



Handelsbanken

Life Science Innovation Day

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BONESUPPORT

Emil Billbäck, CEO

Håkan Johansson, CFO

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CERAMENT – a unique technology for healing bone injuries



Strong commercial traction and market share gains

- Sales (Q3 LTM): **735 mSEK**
- Sales growth: **+64% (CER)**
- Gross Margin: **91,5%**
- Positive operating profit, cash generative

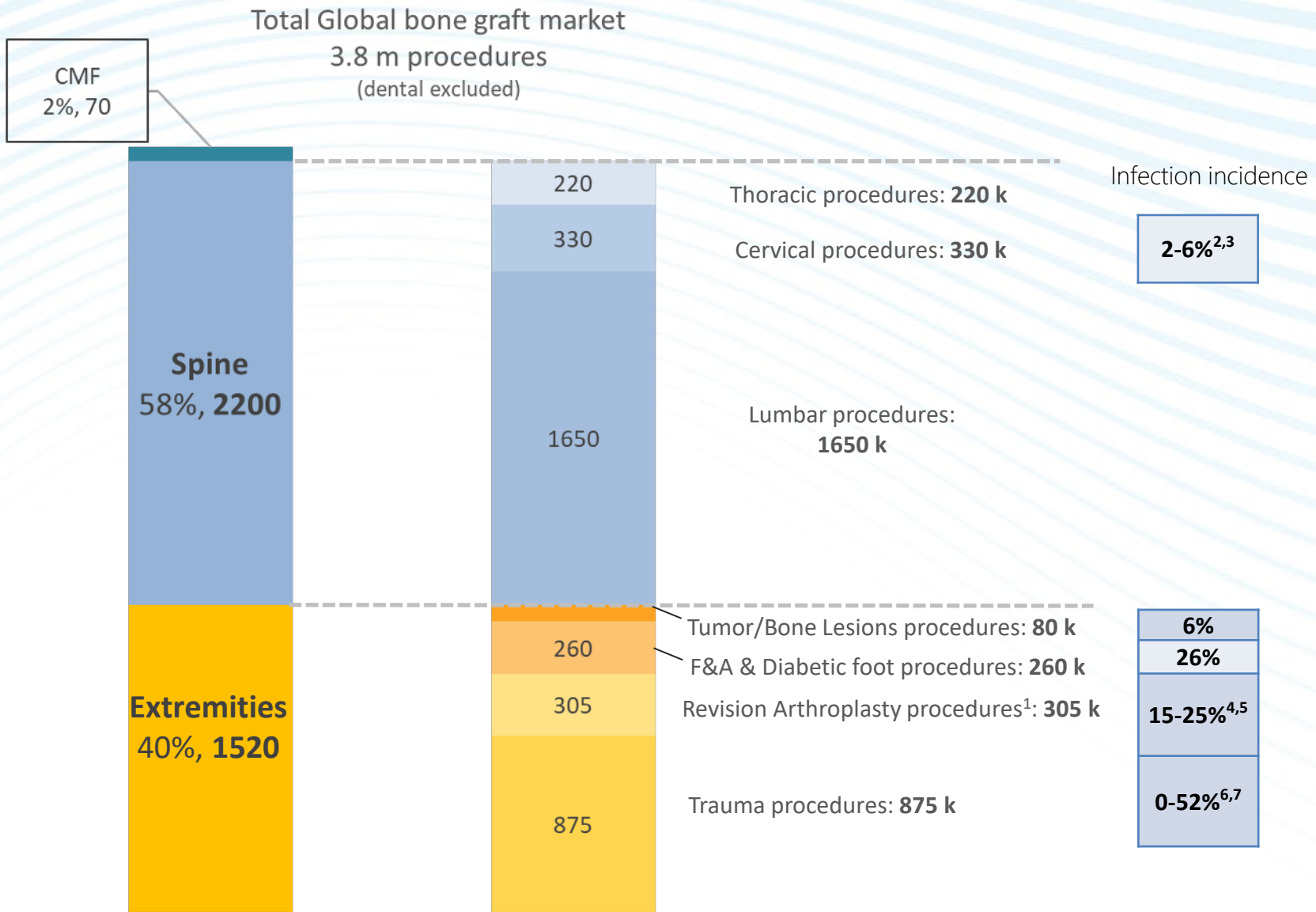
Strong regulatory and reimbursement enablers

- Full portfolio MDR CE-mark certified
- First and only market authorized antibiotic eluting bone graft in USA
- Incremental Medicare reimbursement in hospital (NTAP) and outpatient setting (TPT)

Proprietary and proven technology platform

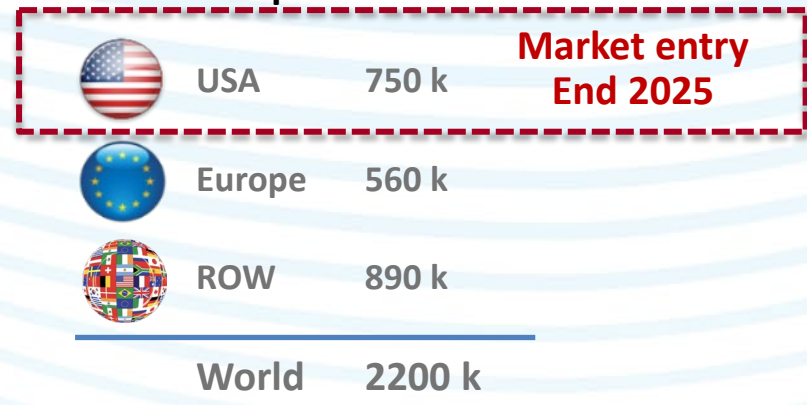
- Strong IP built with 100 patents - 30 core patents valid until 2034.
- Proprietary manufacturing process with significant trade secrets
- Over 240 peer-reviewed clinical papers, validating work mechanism and benefits

Overview Total Graft Market – Segment and sub-segment split

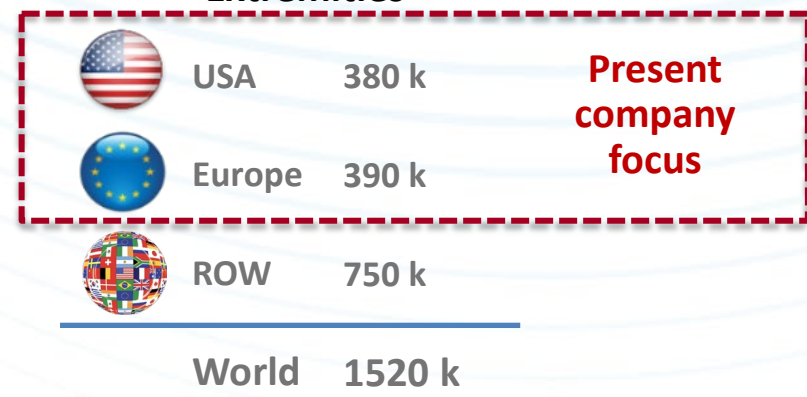


Regional split

Spine

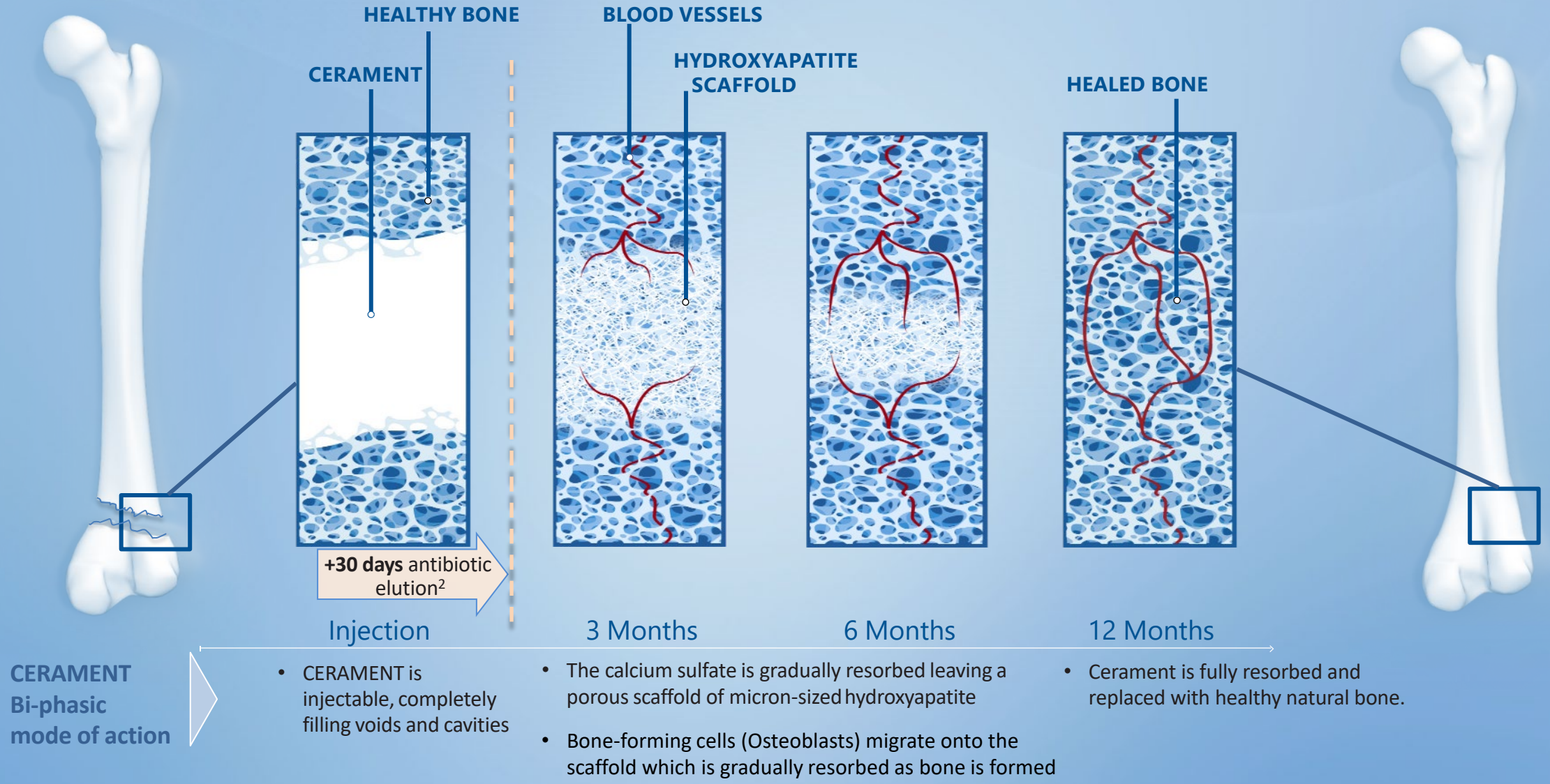


Extremities



1. 3000 k Arthroplasty procedures in the world. Approximately 10% leads to a revision, which has been defined as primary addressable market for CERAMENT 2. Edmiston, C., Leaper, D., Chitnis, A., Holy, C., & Chen, B. (2023). Risk and economic burden of surgical site infection following spinal fusion in adults. *Infection Control & Hospital Epidemiology*, 44(1), 88-95. doi:10.1017/ice.2022.32 3. Chahoud et al. Surgical site infections following spine surgery: eliminating the controversies in the diagnosis Infectious Agents and Disease Volume 1 - 2014 | <https://doi.org/10.3389/fmed.2014.00007> 4. Lum ZC, Shieh AK, Dorr LD. Why total knees fail-A modern perspective review. *World J Orthop* 2018; 9(4): 60-64 [PMID: 29686970 DOI: 10.5312/wjo.v9.i4.60] 5. Karachalios et al. Total hip arthroplasty: Survival and modes of failure. *EFORT Open Reviews*, 3(5), 232-239 doi.org/10.1302/2058-5241.3.170068 6. Gustilo RB et al. Problems in the management of type III (severe) open fractures: a new classification of type III open fractures. *J Trauma*. [Internet]. 1984; 24: 742-746. 7. Jahangir N, Niazi N, Aljawadi A, et al. The use of adjuvant local antibiotic hydroxyapatite biocomposite in the management of open Gustilo Anderson type IIIB fractures. A prospective review. *Journal of orthopaedics*. 2019;16(3):278-282.

CERAMENT® - Promotes and protects natural healing



CERAMENT heals fractures as effectively as autograft, eliminating the need for bone transplants¹

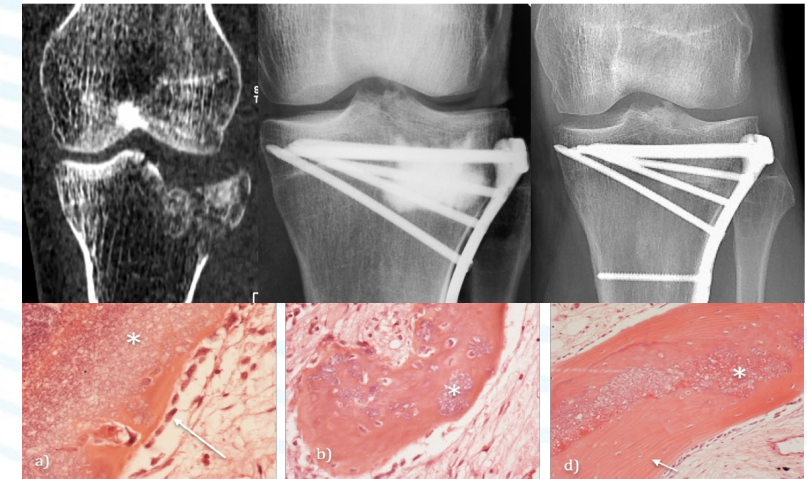
1. Autologous Iliac Bone Graft Compared with Biphasic Hydroxyapatite and Calcium Sulfate Cement for the treatment of Bone Defects in Tibial Plateau Fractures. J Bone Joint Surg Am. 2019;00:1-15
2. CERAMENT G (Gentamicin) and CERAMENT V (Vancomycin)

CERAMENT G unique composition provides antibiotic elution and bone remodeling

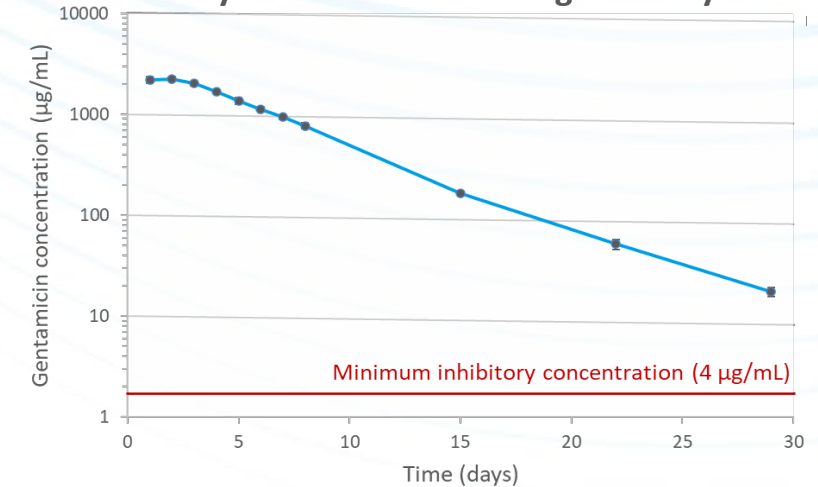
• CERAMENT G

- Purpose engineered ceramic bio-composite
 - Same mineral composition as natural bone
 - Mimics natural healing
 - Resorbs at pace of bone healing
- Full bone remodeling in 6-12 months
 - Gentamicin at high local concentration levels significantly above minimal inhibitory concentration (MIC), with no shown systemic side effect.

Clinically proven bone remodeling ^{5,6}



More than 30 days antibiotic elution significantly above MIC



Clinical evidence (peer-reviewed, published clinical studies) showing:

- **96% infection elimination¹**
- **94-98% Diabetic foot limb salvage rate^{2,3}**
- **74% reduction in open fracture trauma amputation rate⁴**

1. McNally et al. Single-stage treatment of chronic osteomyelitis with a new absorbable, gentamicin-loaded, calcium sulphate, *Bone Joint J* 2016;98-B:1289–96.
2. NL Vasukutty et al. Limb salvage surgery in diabetic foot infection: encouraging early results with a local antibiotic carrier *The Diabetic Foot Journal* Vol 25 No 2 2022
3. Chow J, Imani S, Kavisinghe I, Mittal R, Martin B. Definitive single-stage surgery for treating diabetic foot osteomyelitis: a protocolized pathway including antibiotic bone graft substitute use. *ANZ J Surg.*
4. Henry et al. Long-Term Follow-Up of Open Gustilo-Anderson IIIB Fractures Treated With an Adjuvant Local Antibiotic Hydroxyapatite Bio-Composite, *Cureus* 15(5): e39103. DOI 10.7759/cureus.39103
5. Hofmann A, Gorbulev S, Guehring T, et al. Autologous Iliac Bone Graft Compared with Biphasic HA and Calcium Sulfate Cement for the Treatment of Bone Defects in Tibial Plateau Fractures: A Prospective, Randomized,. *J Bone Joint Surg Am.* 2020;102(3):179-193.
6. J Ferguson et al. A comparison of clinical and radiological outcomes between two different biodegradable local antibiotic carriers used in the single-stage surgical management of long bone osteomyelitis, *Journal of Bone and Joint Infection.*2019; 4(2): 76-84

Significantly improved treatment outcomes with CERAMENT in DFO

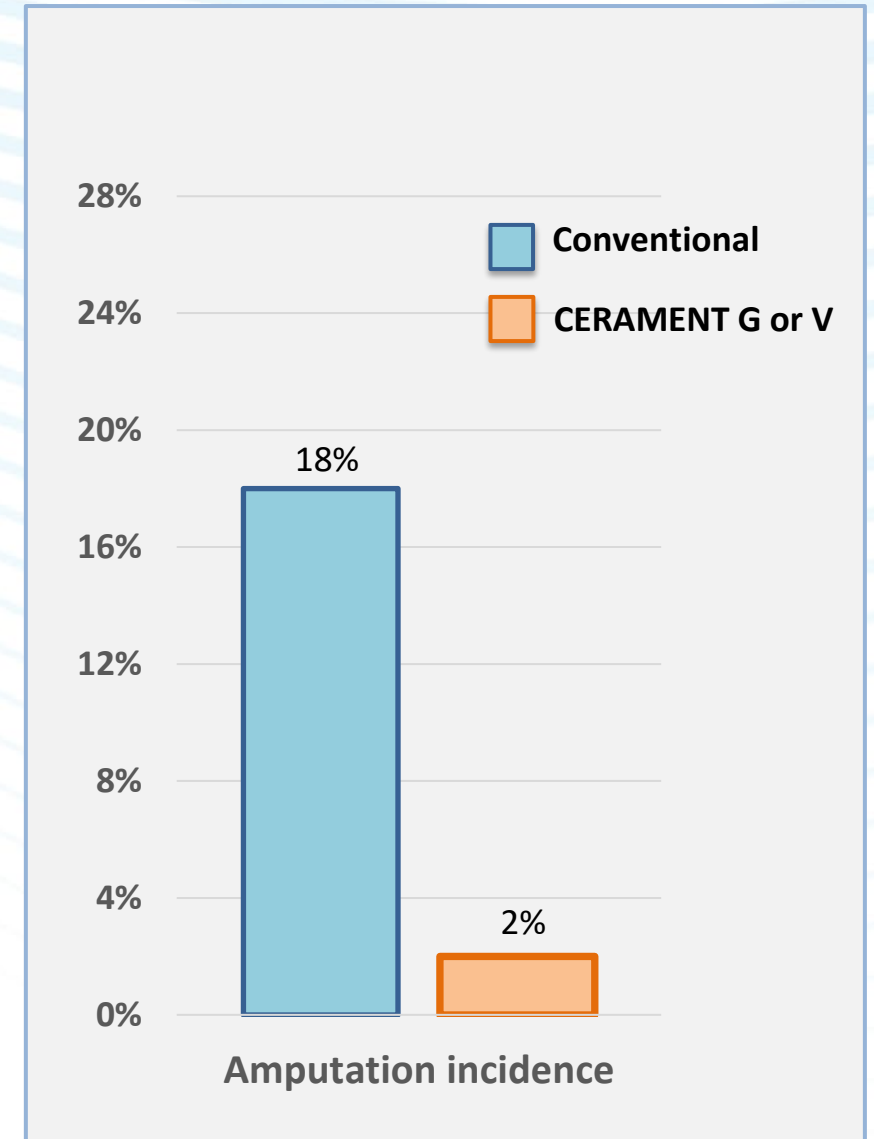
Chow J, Imani S, Kavisinghe I, Mittal R, Martin B. Definitive single-stage surgery for treating diabetic foot osteomyelitis: a protocolized pathway including antibiotic bone graft substitute use. ANZ J Surg.

Retrospective study on patients with Diabetic foot osteomyelitis

- Debridement without local antibiotics (conventional) vs. single-stage procedure including debridement and CERAMENT® G or CERAMENT® V (CERAMENT)
- 136 patients, with 33 conventional, 103 CERAMENT
- Minimum follow up 12 months

Results

- Amputation rates significantly lower in CERAMENT group (**2.0% vs. 18.0%**, $P < 0.001$)
- Significant reduction in surgical procedure numbers in protocolized group (**1.2 vs. 3.5**, $P < 0.001$)
- Shorter hospital length of stay in protocolized group (**12.6 days vs. 25.1 days**) ($P < 0.001$)
- At 12 months follow up – protocolized group exhibited an ulcer healing rate of 89%, with a low rate of recurrence of 3%



CERAMENT G shows clear superiority in clinical comparison



Clinical evidence for FDA market authorization approval;

CERAMENT G:

- Single-stage surgery (one intervention, one hospital stay)
- Infection recurrence rate: **5.5%**¹

US Standard of care (PMMA-beads with antibiotics):

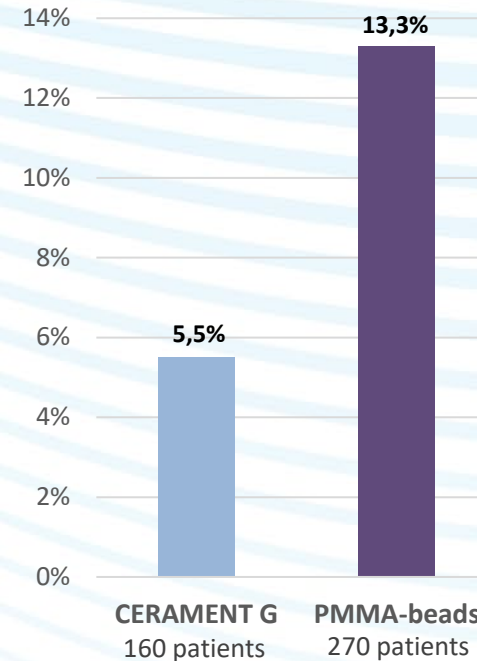
- Two-stage surgery (min two interventions, min two hospital stays)
- Infection recurrence rate (meta-analysis on published data): **13.3%**²

Strong health economic and payor benefits;

- 366 patients pooled, long-bone fracture, 2 years total cost model. CERAMENT G in single-stage surgery versus multi-stage standard of care (PMMA)
- CERAMENT G is cost favorable with **28 000 USD** compared to standard of care (over 2 yrs)³

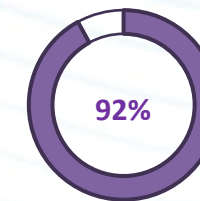
Strong preference for “Getting it right the first time!”;

- **92% of US orthopedic surgeons** stated that they prefer a single-stage procedure, rather than multi-stage procedure⁴



Infection recurrence^{1,2}

- 430 patients.
- 17 000 data points
- Peer-reviewed published clinical studies
- Mean follow up; 4 years



Procedure preference⁴

92% of US orthopedic surgeons states preference for single-stage procedure

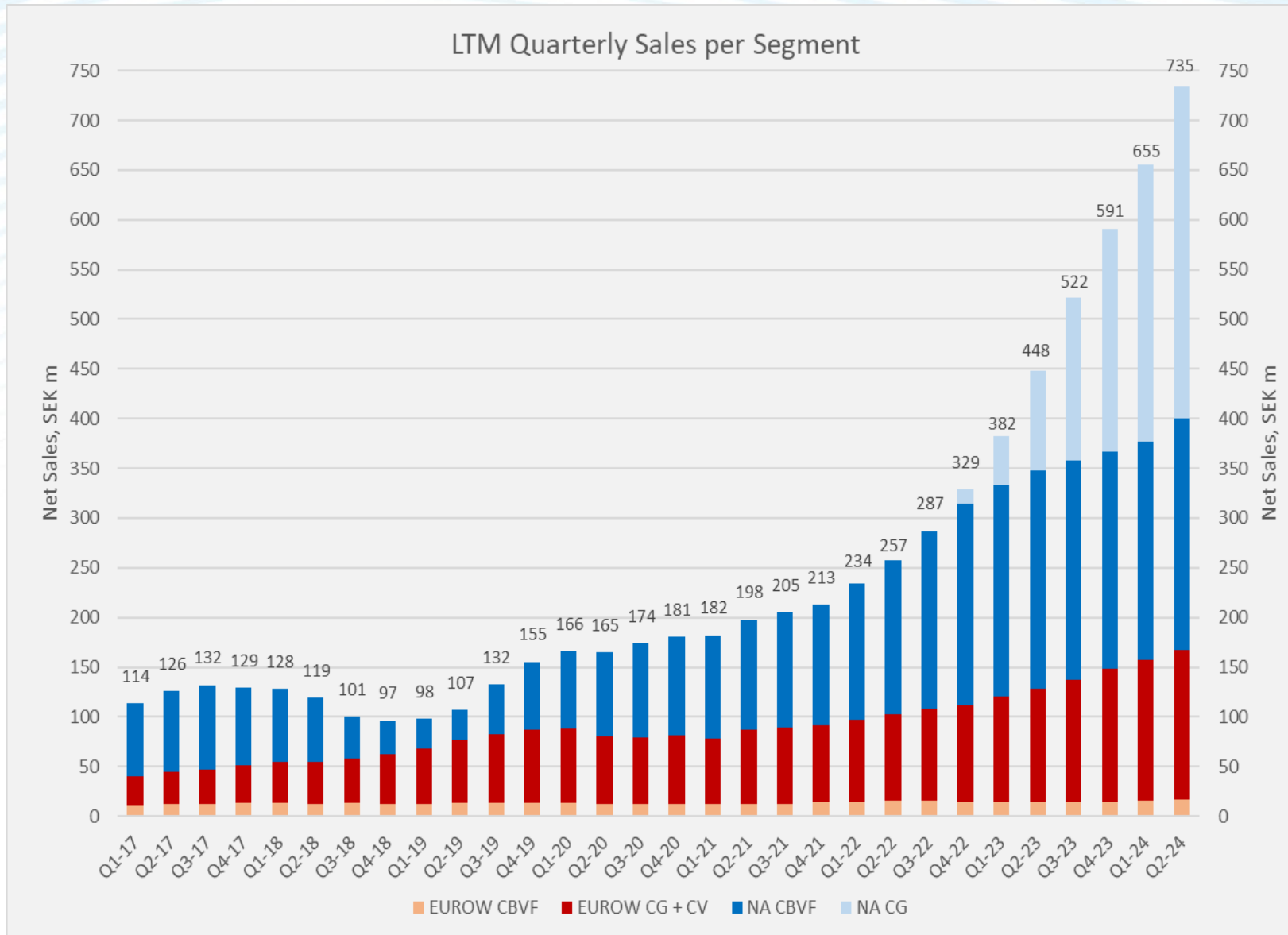
1. Fergusson et al, Radiographic and Histological Analysis of a Synthetic Bone Graft Substitute Eluting Gentamicin in the Treatment of Chronic Osteomyelitis; Journal of bone and joint infection, 2019 vol 4

2. Meta-analysis of published data from 7 studies on PMMA-beads as part of treatment of osteomyelitis, submitted to FDA as part of CERAMENT G application

3. Carter, M., et al. "EE240 Does Single Stage Surgery of Long Bone Infection Using Gentamicin-Eluting Bone-Graft Substitutes Result in Decreased Cost and Improved Quality of Life Compared to Traditional Approaches?." Value in Health 25.12 (2022): S100.

4. US market insight – Commissioned Inspired Health Market research, QB23: 177 respondents

Strong launch momentum for CERAMENT G in the US



- CERAMENT G in the US surpassing 100 mSEK in the quarter
- Total antibiotic eluting CERAMENT grew with 82% versus Q2 2023

CBVF= CERAMENT Bone Void Filler
 CG = CERAMENT G (Gentamicin)
 CV = CERAMENT V (Vancomycin)

SEK m	FY 2021	FY 2022	FY 2023
Net sales	212,9	328,8	591,1
North America	121,7	216,9	442,4
EUROW	91,2	111,9	148,6
Gross Profit	189,7	297,7	540,9
Gross Margin	89,1%	90,5%	91,5%
Sales commission and fees	-45,1	-80,4	-154,1
Other operating expenses	-219,8	-253,5	-332,7
EBIT, Adj	-75,2	-36,1	54,0
Cash at period end	206,5	201,3	167,4

Full year 2023 (FY2023):

- Strong market share gains. Sales growth of 80% (72% in CER)
 - North America 104% (95% in CER)
 - EUROW 33% (28% in CER)
- Gross margin improvement from geographic and product mix
- Other operating expenses increases from the launch of CERAMENT G and increased momentum in marketing and sales promotion activities in both the US and EUROW.
- Profit before effects from the Group's incentive programs improved by SEK 90.3 million – Positive result in each individual quarter 2023

SEK m	H1 2023	H1 2024
Net sales	260,1	404,2
North America	189,8	314,5
EUROW	70,3	89,7
Gross Profit	236,5	373,6
Gross Margin	90,9%	92,4%
Sales commission and fees	-67,1	-110,4
Other operating expenses	-151,2	-185,5
EBIT	18,2	77,7
Cash at period end	149,8	114,6

First half of 2024 (H1 2024):

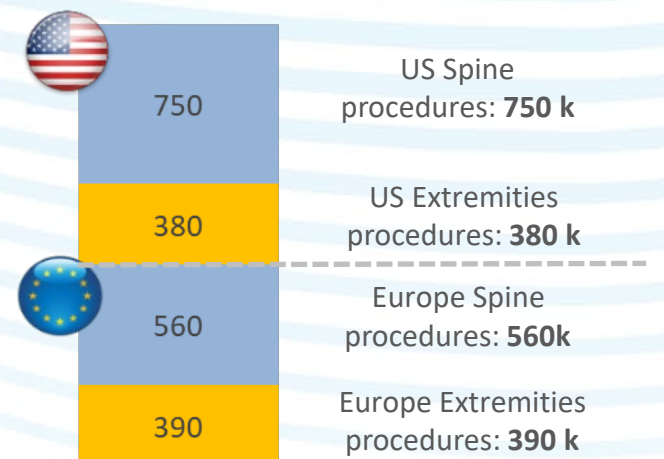
- Continued strong sales momentum. Sales growth of 55% (54% in CER)
 - North America 66% (65% in CER)
 - EUROW 28% (26% in CER)
- Continued improved Gross margin from geographic and product mix
- Strong operating leverage despite both commercial and R&D investments. EBIT improvement 43% of gross margin improvement.
- Safety stock investments having a temporary impact on cash flow.

Bonesupport next chapter

As presented at Capital Markets Day Nov 28th, 2023

- **BONESUPPORT entering the spinal fusion segment in US**

- Adding **750 k procedures** of addressable market
- Entering with a **strong value proposition**:
 - 1/5 of spinal procedures fail to fuse
 - 2-6% of procedures get infected
 - Off-label local antibiotics used in 40% of procedures
- **2024** generate and collect additional application evidence
- **First wave**: Build and extend (IBF), upon current label (PLF) for CERAMENT BVF
- **Second wave**: Introduce antibiotic eluting CERAMENT for spinal fusion procedure (Timing TBD)



- **Bonesupport seeking marketing authorization for CERAMENT V in the US**

Guidance: Sales growth in 2024 above 50% (in constant currency)

Guidance updated with Q2 report