general interest of investors, customers, surgeons and business partners towards Bioretec, as well as to further improve Bioretec's attractiveness among potential employees and to maintain the high level of commitment among its current employees. Furthermore, the IPO is expected

to widen Bioretec's ownership base with Finnish and international investors, thus providing liquidity for Bioretec's shares in the future.

The contemplated IPO is expected to consist of a share issue by Bioretec as well as a potential overallotment option. Gross proceeds from the new shares issued are expected to be approximately EUR 25 million (without the over-allotment option) and are intended to be used to support Bioretec's growth strategy by allowing further investments to the commercialization and development of RemeOs[™] products, expansion of production as well as to strengthen Bioretec's capital structure.

Handelsbanken Fonder AB, Mandatum Life Insurance Company Limited and Kaleva Mutual Insurance Company (the **"Cornerstone Investors"**) have in total, subject to certain conditions, committed to subscribe for shares amounting to EUR 8 million in the IPO at a post-money equity value of up to EUR 71 million.

Advisors

Danske Bank A/S, Finland branch, is acting as the sole global coordinator and bookrunner (the **"Sole Global Coordinator and Bookrunner"**) in connection with the contemplated IPO. Krogerus Attorneys Ltd is acting as legal adviser to Bioretec. Borenius Attorneys Ltd is acting as legal adviser to the Sole Global Coordinator and Bookrunner. Miltton Ltd is acting as communications adviser to Bioretec. Danske Bank A/S, Finland branch, will act as Bioretec's certified adviser in accordance with the Nasdaq First North Growth Market Rulebook.

Further enquiries

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Information about Bioretec

Bioretec Ltd is a medical device company focusing on the development of strong, safe and reliable bioresorbable implants for pediatric and adult orthopedics. The company develops, manufactures and commercializes innovative bioresorbable orthopedic implants and materials for bone and soft tissue injuries. Bioretec's products are used worldwide, and the company continues to further develop materials and products for high load-bearing clinical applications. Based in Tampere, Finland, Bioretec employs 24 dedicated professionals, supported by a top class Scientific Advisory Board with internationally recognized medical experts and surgeons as members.

IMPORTANT INFORMATION

Neither this release nor the information contained herein is for publication, distribution or release, in whole or in part, directly or indirectly, in or into the United States, Australia, Canada, Hong Kong, Japan, New Zealand, South Africa or Singapore or any other jurisdiction in which publication or distribution would be unlawful. The information contained herein does not constitute an offer of securities for sale in the United States, nor may the securities be offered or sold in the United States. Bioretec Ltd (the **"Company"**) does not intend to register any portion of the offering in the United States under the U.S. Securities Act of 1933, as amended (the **"Securities Act"**) or to offer securities to the public in the United States.

The issue, exercise and/or sale of securities are subject to specific legal or regulatory restrictions in certain jurisdictions. The Company or Danske Bank A/S, Finland Branch, assume no responsibility in the event there is a violation by any person of such restrictions.

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The Company has not authorized any offer to the public of securities in the United Kingdom or in any Member State of the European Economic Area other than Finland. With respect to the United Kingdom and each Member State of the European Economic Area other than Finland and which applies the Prospectus Regulation (each, a "**Relevant Member State**"), no action has been undertaken or will be undertaken to make an offer to the public of securities requiring publication of a prospectus in any Relevant Member State. As a result, the securities may only be offered in the United Kingdom and in Relevant Member States (a) to any legal entity, which fulfils the requirements of a qualified investor as defined in the Prospectus Regulation; or (b) in any other circumstances falling within Article 1(4) of the Prospectus Regulation. For the purposes of this paragraph, the expression an "offer of securities to the **public**" means a communication to persons in any form and by any means, presenting sufficient information on the terms of the offer and the securities to be offered, so as to enable an investor to decide to purchase or subscribe for those securities. The expression "**Prospectus Regulation**" means Regulation (EU) 2017/1129 of the European Parliament and of the Council, as amended.

This communication is directed only at (i) persons who are outside the United Kingdom or (ii) persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "**Order**") and (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2) of the Order (all such persons together being referred to as "**Relevant Persons**"). Any investment activity to which this communication relates will only be available to and will only be engaged with, Relevant Persons. Any person who is not a Relevant Person should not act or rely on this document or any of its contents.

Full terms, conditions and instructions for the contemplated initial public offering will be included in the prospectus that will be prepared by the Company in connection with the contemplated initial public offering. The prospectus will be published on the website of the Company at www.bioretec.com/ipo.

Investors are advised to read the prospectus before making an investment decision to fully understand the risks and rewards associated with the investment. The approval by the Finnish Financial Supervisory Authority of the prospectus, once received, shall not be considered as an endorsement of the securities offered.

FORWARD-LOOKING STATEMENTS

Certain statements in this release are "forward-looking statements." Forward-looking statements include statements concerning plans, assumptions, projections, objectives, targets, goals, strategies, future events, future revenues or performance, capital expenditures, financing needs, plans or intentions relating to acquisitions, the Company's competitive strengths and weaknesses, plans or goals relating to financial position, future operations and development, its business strategy and the anticipated trends in

the industry and the political and legal environment in which it operates and other information that is not historical information. In some instances, they can be identified by the use of forward-looking terminology, including the terms "believes," "intends," "may," "will" or "should" or, in each case, their negative or variations on comparable terminology.

Forward-looking statements in this release are based on assumptions. Forward-looking statements involve inherent risks, uncertainties and assumptions, both general and specific, and the risk exists that the predictions, forecasts, projections, plans and other forward-looking statements will not be achieved. Given these risks, uncertainties and assumptions, you are cautioned not to place undue reliance on such forward-looking statements. Any forward-looking statements contained herein speak only as at the date of this release. Save as required by law, the Company does not intend to, and does not assume any obligation to, update or correct any forward-looking statement contained in this release.