



# BONESUPPORT™

## ВОНЕСПОРТ

Q3 Conference Call Presentation

2 November 2017

# Presenting Team



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CEO



**BJÖRN WESTBERG**  
CFO

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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**

- Fast growing business
- 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



# Q3 Highlights

- Solid sales growth – 23% increase in Q3 to SEK 32.7 million
  - 28% growth in EU and RoW – driven by antibiotic-eluting products
  - 21% growth North America – slower growth due to Zimmer Biomet hardware supply issues
- Improved gross margins - increasing proportion of sales from higher margin antibiotic-eluting products
- Broad range of compelling clinical data presented at the European Bone and Joint Infection Society conference and British Orthopaedic Association Congress
- Recruited the first patient in Italian revision arthroplasty clinical study with CERAMENT G/V
- Signed new distributor agreement in France – entry into French market
- Jerry Chang appointed EVP Research & Development – drive pipeline activities
- Helena Brandt appointed Head of Human Resources – support our growth plans

# Experienced Recent Additions to the Leadership Team



**HÅKAN BJÖRKLUND**

Chairman

December 2016

Nycomed



**RICHARD DAVIES**

CEO

Joined January 2016

Hospira



**PATRICK O'DONNELL**

EVP Commercial US

Joined November 2016

Confluent Surgical



**BJÖRN WESTBERG**

CFO

Joined January 2017

Recipharm



**MICHAEL DIEFENBECK**

Chief Medical Officer

Joined April 2017

Orthopedic surgeon



**DR JERRY CHANG**

EVP R&D

Joined September 2017

Zimmer Biomet Etex



**Helena Brandt**

Head of Human  
Resources

Joined October 2017

TetraPak

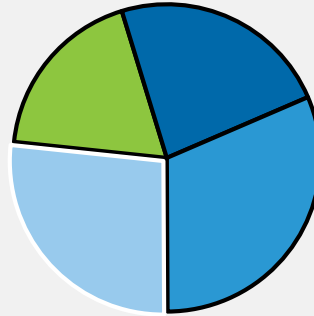
# Bone void management – a sizeable growth market

## Market Opportunity

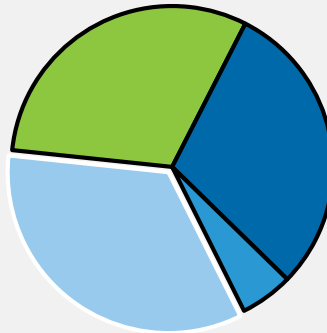
**Current  
addressable  
market**





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

% US Procedures <sup>(2)</sup> 



% EU Procedures <sup>(2)</sup> 



 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
- Drive 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

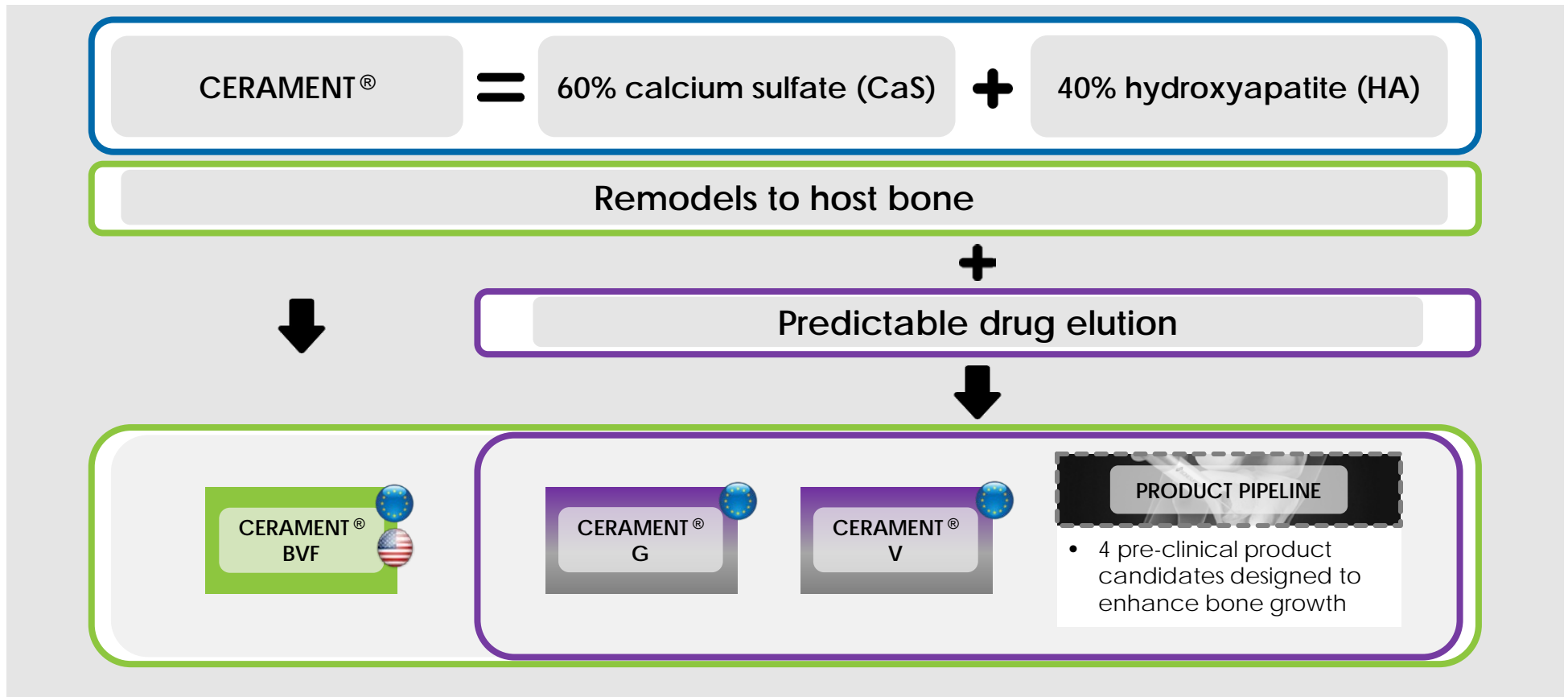
1) Xenografts (tissues from another species) are also used as a bone grafts, although less commonly in the US and Europe where autografts and allografts are the preferred treatment option

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



# Our proprietary CERAMENT<sup>®</sup> platform

CERAMENT<sup>®</sup> platform generates products that provide clear benefits to surgeons, patients and payors



BONESUPPORT expects to generate significant value from products that capitalize on CERAMENT<sup>®</sup>'s predictable therapeutic eluting properties



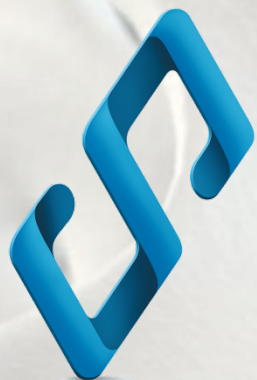
# CERAMENT® products well positioned for growth

- Unique composition remodels to bone in 6-12 months – all products
- CERAMENT G and CERAMENT V's ability to elute antibiotics is improving the way many orthopedic indications are managed - allowing them to rapidly gain market share
- Industry-leading clinical and pre-clinical data – highly supportive of key benefits – 105 clinical papers and abstracts published
- Generating further compelling HEOR data
- Increasing KOL support
- All products are easy for surgeons to use

Our CERAMENT products are in a strong position to gain market share from both bone grafts and synthetic bone graft substitutes

# Committed to implementing our strategy to deliver targets

- **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



# BONESUPPORT™

## BOVINEZONIBOVI

Our Commercial Activities

# Growing CERAMENT™ BVF sales in the US

## Our commercial footprint

- BONESUPPORT US Team drive sales via Zimmer Biomet
  - 8 regional managers,
  - 3 product technical specialists,
  - 1 marketing support drive
- CERAMENT BVF distributed via Zimmer Biomet's 53 independent distributors
- Rolling agreement with Zimmer Biomet

## Our activities

- Sales growth negatively impacted by Zimmer Biomet hardware supply issues
  - CERAMENT BVF used in conjunction with Zimmer hardware
- Appointed Program Manager of Post-Market Clinical Research - initiate U.S. generated clinical data and peer-reviewed publications
- Growing traction with CERAMENT BVF in the orthopedic oncology market segment at several major cancer and oncology centers
- One regional manager and 3 products technical specialists added in the last 6 months



# Growing CERAMENT™ G&V 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
- Following new distribution agreement to enter the French market

## Our activities

- Continue to focus on driving adoption at the top trauma centers in our key European markets
- Further important data presented at key orthopedic conferences designed to increase the adoption of CERAMENT™ G/V
  - EBJIS – 6 podium presentations
- Develop HEOR models for Europe
  - CHOP application accepted in Switzerland
- Added 2 reps in Germany and 1 rep in Switzerland in 2017





# BONESUPPORT™

## ВОИЕЗНЬБОВІ

Clinical update



# Ongoing and Planned Clinical Studies

## Larger Clinical Studies

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

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

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



Milestone achieved



# On-going post-marketing clinical studies

## 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

## CERTiFy study

- Controlled study investigating the use of CERAMENT™ BVF in tibial plateau fractures
- CERTiFy completion of enrollment around the end of 2017
  - Data expected in late 2018

## Successful study outcome would show:

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

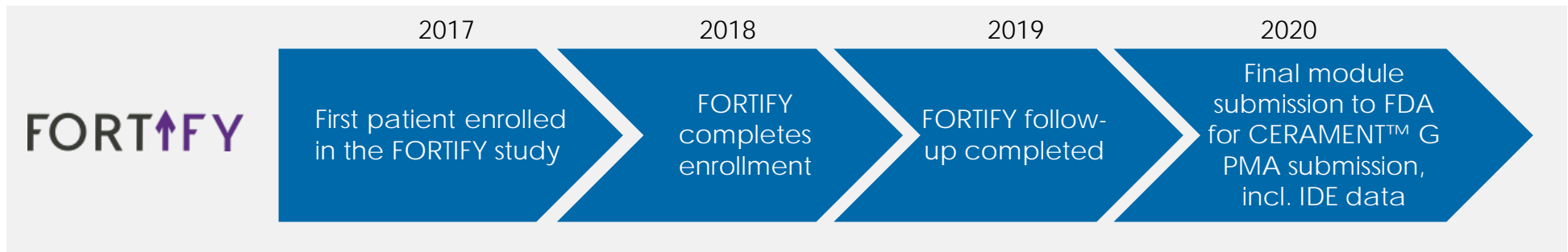
## Successful study outcome would:

- 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

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

# FORTIFY to support approval of CERAMENT™ G in US

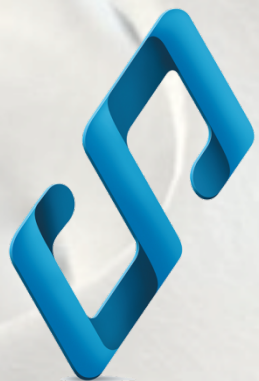
## FORTIFY trial timeline



## Proposed "Indication for Use"

- Preferred indication has been discussed at prior FDA meetings and was submitted as part of the approved IDE
- Resorbable, gentamicin-loaded ceramic bone graft for use in bony voids and gaps
- Product supports bone healing and reduces subsequent infection

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

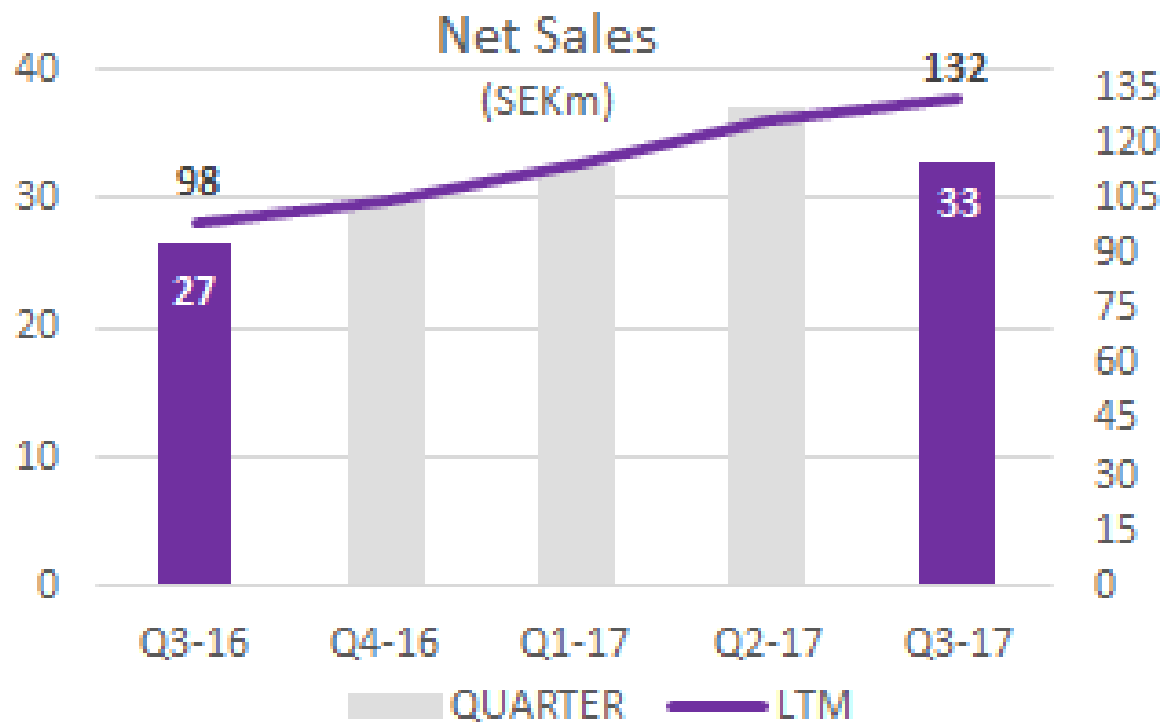


# BONESUPPORT™

## БОНЕСУПОРТ

Financial Review

# 23% increase in Net sales

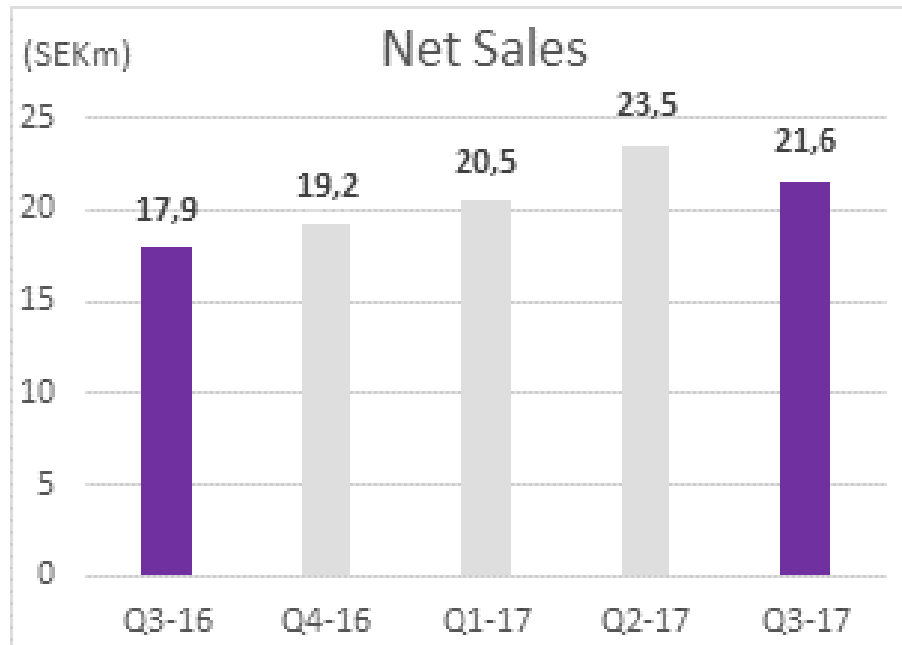


+23%  
Q3 Net  
Sales

+36%  
LTM Net  
Sales

# North America Analysis

|              | Jul-Sep |      | FY   |
|--------------|---------|------|------|
| (SEKm)       | 2017    | 2016 | 2016 |
| Net Sales    | 21.6    | 17.9 | 68.8 |
| Gross profit | 19.3    | 14.6 | 59.5 |
| Contribution | 6.6     | 2.1  | 22.5 |



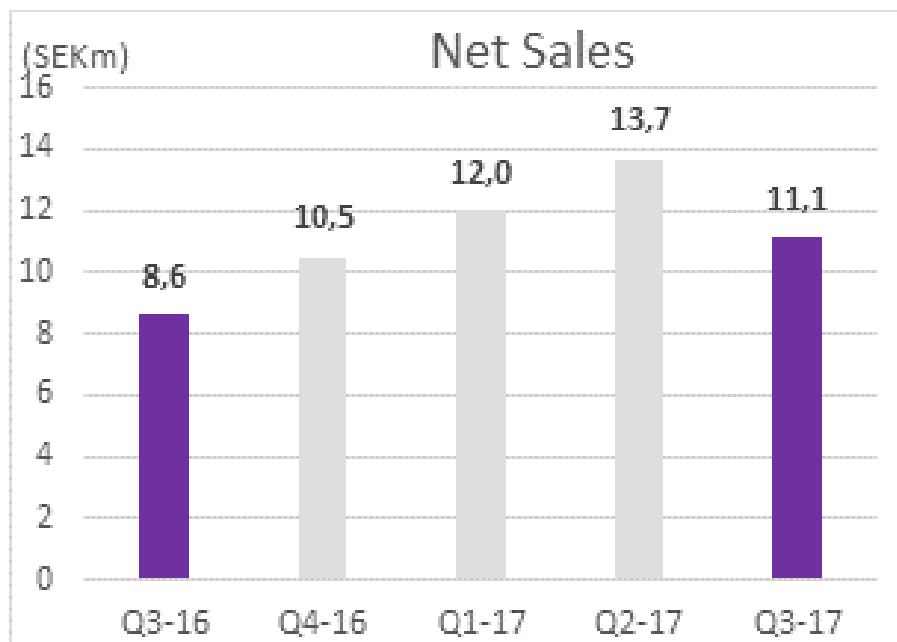
**+21%  
Net Sales  
Q3**

**+32%  
Net Sales  
YTD**

# Europe and RoW Analysis

|              | Jul-Sep |      | FY    |
|--------------|---------|------|-------|
| (SEKm)       | 2017    | 2016 | 2016  |
| Net Sales    | 11.1    | 8.6  | 35.7  |
| Gross profit | 9.4     | 6.4  | 28.8  |
| Contribution | -3.6    | -4.1 | -12.2 |

**+28%  
Net Sales  
Q3**



✓ Drug eluting products increased by 48% in Q3

**+45%  
Net Sales  
YTD**

# Operating result development

|                   | Jul-Sep |       | Jan-Sep |        | FY     |
|-------------------|---------|-------|---------|--------|--------|
| (SEKm)            | 2017    | 2016  | 2017    | 2016   | 2016   |
| Net Sales         | 32.7    | 26.5  | 102.3   | 75.0   | 104.6  |
| Cost of sales     | -4.0    | -5.5  | -12.4   | -12.7  | -16.3  |
| Gross profit      | 28.7    | 21.0  | 89.9    | 62.3   | 88.3   |
| Selling expenses  | -24.4   | -25.0 | -71.4   | -65.1  | -79.8  |
| R&D expenses      | -12.8   | -10.9 | -40.9   | -23.0  | -38.2  |
| Admin expenses    | -11.2   | -11.4 | -42.0   | -35.7  | -60.7  |
| O.Operating items | -0.4    | 0.4   | -1.6    | 1.1    | 1.6    |
| Total costs       | -48.8   | -46.9 | -155.8  | -122.6 | -177.0 |
| Operating loss    | -20.1   | -25.9 | -65.9   | -60.3  | -88.7  |

✓ 87.8% GM Q3 (79.2)

✓ Increase YTD driven by FORTIFY study



# KPIs

|                                  | Jul-Sep |       | Jan-Sep |       | 12M    |
|----------------------------------|---------|-------|---------|-------|--------|
| (SEKm)                           | 2017    | 2016  | 2017    | 2016  | LTM    |
| Net Sales                        | 32.7    | 26.5  | 102.3   | 75.0  | 131.9  |
| Sales Growth (%) <sup>1/</sup>   | 23.1    | 155.9 | 36.4    | 93.4  | 34.6   |
| Gross profit                     | 28.7    | 21.0  | 89.9    | 62.3  | 115.9  |
| Gross margin (%) <sup>1/</sup>   | 87.8    | 79.2  | 87.9    | 83.1  | 87.9   |
| Operating loss                   | -20.1   | -25.9 | -65.9   | -60.3 | -94.3  |
| Loss for the period              | -22.9   | -34.9 | -77.5   | -75.5 | -112.2 |
| Equity at period end             | 499.9   | -43.2 | 499.9   | -43.2 | 499.9  |
| Net debt <sup>1/</sup>           | -476.3  | 45.2  | -476.3  | 45.2  | -476.3 |
| Operating cash flow              | -35.8   | -29.3 | -81.8   | -51.4 | -112.3 |
| Cash at period end               | 567.6   | 72.8  | 567.6   | 72.8  | 567.6  |
| Earnings per share <sup>2/</sup> | -0.47   | -1.39 | -2.13   | -3.01 | -3.31  |

# Tracking towards our targets

## TARGETS 2020

- Net Sales > SEK 500 million  
(implies 48% CAGR 2016-2020)

## LTM Q3-17

SEK 132M  
35%

- Gross margin > 85.0%

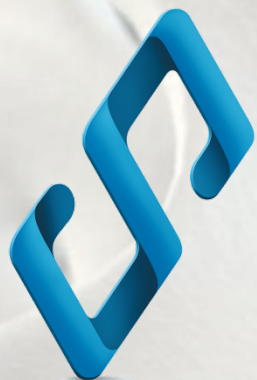
87.9%



- Positive operating result

SEK -94M





# BONESUPPORT™

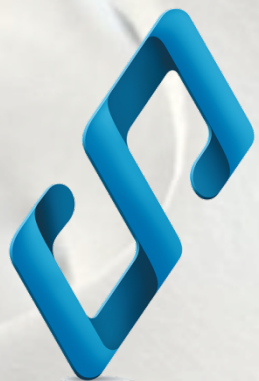
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Wrap up

# Well positioned to generate shareholder value

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





# BONESUPPORT™

ВОИЕЗНЬБОВІ

Q&A