

# BONESUPPORT™

BONESUPPORT

Q4 Conference Call Presentation

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# Presenting Team



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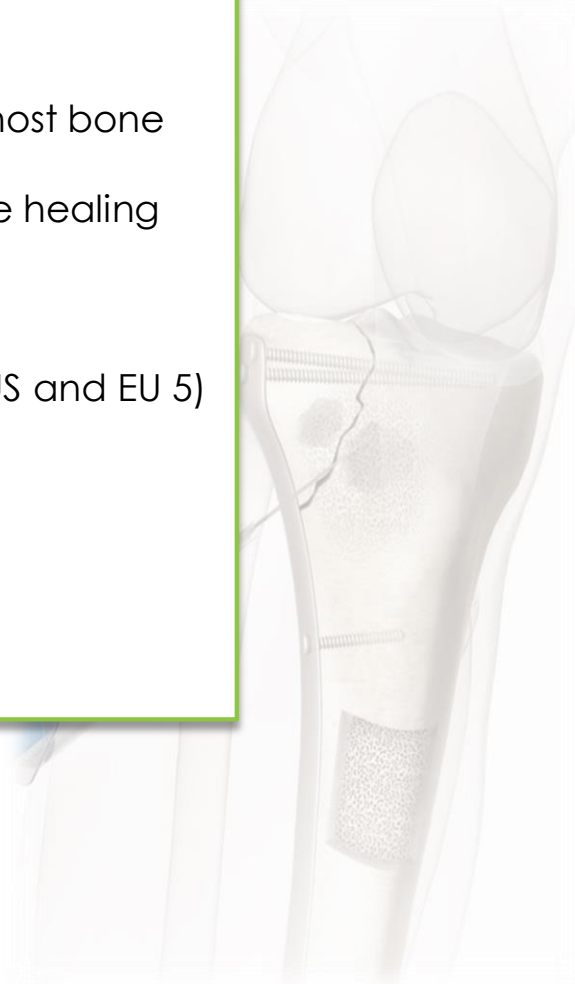
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# Innovative, rapidly growing orthobiologics company

## **BONESUPPORT – an innovative company focused on developing and commercializing products for the management of bone voids**

- Commercializing 3 synthetic bone grafts - clinically proven to remodel to host bone
- CERAMENT G and V clear differentiation - elute antibiotics to protect bone healing
- Industry leading data to support surgeon/patient/payor benefits
- Targeting a significant addressable market of 650k procedures annually (US and EU 5)
- R&D focused on pipeline of products designed to enhance bone growth
- Financed through to end of 2020



# Q4 Highlights

- Net sales of SEK 27.0 million – decrease of 9%
  - Strong sales growth in EU and RoW – up 39% to SEK 14.5 million – driven by continued success with antibiotic-eluting products and pick-up in other product sales
  - Slowdown in North America – Sales decline of 35% – driven by Zimmer Biomet hardware supply issues and destocking – improvement expected going forward as situation is improving
- Enrolment in CERTiFy complete – initial data expected second half of 2018
- Recruited first patient in Italian revision arthroplasty study assessing CERMAMENT G and CERAMENT V - recruitment is progressing well
- Signed new distributor agreement in Italy
- First sales in France post new distributor agreement in September - pathway for listing on high tech reimbursement list confirmed
- High profile publication demonstrated potential of CERAMENT G to prevent and manage biofilm-related bone infections
- Helena Brandt appointed Head of Human Resources – support our growth plans

# Post-period events

- Newly in-licensed CERAMENT based carrier reported to deliver bone active agents to enhance bone formation in prestigious publication – Journal of Controlled Release
- Outstanding Kreos loan repaid – EUR 9.5 million
- Emil Billbäck appointed as CEO, effective 1 March 2018

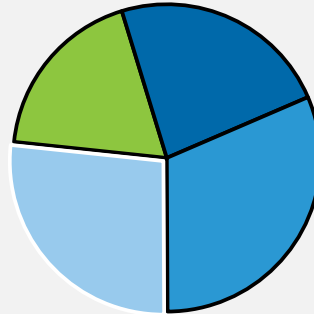
# Bone void management – a sizeable growth market

## Market Opportunity

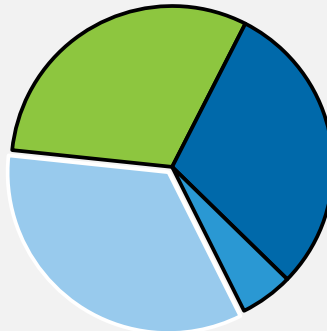
**Current  
addressable  
market:  
EU-5 +US: ~ 650k  
procedures p.a.**

**Global market for  
bone void filling  
USD 2.7 – 3.4  
billion**

% US Procedures (2) 



% EU Procedures (2) 



■ Allografts ■ DBM ■ Autografts  
■ Synthetic BVF graft substitutes

**Further growth for  
BONESUPPORT will be  
achieved by**

- **Gaining share** of the synthetic bone graft substitute market driven by our antibiotic eluting products
- **Driving penetration** into other treatment options including bone grafting

Our CERAMENT products have been designed to address the limitations of current bone graft substitutes plus elute therapeutics into the bone to provide further important clinical benefits

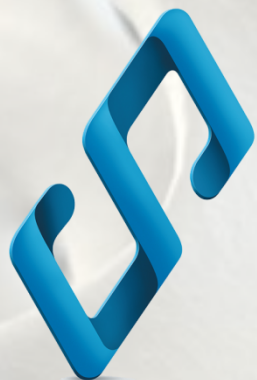
1) Xenografts (tissues from another species) are also used as a bone grafts, although less commonly in the US and Europe where autografts and allografts are the preferred treatment option

2) i-data for market penetration in 2014 (based on procedures)

# Our value-generating strategy

- **Driving sales of currently approved products in existing markets**
  - Generating further supportive clinical data to drive the adoption of our CERAMENT products for broader range of indications including trauma and revision arthroplasty
  - Generating compelling HEOR data to increase market access
  - Increasing commercial/sales investment in both the EU and US
- **Gain marketing approval for CERAMENT G in US**
  - Successfully completing the FORTIFY IDE study
  - Clinical data to support a planned PMA filing with FDA for CERAMENT G in 2020
- **Progressing our pipeline of CERAMENT product candidates**
  - Novel product candidates targeting enhanced bone growth
  - Capitalize on CERAMENT's bone remodelling and therapeutic eluting capabilities
- **Exploiting opportunities for expansion of our product offering**
  - Short and medium-term opportunities currently under evaluation





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Our Commercial Activities

# Europe

## Growing CERAMENT G,V and BVF sales in Europe

### Our commercial footprint

- European commercial organization comprises 20 people including the leadership team
- Present in 5 countries (direct) – UK, Germany, Switzerland, Sweden and Denmark
- Access to a further 8 countries via specialty distributors
  - New distribution agreement signed for Italy in Q4
  - Signed distribution agreement in September to initiate access to French market – first sales in Q4

### Our activities

- Continue to focus on driving adoption at the top trauma centers in our key European markets
  - Black Forest Expert Meeting on Bone Infection – 75 surgeons – live CERAMENT G surgery
  - Association Diabetic Foot Surgeons – Venice – 4 supportive presentations from key surgeons
- HEOR initiatives
  - CHOP application accepted in Switzerland
  - CERAMENT G study to commence in 2018 - allow application for a reimbursement listing on the High Tech Medicine list in France
- Added 2 reps in Germany and 1 rep in Switzerland in 2017

# US

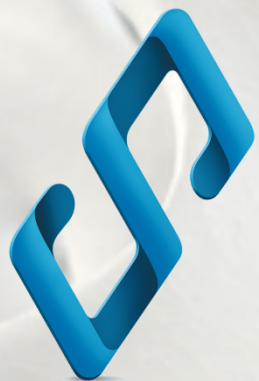
## CERAMENT BVF sales in the US

### Our commercial footprint

- BONESUPPORT US Commercial Team drive sales via Zimmer Biomet
  - 2 Area Sales VPs
  - 8 Regional Managers,
  - 2 Regional Technical Managers
  - 1 Post Market Clinical Research Project Manager
- CERAMENT BVF distributed via Zimmer Biomet's 54 independent distributors
- Rolling agreement with Zimmer Biomet

### Our activities

- Sales impacted by Zimmer Biomet hardware supply issues and some destocking in Q4
  - CERAMENT BVF used in conjunction with Zimmer hardware
- New sales management organization implemented to increase regional and local CERAMENT product focus and sales follow through
- Appointed Program Manager of Post-Market Clinical Research - initiate U.S. generated clinical data and peer-reviewed publications
- Preparing to exhibit at the American Academy of Orthopedic Surgeons in early March



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Clinical update

# Ongoing and Planned Clinical Studies

POST-MARKETING STUDIES	Feasibility <sup>1/</sup>	Initiated study	FPI <sup>1/</sup>	LPI <sup>1/</sup>	Publication
CERTiFy (DE) – BVF					
Revision Arthroplasty (IT) – G&V					
Diabetic Foot (IT) – G					
Osteomyelitis (FR) – G					

REGULATORY STUDY	Feasibility <sup>1/</sup>	Initiated study	FPI <sup>1/</sup>	LPI <sup>1/</sup>	Regulatory Filing
FORTIFY (US, DE, PL, SE, UK)					

Feasibility: Feasibility assessment; FPI: First Patient In; LPO: Last Patient Out



Milestone achieved

# Ongoing post-marketing clinical studies

## **CERTiFy study**

- Controlled study investigating the use of CERAMENT™ BVF in tibial plateau fractures
- CERTiFy enrollment complete – 136 patients recruited
  - Data expected second half of 2018

## **Italian-Revision Arthroplasty Study**

- First patient recruited in study evaluating CERAMENT G/V in patients undergoing hip and knee arthroplasty revisions
- Professor Carlo Romano – is the study's principle investigator – previously conducted a positive RA study with CERAMENT G
- Targeting to recruit 135 patients at 6 Clinical centers in Italy – recruitment going well

## **Successful study outcome would:**

- Mean that CERAMENT™ BVF would be the only synthetic bone graft substitute with level 1 randomized clinical data
- Would allow share capture in all geographies
- Also enable a publication to support reimbursement both in Germany and other geographies

## **Successful study outcome would show:**

- An improved clinical outcome and a lower infection rate (PJIs) for the CERAMENT G or CERAMENT V group vs retrospective control group
- Reduction in the rate of PJIs according to the Musculoskeletal Infection Society (MSIS) criteria during the one year follow-up

**Post-marketing studies designed to build on BONESUPPORT'S industry leading database of supportive clinical data and to provide further HEOR data to enhance market access**

# Recruitment on track in FORTIFY study to support approval of CERAMENT G in US

## FORTIFY trial timeline



## FORTIFY – Key points

- Recruitment on track – protocol amendment approved by FDA (Jan) to allow enrollment of patients with smaller fractures – patient screening to-date suggests this could improve the recruitment rate
- Primary endpoints of the trial include the absence of deep infection at the fracture site and the lack of secondary procedures intended to promote fracture union
- Preferred indication has been discussed at prior FDA meetings and was submitted as part of the approved IDE

**Final approved label will be dependent upon the strength of clinical effectiveness and safety data at time of PMA approval**



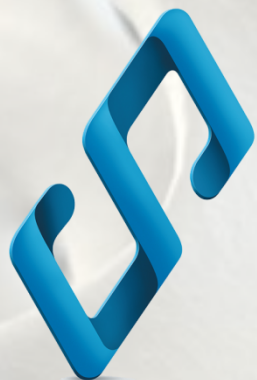
# Approval of CERAMENT G in the US Would Create a Significant Commercial Opportunity

Important large market with no comparable product – bone infections dramatically affect hospital profitability

**Dr. McKee - Chairman of the Department of Orthopaedic Surgery at the University of Arizona College of Medicine:**

“Readmission for an **infection** within the first 30 days post-op is an economic killer for the hospital. In addition to complications for the patient, just **one readmission takes away the profit made from eight to ten other patients**. The focus is to stop this from happening and minimize readmission rates.”



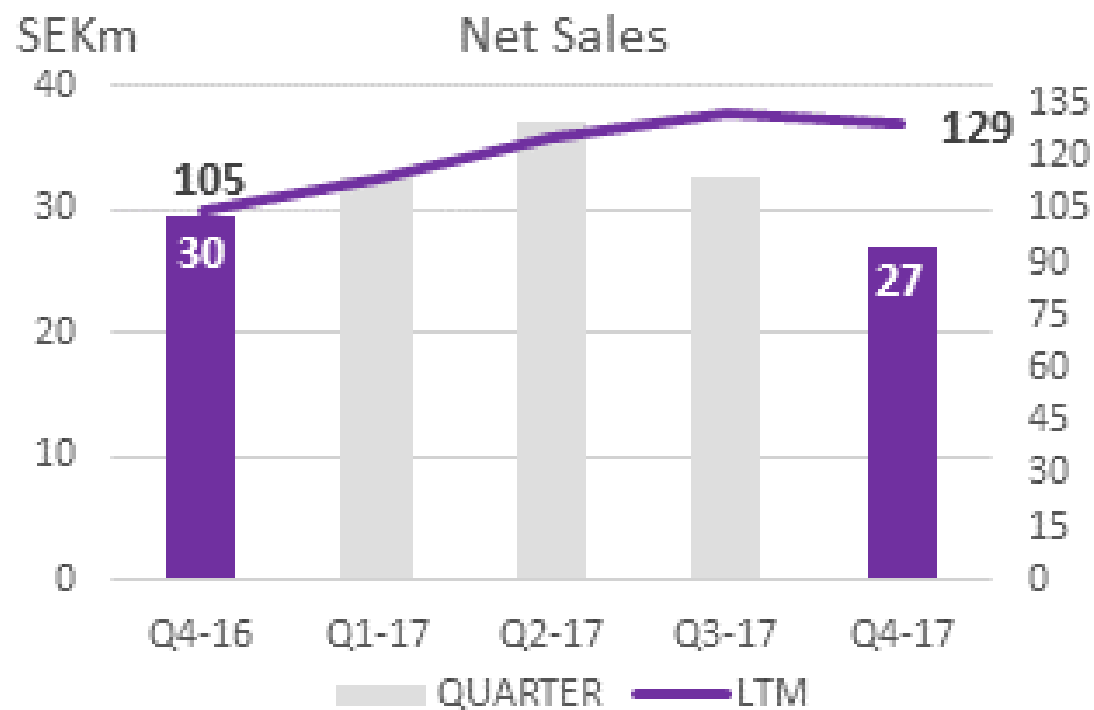


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Financial Review

# 24% increase in 2017 Net sales

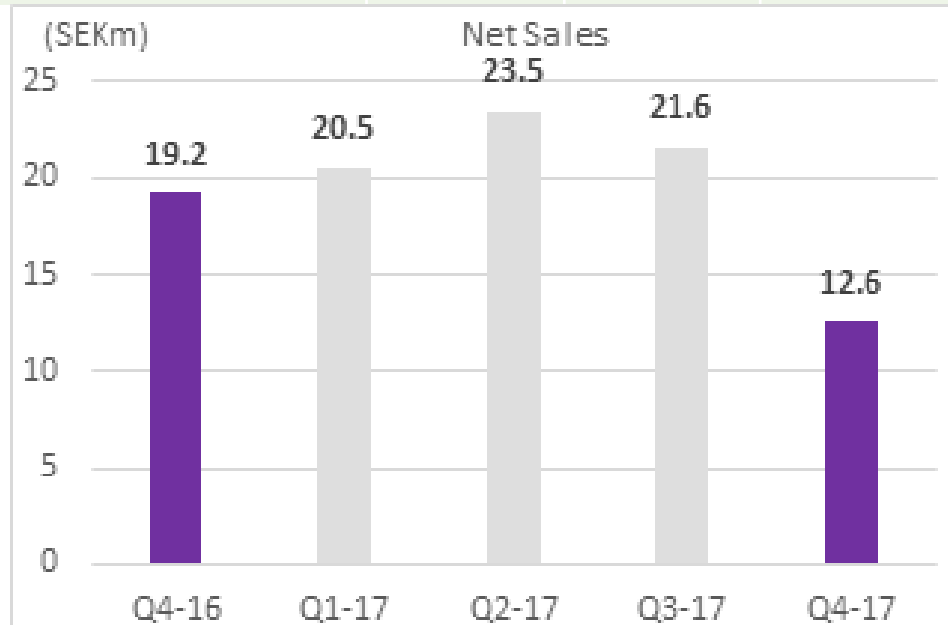


**-9%**  
Net Sales  
Q4

**+24%**  
Net Sales  
FY

# North America Analysis

	Oct-Dec		FY
(SEKm)	2017	2016	2016
Net Sales	12.6	19.2	68.8
Gross profit	10.7	17.1	59.5
Contribution	-3.5	7.3	22.5

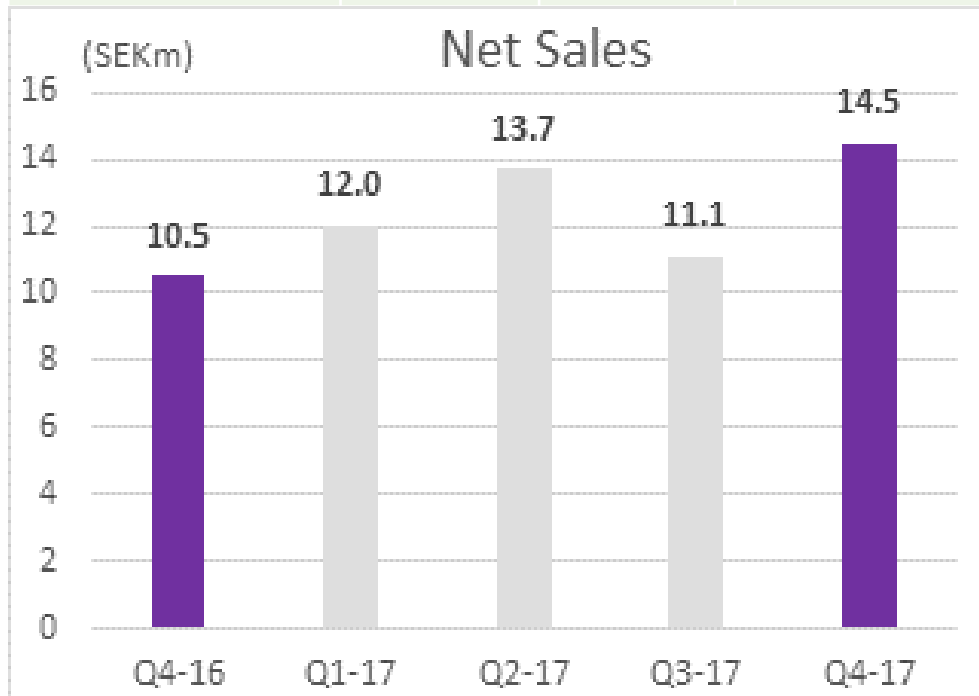


**-35%**  
**Net Sales**  
**Q4**

**+13%**  
**Net Sales**  
**FY**

# Europe and RoW Analysis

	Oct-Dec		FY
(SEKm)	2017	2016	2016
Net Sales	14.5	10.5	35.7
Gross profit	11.8	9.0	28.8
Contribution	0.8	-2.9	-12.2



**+39%**  
**Net Sales**  
**Q4**

✓ Direct markets increased by 42% in Q4

**+43%**  
**Net Sales**  
**YTD**

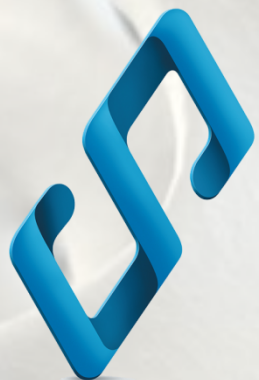
# Operating result development

	Oct-Dec		Jan-Dec	
(SEKm)	2017	2016	2017	2016
Net Sales	27.0	29.6	129.3	104.6
Cost of sales	-4.5	-3.6	-16.9	-16.3
Gross profit	22.5	26.0	112.4	88.3
Selling expenses	-21.5	-14.7	-92.9	-79.8
R&D expenses	-19.7	-15.3	-60.6	-38.2
Admin expenses	-15.5	-25.0	-57.5	-60.7
O.Operating items	0.8	0.5	-0.8	1.6
Total costs	-55.9	-54.5	-211.7	-177.0
Operating loss	-33.4	-28.4	-99.3	-88.7

- ✓ Increased activities
- ✓ FORTIFY study
- ✓ Less ESOP costs

# KPIs

	Oct-Dec		Jan-Dec	
(SEKm)	2017	2016	2017	2016
<b>Net Sales</b>	27.0	29.6	129.3	104.6
Sales Growth (%) <sup>1/</sup>	-8.8	28.8	23.6	69.4
Gross profit	22.5	26.0	112.4	88.3
<b>Gross margin (%)<sup>1/</sup></b>	83.3	87.8	87.0	84.4
<b>Operating loss</b>	-33.4	-28.4	-99.3	-88.7
Loss for the period	-51.4	-34.6	-128.9	-110.2
Equity at period end	450.8	34.3	450.8	34.3
Net debt <sup>1/</sup>	-434.7	-31.8	-434.7	-31.8
Operating cash flow	-25.7	-30.5	-107.5	-81.9
Cash at period end	533.4	141.5	533.4	141.5
Earnings per share <sup>2/</sup>	-1.03	-1.24	-3.24	-4.26



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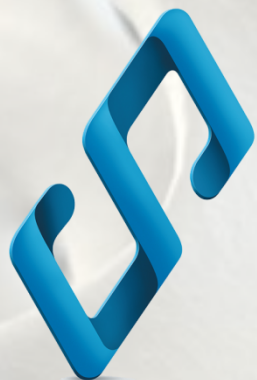
Wrap up

# Well positioned to generate shareholder value

- CERAMENT G and CERAMENT V unrivalled clinical and economic benefits – potential to gain significant share of the global market
- Focused on generating further clinical and HEOR data to enhance competitive positioning and drive sales growth
  - CERTiFy on track to read-out in H2 2018
- Recruitment on track in pivotal study – FORTIFY – a key step in gaining approval for CERAMENT G in the US
- Evaluating opportunities to expand product offering in the near and medium term
- Progressing pipeline of CERAMENT product candidates designed to enhance bone growth
- Experienced management team with the funding needed to deliver significant shareholder value







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Q&A