

BBS

Bioactive Bone Substitutes

Company presentation

Paul Watkins, Chief Commercial Officer

June 2019



Bioactive Bone Substitutes Oyj

BBS-Bioactive Bone Substitutes Oyj is a biotech company that designs, develops, and manufactures innovative next generation bioactive bone graft substitute medical devices with medicinal properties.

Headquarters: Oulu, Finland.

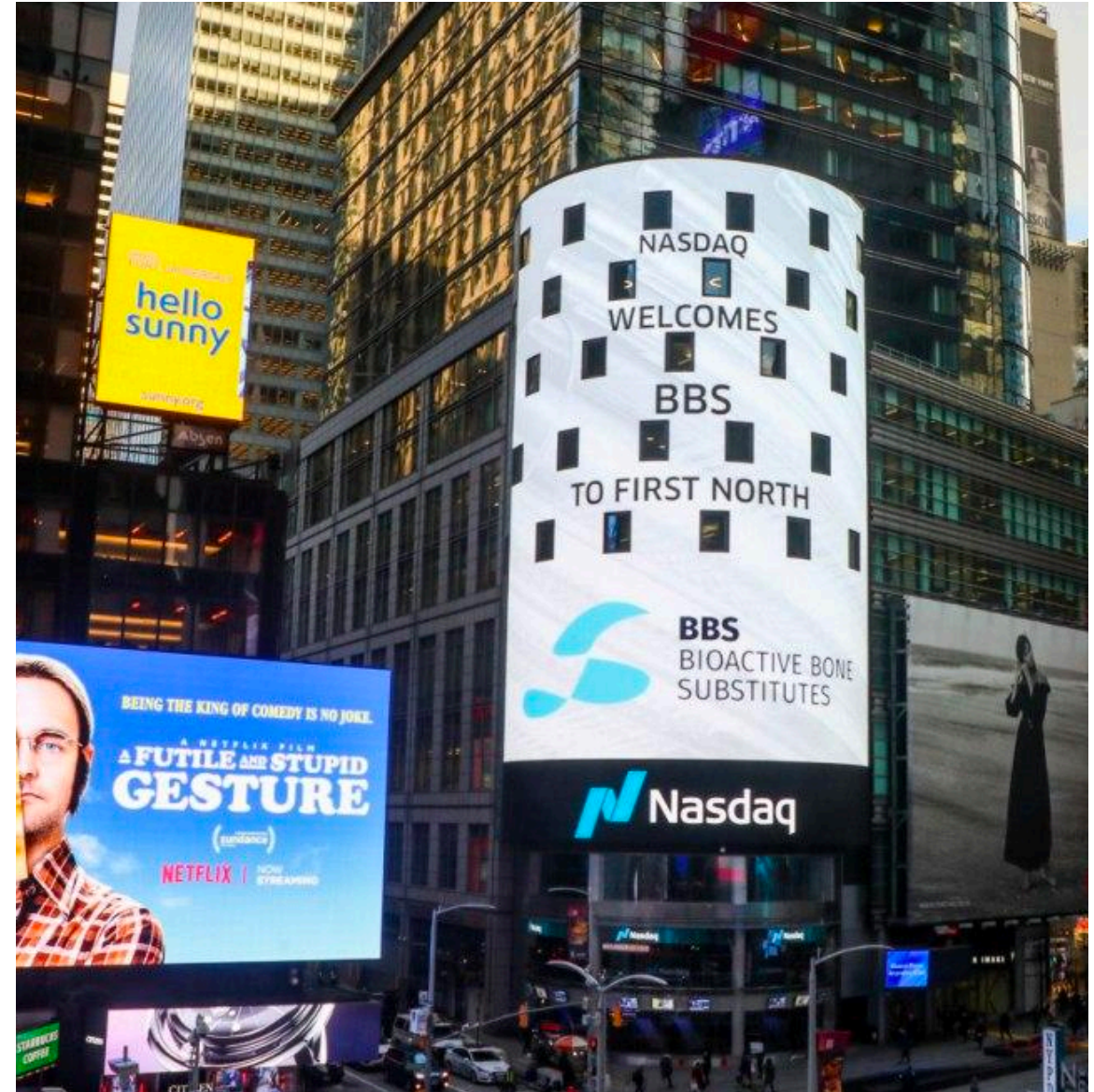
Founded: 2005 by Professor Pekka Jalovaara.

Employees: 12 people in year 2018.

Manufacturing facility: Located in Reisjärvi with production potential of 25,000 implants.

Stock market: Listed since February 28, 2018 on Nasdaq First North Nordic:

- Helsinki (BONEH)
- Stockholm (BONES)



“

As a practicing orthopedic surgeon I realized that the current method of treating bone problems, where a bone graft was required, was inadequate. The procedure, called an **autograft**, requires harvesting bone from another site on the patient's body. This **increases complication risk** and up to half of patients have **significant and long-lasting pain from the second surgery**. I started the **Bone Transplantation Unit** at the University of Oulu to find an **alternative to autograft**. Twenty years later, there is still no optimal alternative to autograft.

We conducted research studies on bone extracts made from different animals and found that **reindeer bone** had the greatest **bone growth stimulating potential** compared to other animal sources. This finding was the start of BBS. Today we are ready to bring our first **ARTEBONE®** medical product to the market.”



Pekka Jalovaara, MD, PhD
Professor of Orthopedic Surgery
Founder of BBS
Internationally recognized
3,000 citations within the
orthopedics field

ARTEBONE® products have both principal components needed to provide superior bone regeneration

Necessary components for effective bone healing:

- **Osteoinduction:** starts bone growth, requires proteins
- **Osteoconduction:** physical scaffold for bone growth

ARTEBONE® medical device class III - composition

- Reindeer bone contains biologically active bone proteins and growth factors, which provide the osteoinductive component.
- Synthetic β -TCP (tricalcium phosphate) provides the osteoconductive structural matrix (scaffold) on which new bone grows.
- Reindeer bone proteins accelerate the resorption of the β -TCP granules, resulting in faster and better bone healing.



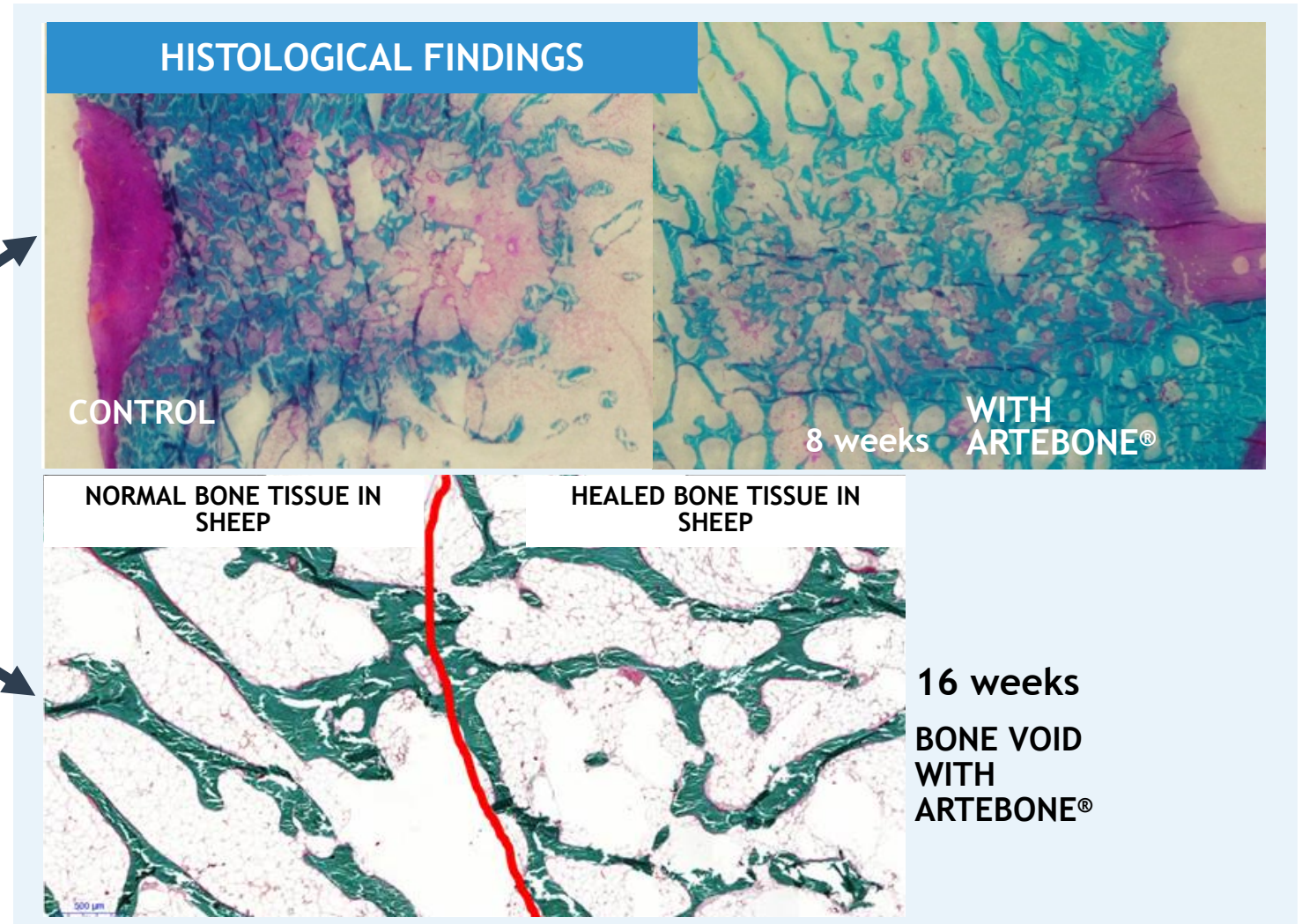
A preclinical study of ARTEBONE® demonstrated excellent healing of bone defect in sheep model

EFFECT ON CRITICAL SIZE FEMUR HOLE-DEFECT MODEL

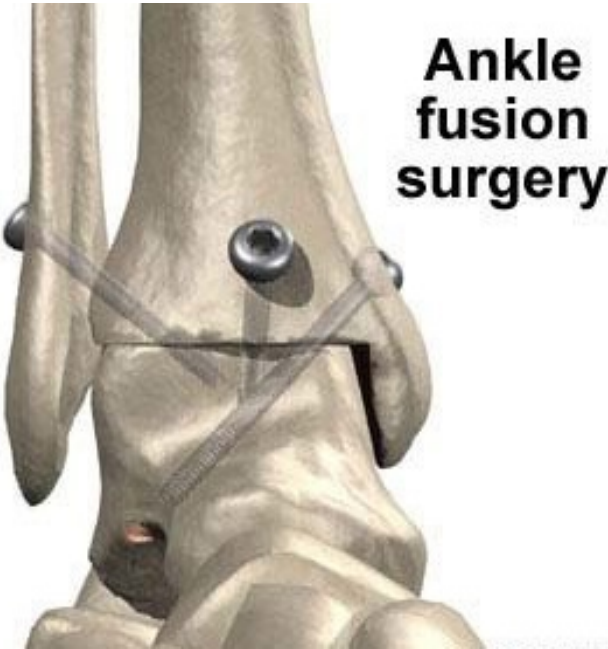
3 weeks: More new bone.

8 weeks: Good quality new bone and increased resorption of TCP granules.

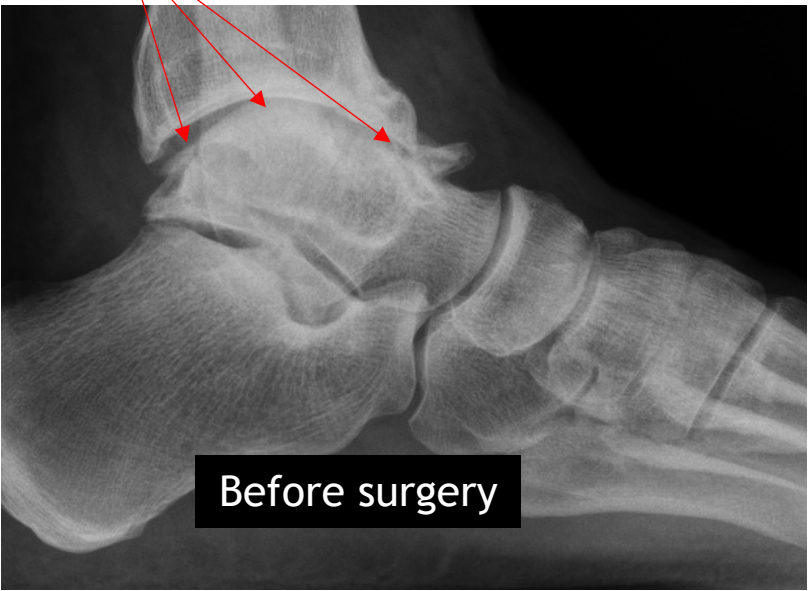
16 weeks: Complete bone healing and no TCP granules left. No uncontrolled bone growth outside the defect.



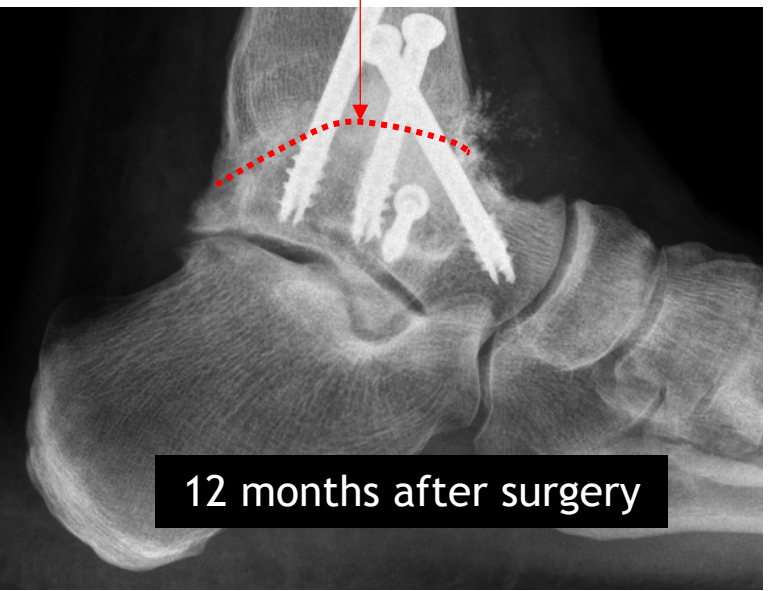
Clinical study with ARTEBONE® showed successful bone healing 12 months after ankle fusion surgery



Painful post-traumatic osteoarthritis of upper ankle



Treated successfully with ARTEBONE® resulting in complete fusion



*A Prospective Clinical Investigation to Assess Safety and Performance of ARTEBONE as Bone Void Filler in a Single Arthrodesis Procedure of the Ankle (25) and Subtalar Joint (9).
Completion Date: December 2017.*

ARTEBONE® is the next generation bone substitute product that has optimal performance, is safe and cost effective

ARTEBONE® PORTFOLIO

Lead product
Ready for commercial launch following CE-marking (in final stages)

ARTEBONE®
ready-to-use
paste



ARTEBONE® protein-coated granules



In pipeline

ARTEBONE® protein-coated blocks



In pipeline

NEXT GENERATION
BONE SUBSTITUTE

READY-TO-USE
NO MIXING

HIGH MANUFACTURING CONSISTENCY

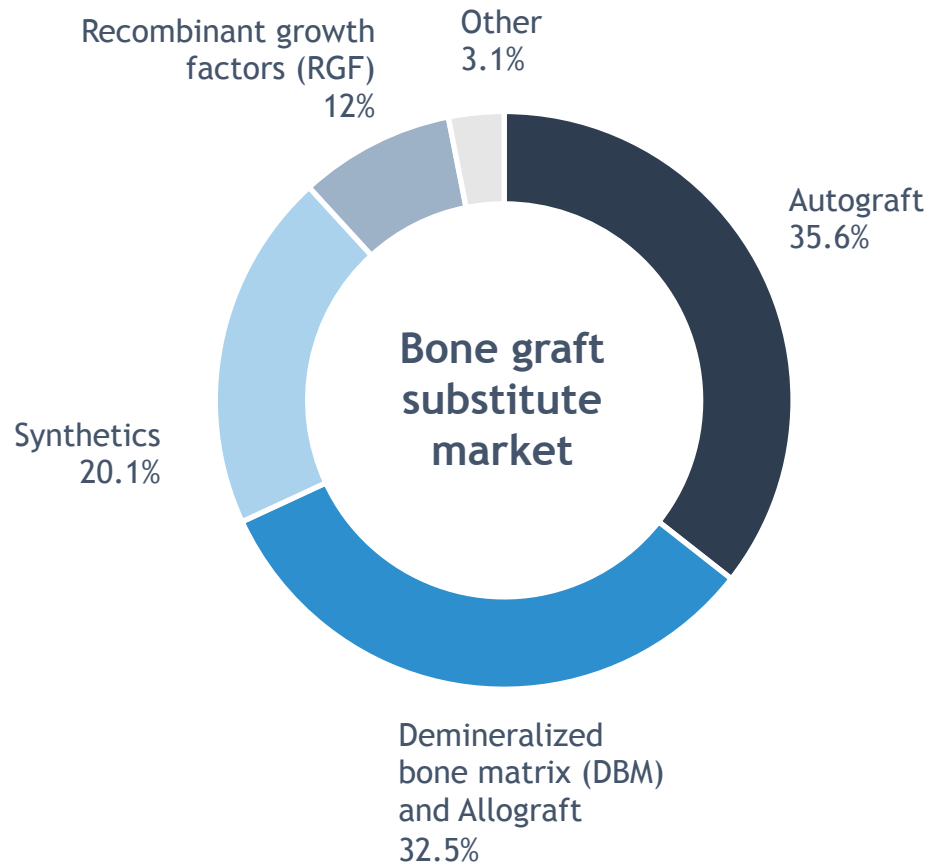
REDUCES
OPERATING TIME, RISKS AND COST

SAFETY

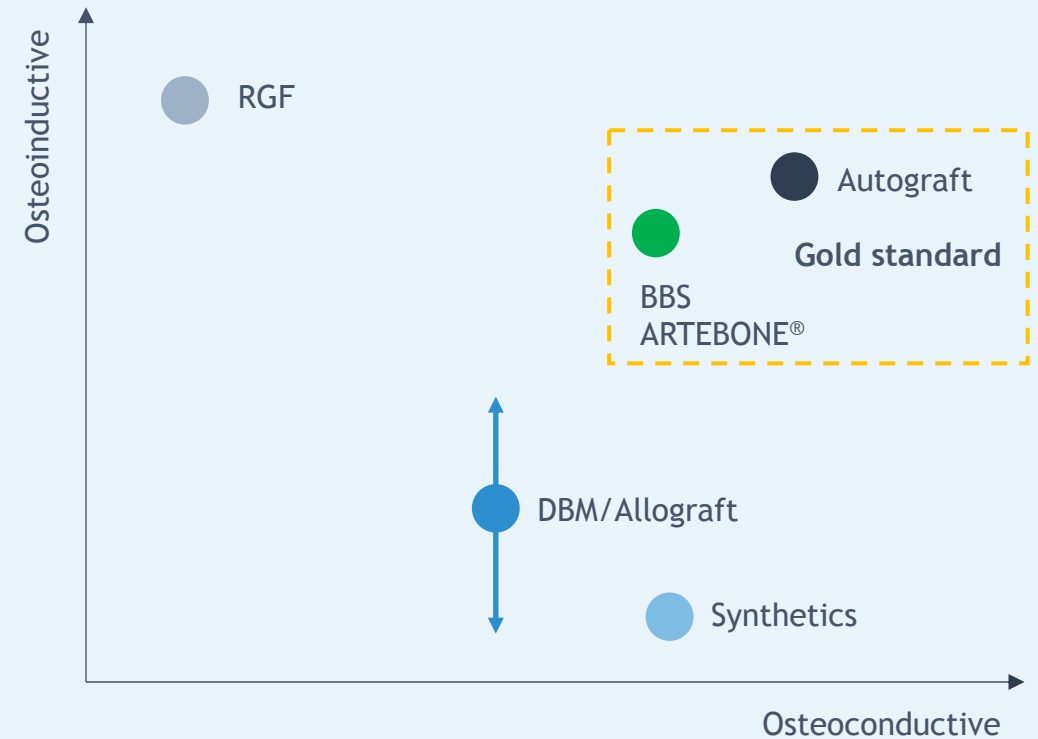
COMPETITIVE PRICE

The ARTEBONE® family products are positioned in the bone graft substitute market

Division of procedures

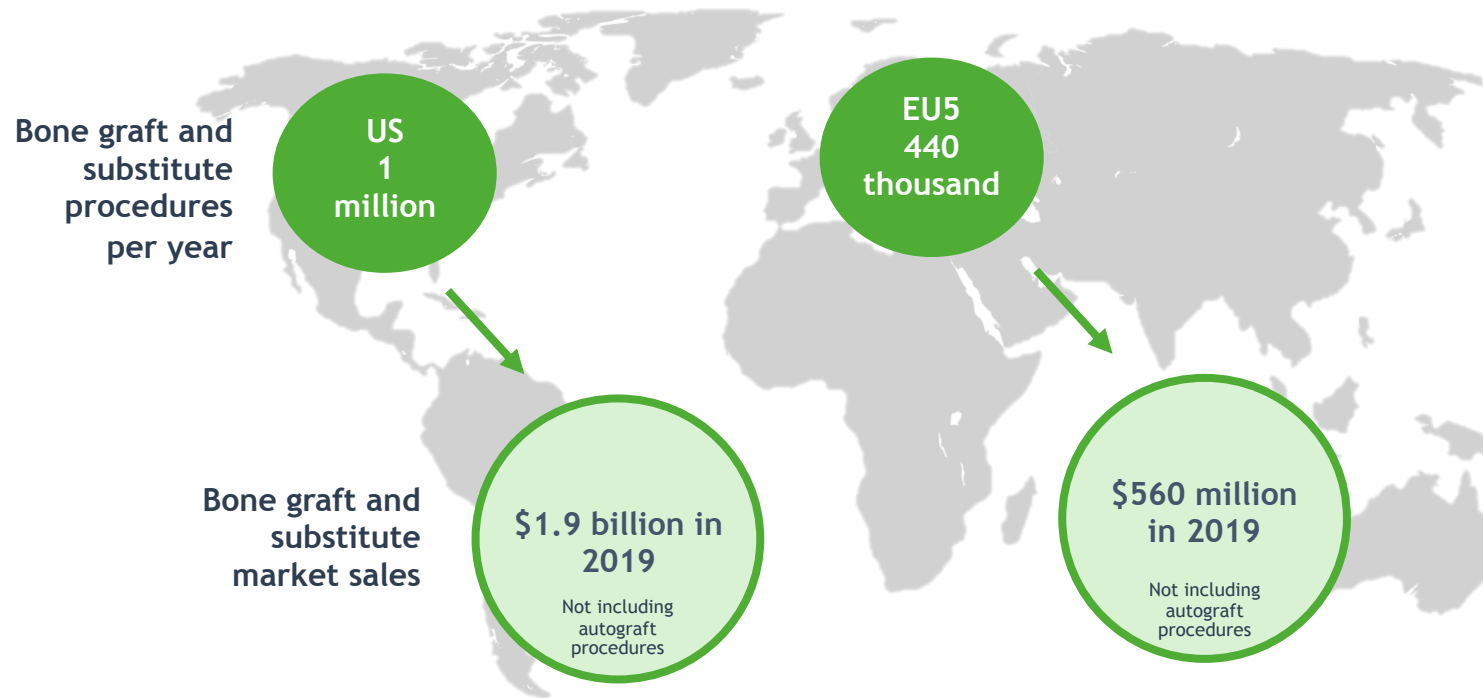


Positioning of ARTEBONE® in the bone substitute segment



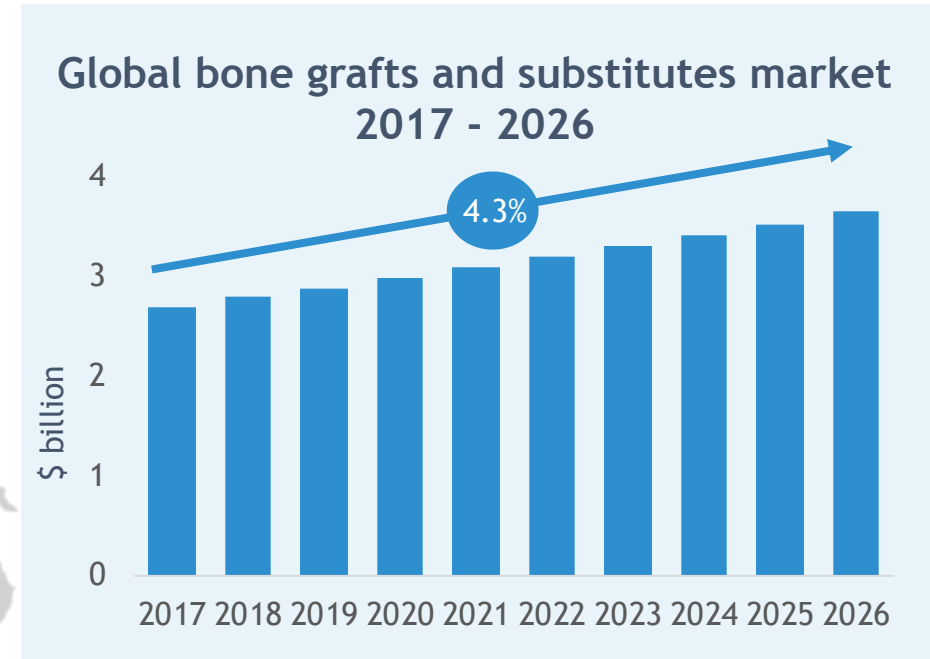
The current bone grafts and substitutes market in 10MM is worth more than \$2.9 billion and is expected to grow at a rate of 4.3%

Bone grafts and substitutes market overview



Market size in 10MM: \$2.9 billion

10 major markets (10MM): US, UK, Germany, France, Spain, Italy, Japan, Brazil, China and India
EU5: US, UK, Germany, France, Spain and Italy



Growth drivers:

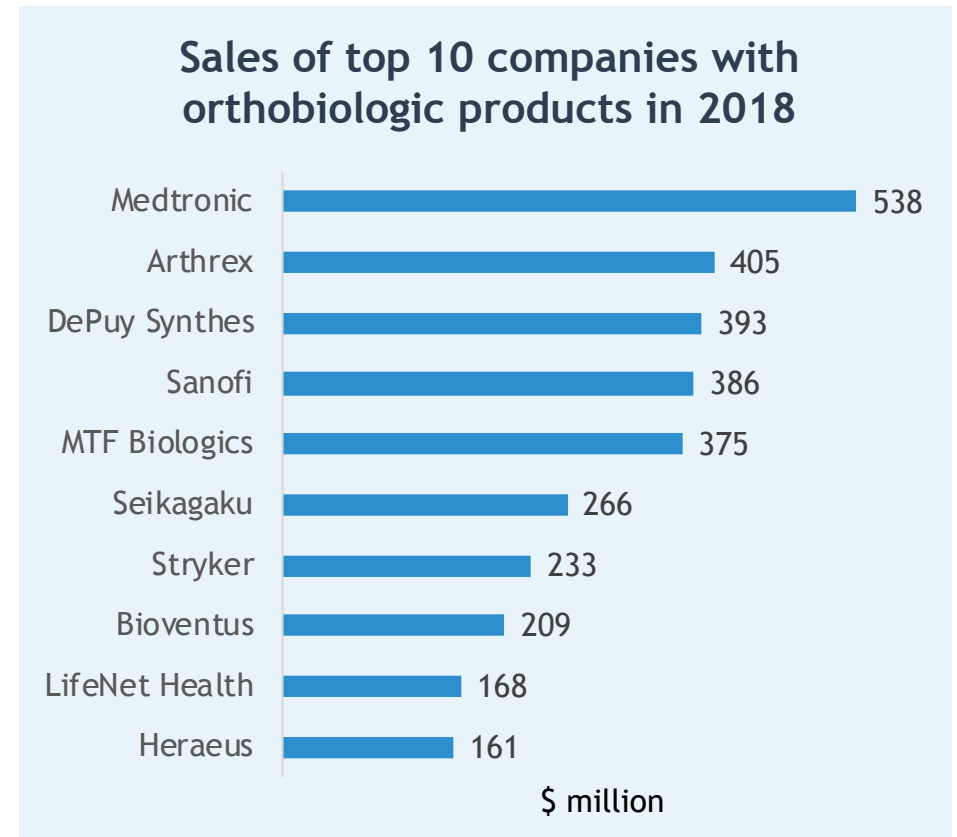
- Ageing population
- Young surgeons adopting new technologies
- Preference for minimally invasive procedures

The worldwide market opportunity for the ARTEBONE® product family is worth up to \$242 million per year

- The market opportunity of BBS products in the bone graft and substitute market is of \$158 million in the US and EU5 alone.

| Market opportunity | | | |
|---|----------------------------|---------------------------|--------------------------|
| | Worldwide | US | EU5 |
| Number of bone graft surgeries | 2 200 000 | 1 000 000 | 440 000 |
| Cost ARTEBONE dose* | \$1,100 | \$1,100 | \$1,100 |
| Market penetration | 5-10% | 5-10% | 5-10% |
| Market opportunity for ARTEBONE® | \$121 - 242 million | \$55 - 110 million | \$24 - 48 million |

*ARTEBONE® is priced between €800 - 1,000 (\$900 - 1,100) per dose.
EU5: US, UK, Germany, France, Spain and Italy.



Note: The annual sales figure of these companies include more than one product portfolio or products that correspond to the bone substitute orthobiologic market.

ARTEBONE® will compete effectively across all market segments

ARTEBONE® competitive advantage

- Products can be applied in a broad array of orthopedic procedures
- Strong patent portfolio
- High optimal performance in bone healing
- Favorable safety profile
- Cost-effective solution
- Production capability of up to 500,000 doses per year

| Competing segments | Performance | Safety issues | Availability of raw material | Cost per dose |
|----------------------------------|-------------|---------------|------------------------------|--------------------|
| Autograft | High | Medium | Possible for most patients | High |
| Recombinant growth factors | High | High | High | \$3,500 - 5,500 |
| Machined and bank bone allograft | Medium | Medium | Donor supply limited | \$300 - 600 |
| DBM and Allograft | Medium | Medium | Donor supply limited | \$600 - 900 |
| Synthetics | Medium | Low | High | \$900 - 1,300 |
| BBS ARTEBONE® | High | Low | High | \$900-1,100 |

BBS has a strong patent portfolio that provides protection in Europe, Asia and North America

| Portfolio, status and coverage | Europe | | | | | | | | Asia | | North America | |
|---|--------|-------|-------|-----|-------|-------|-------|------|-------|--------|---------------|-----|
| Patent description | EU | Germ. | Fran. | UK | Italy | Spain | Swed. | Fin. | India | Euras. | Can. | USA |
| Device and method: An osteogenic device and a method for preparing the device. | G | G | G | G | G | G | G | G | | | | G |
| Method and Preparation: A method for preparing a bone protein preparation. | G | EPO | EPO | EPO | EPO | EPO | EPO | EPO | | G | P | P |
| rRdBMP-3c: Bone morphogenetic protein 3 and osteogenic devices and pharmaceutical products containing morphogenetic protein 3. | P | EPO | EPO | EPO | EPO | EPO | EPO | EPO | G | | | G |
| rRdBMP-4: Bone morphogenetic protein 4 and osteogenic devices and pharmaceutical products containing morphogenetic protein 4. | G | G | G | G | EPO | EPO | EPO | EPO | G | | | G |
| rRdBMP-6: Bone morphogenetic proteins containing a heparin binding site and osteogenic devices and pharmaceuticals | G | G | G | G | EPO | EPO | EPO | EPO | G | | | G |

G: Patent granted

P: Patent pending

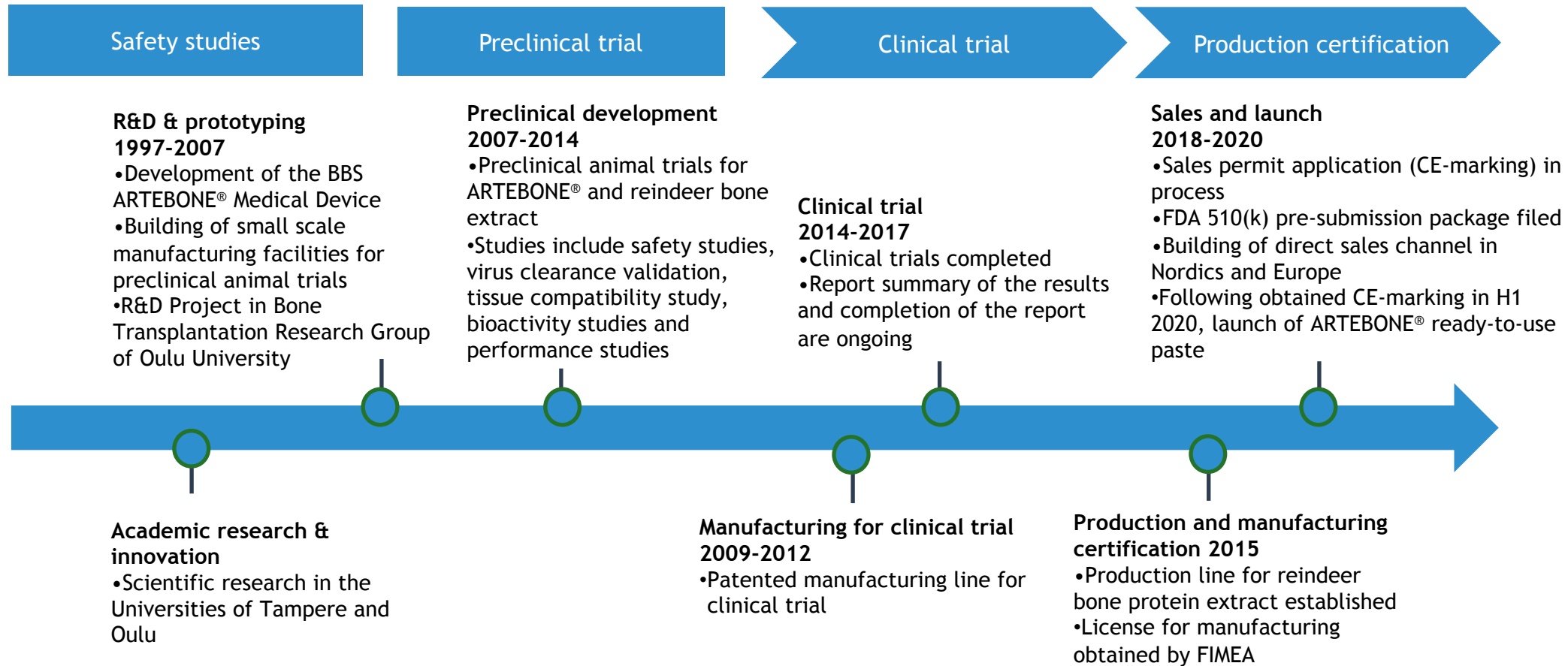
EPO: Patent covered through European Patent Office (EPO)

Manufacturing production facility in Reisjärvi is owned by BBS

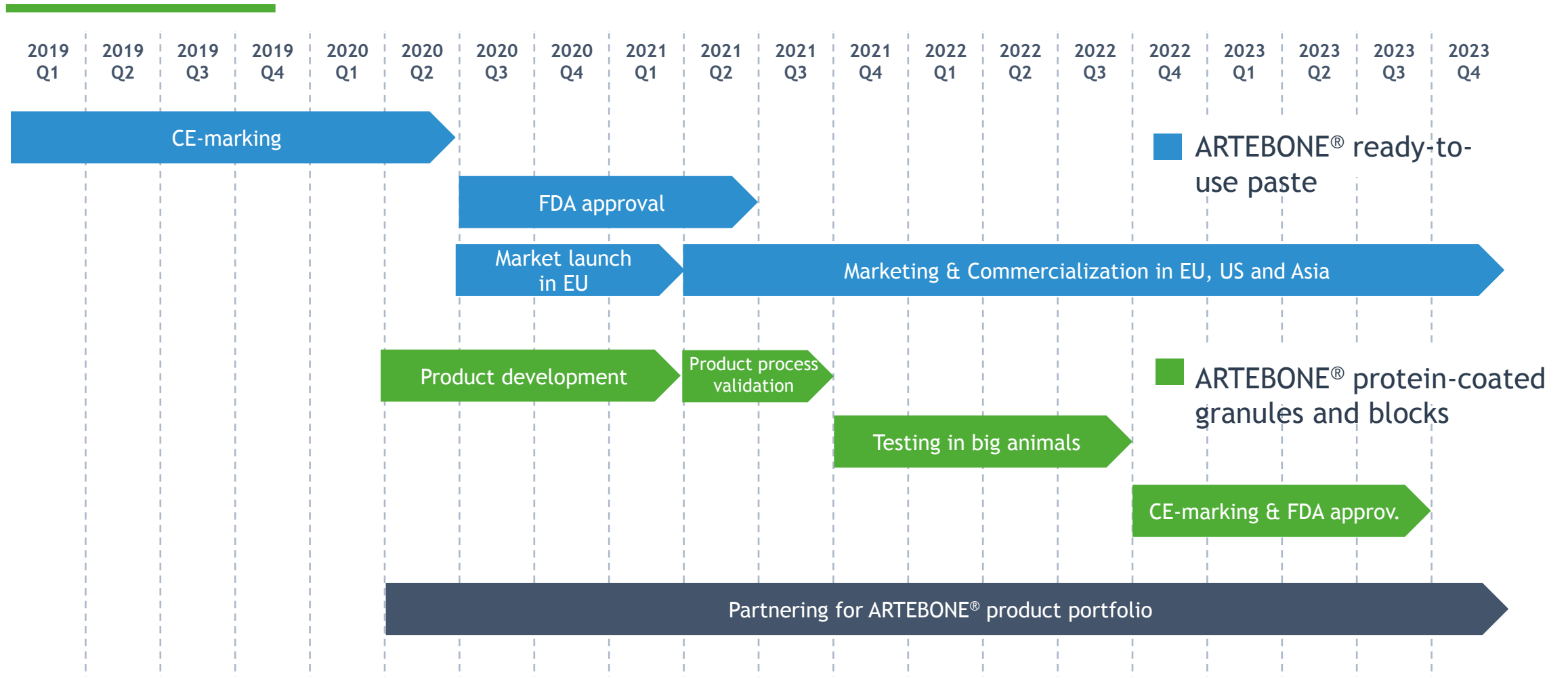
- **90,000 reindeers** are slaughtered every year in Finland.
- **GMP manufacturing process** for bone proteins is authorized by the Finnish Medicine Agency (FIMEA).
- Current production capacity is 25,000 doses of ARTEBONE® per year.
- **Maximum capacity is 500,000 doses** of ARTEBONE® per year based on the number of reindeer slaughtered.
- ARTEBONE® Medical Device is ready for ISO 13485 certification.



ARTEBONE®: Developed as a novel next-generation product and ready for commercialization



Development timeline of ARTEBONE® product portfolio

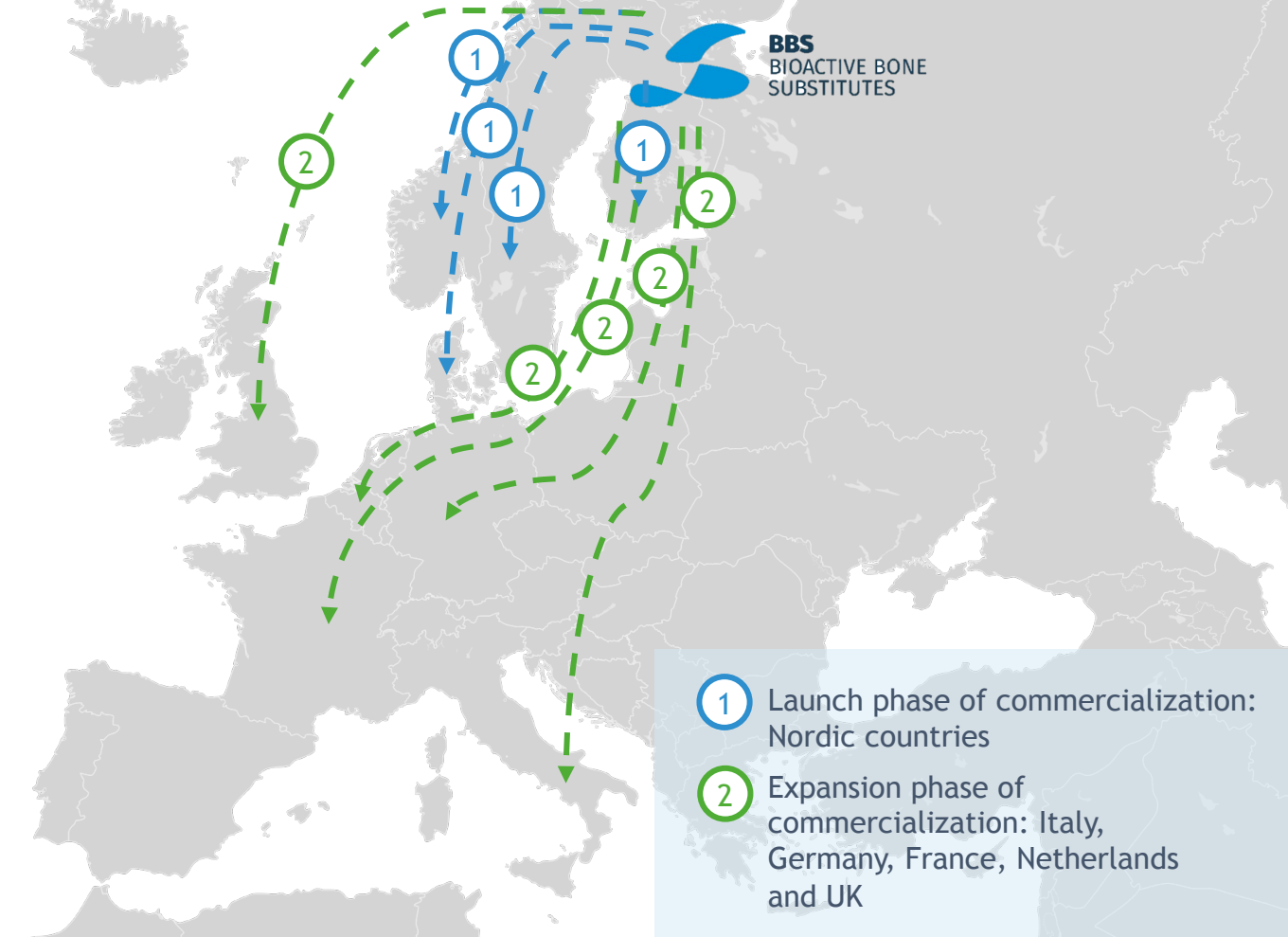


This timeline is an estimation based on information as of May 2019.

Sales and partnering strategy will first target the Nordic market followed by selected EU countries

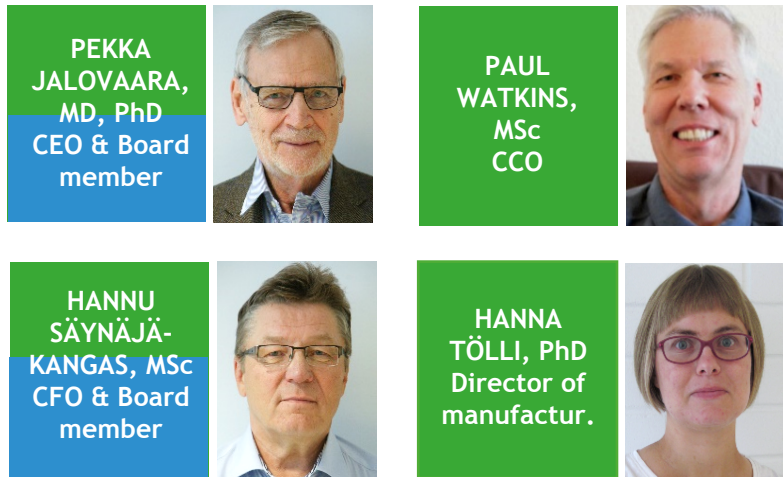
Promotional strategy to increase market uptake and expansion

- Publication of clinical trial results
- Surgeon champions will present in conferences, workshops, lectures, etc.
- Distribution of high quality collateral materials
- Training for surgeons via bench-top workshops, seminars, and live surgeries
- Communications through to the public via press releases, newsletters, magazine and newspaper interviews and website

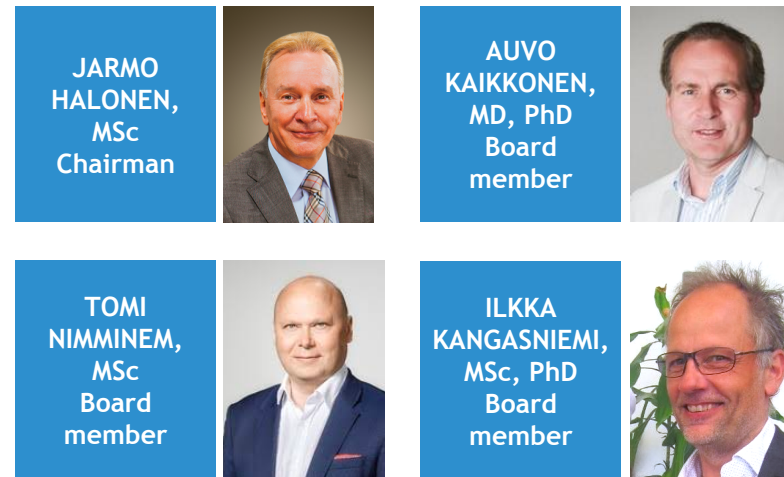


The team is highly experienced and knowledgeable in orthopedics, biomaterials, medtech, business development and manufacturing

Core management team



Board members



Scientific advisors



Why invest in BBS?

ARTEBONE®

Promotes effective bone healing in the treatment of bone fractures and defects

- A unique orthobiologic product with potential to replace existing bone-graft substitutes
- Market for bone graft substitutes is nearly \$3 billion and with a growing demand
- With a view to marketing authorization (CE) in the EU and later the US (FDA)
- FIMEA authorized facility for production of proteins
- Self-sustained manufacturing line for ARTEBONE® ready-to-use paste, not reliant on third-parties
- A strong patent portfolio

BBS

Bioactive Bone Substitutes

Contact: +358 207 924 700 | info@bbs-artebone.fi

Headquarter

Kiviharjunlenkki 6
90220 Oulu
Finland

Production site

Teollisuustie 4
85900 Reisjärvi
Finland

