

# Bactiguard enters global license agreement with Zimmer Biomet

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**27 September 2019**

Christian Kinch, Chief Executive Officer  
Cecilia Edström, CFO and Deputy CEO

# Global license agreement with Zimmer Biomet

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## Highlights

- Exclusive global license agreement for orthopedic trauma implants
- Up-front license fee of USD 3 million at signing
- USD 2 million in milestone payments, contingent on U.S. regulatory clearance
- Royalties on net sales following commercialization
- Current CE mark used as a reference in obtaining regulatory clearance

# Why partner with Zimmer Biomet?

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- A major, global player in orthopedics
- Strong market position in the Americas, Europe, MEA and Asia Pacific
- Revenues of USD 7.9 billion in 2018
- Broad range of products
- 90-year heritage of proven clinical performance
- Strategy of addressing unmet clinical needs
- Common vision of improving patient outcomes and quality of life

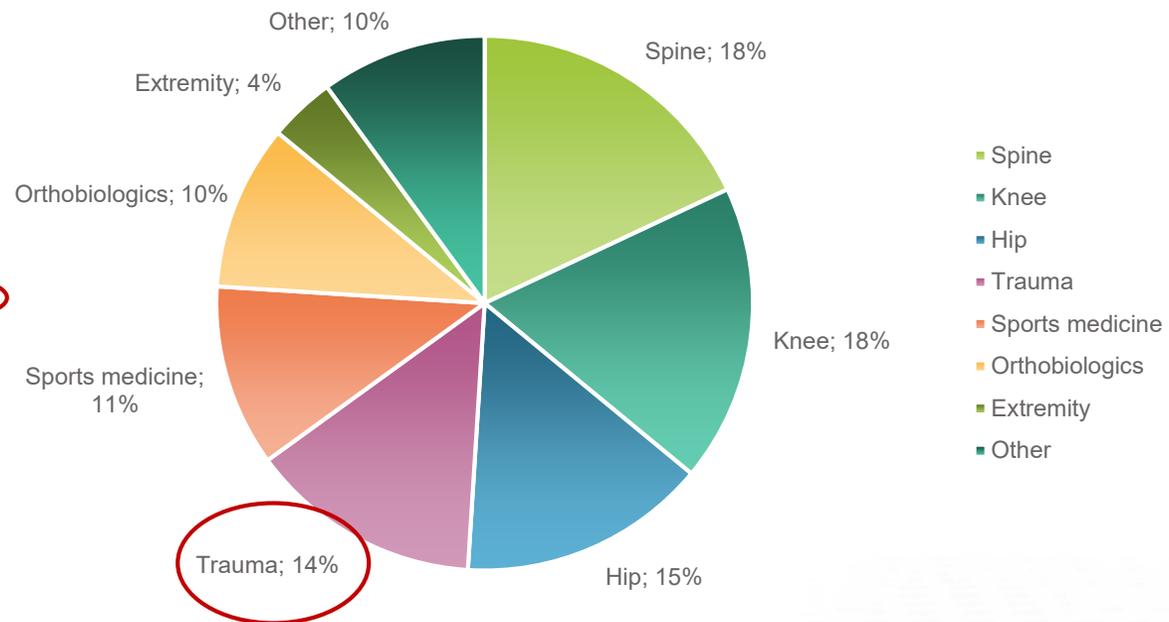
# Orthopedic market segments

Total market USD 51 billion, whereof trauma USD 7 billion and above average growth

Product Segment Performance: 2018 vs. 2017 (\$Millions)

Segment	2018	2017	% change
Joint Replacement	\$18,919.7	\$18,242.7	3,7%
Knee	\$9,058.2	\$8,783.3	3,1%
Hip	\$7,582.3	\$7,349.4	3,2%
Extremity	\$2,279.2	\$2,110.0	8,0%
Spine	\$9,324.7	\$9,080.9	2,7%
Trauma	\$7,205.9	\$6,920.0	4,1%
Sports Medicine	\$5,614.4	\$5,318.5	5,6%
Orthobiologics	\$5,088.5	\$5,097.1	-0,2%
Other	\$5,075.0	\$4,833.3	5,0%
<b>Total</b>	<b>\$51,227.7</b>	<b>\$49,492.5</b>	<b>3,5%</b>

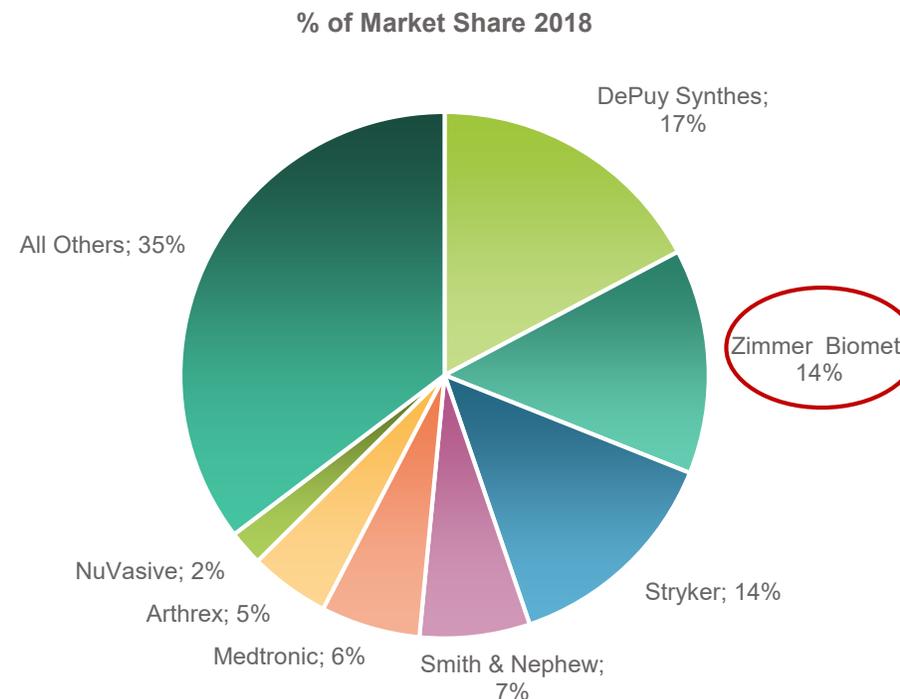
2018 Orthopaedic Product Sales by Market Segment



# Three major players in orthopedics

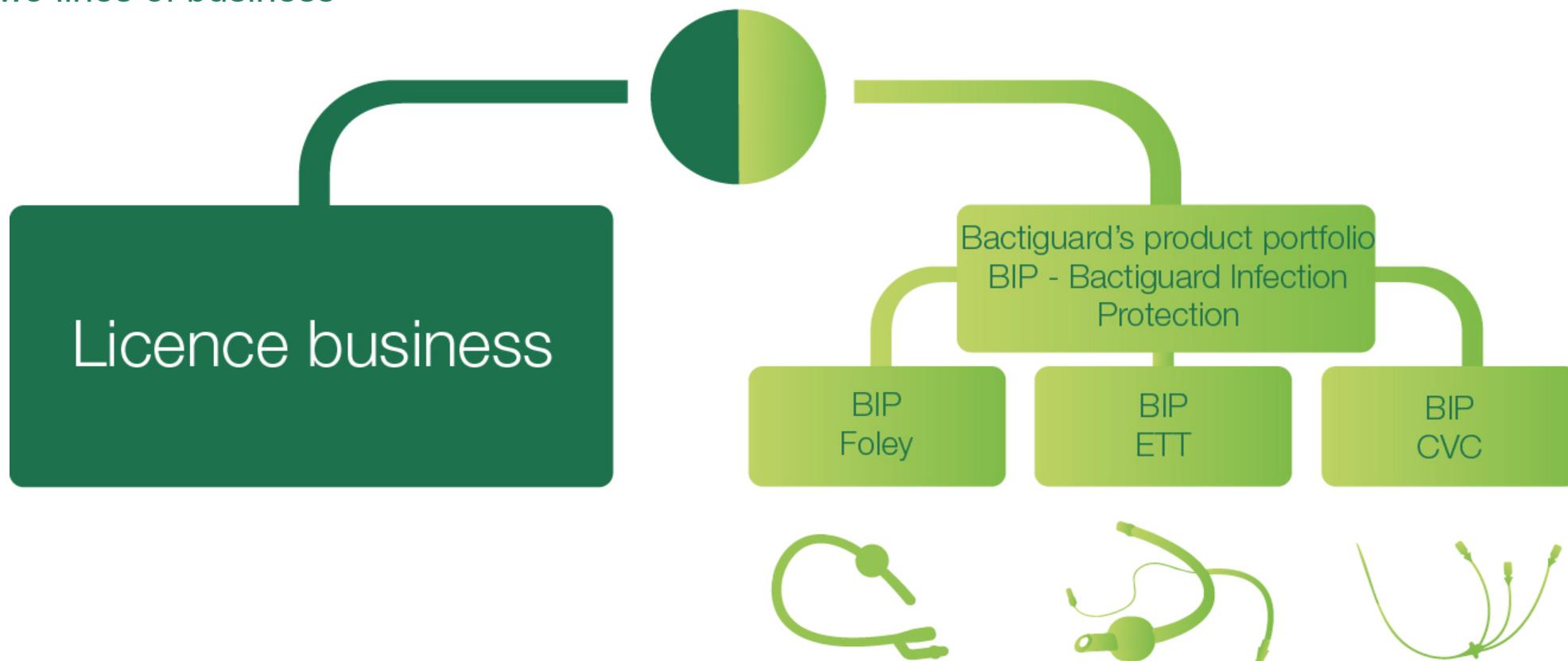
## Revenues and market shares

Companies	2018	2017	% change
DePuy Synthes	\$8,827.4	\$8,987.9	-1,8%
Zimmer Biomet	\$7,081.7	\$6,964.4	1,7%
Stryker	\$7,029.2	\$6,608.7	6,4%
Smith & Nephew	\$3,456.6	\$3,353.4	3,1%
Medtronic	\$3,116.7	\$3,059.8	1,9%
Arthrex	\$2,514.3	\$2,306.3	9,0%
NuVasive	\$1,101.7	\$1,026.7	7,3%
All Others	\$18,099.9	\$17,175.3	5,4%
<b>Market total</b>	<b>\$51,227.7</b>	<b>\$49,492.5</b>	<b>3,5%</b>



# Business model

Two lines of business



License agreements for various applications with Bactiguard technology

Proprietary product portfolio – sold through distributors

# Licensing business

## BD (C.R. Bard)

- Successful partnership since 1995
- Bactiguard coated Foley catheters for the US, Japan and UK/Ireland
- Generating stable annual revenues



## Vigilenz Medical Devices

- Bactiguard coated orthopedic trauma implants for the ASEAN markets
- CE mark awarded in December 2018, concluding clinical trial



## Smartwise Sweden AB

- Advanced Bactiguard coated vascular injection catheters
- Collaboration agreement with AstraZeneca initiated in Q2 2018



## Well Lead Medical

- License agreement for Foleys, CVCs and ETTs in China
- Ambition to accelerate growth in China, while regulatory developments are shifting towards locally produced devices



## Zimmer Biomet

- Global license agreement for Bactiguard coated orthopedic trauma implants



## Other ongoing discussions

# Development project for vascular stents

- **To reduce the risk of thrombosis in connection with interventions in the bloodstream**
- Project led by Professor Staffan Holmin and his research group at the Karolinska Institute
- Research grant of SEK 1.5 million from Vinnova
- The grant makes it possible to carry out advanced experiments to study both efficacy and safety of the method



“ By coating the stents with Bactiguard's technology, we hope to reduce the risk of thrombosis in the acute- and subacute phase and thereby reduce the need of drugs... ”

Staffan Holmin, Professor  
Karolinska Institute

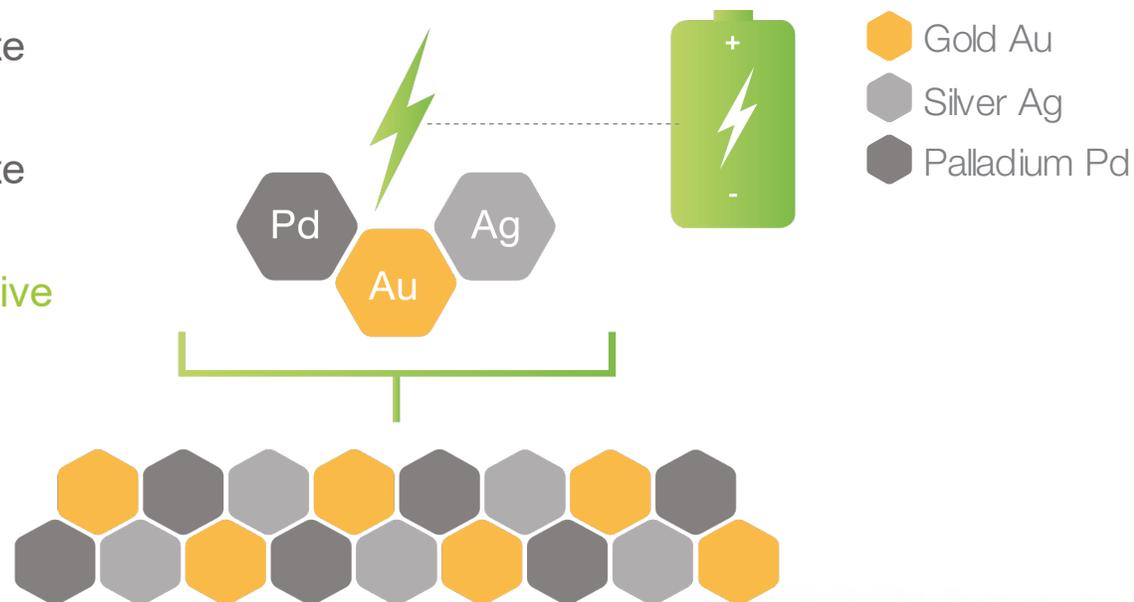
## Stents save lives

- Stents are used when blood vessels in the heart or nervous system need to be widened to allow the blood to pass freely
- Used in both acute care and as a preventive measure for heart attack and stroke
- Treatment leads to greatly increased risk of thrombosis formation (blood clotting)
- Managed by double doses of anti-platelet therapy for several months, which increases the risk of bleeding and gastrointestinal complications

# The technology

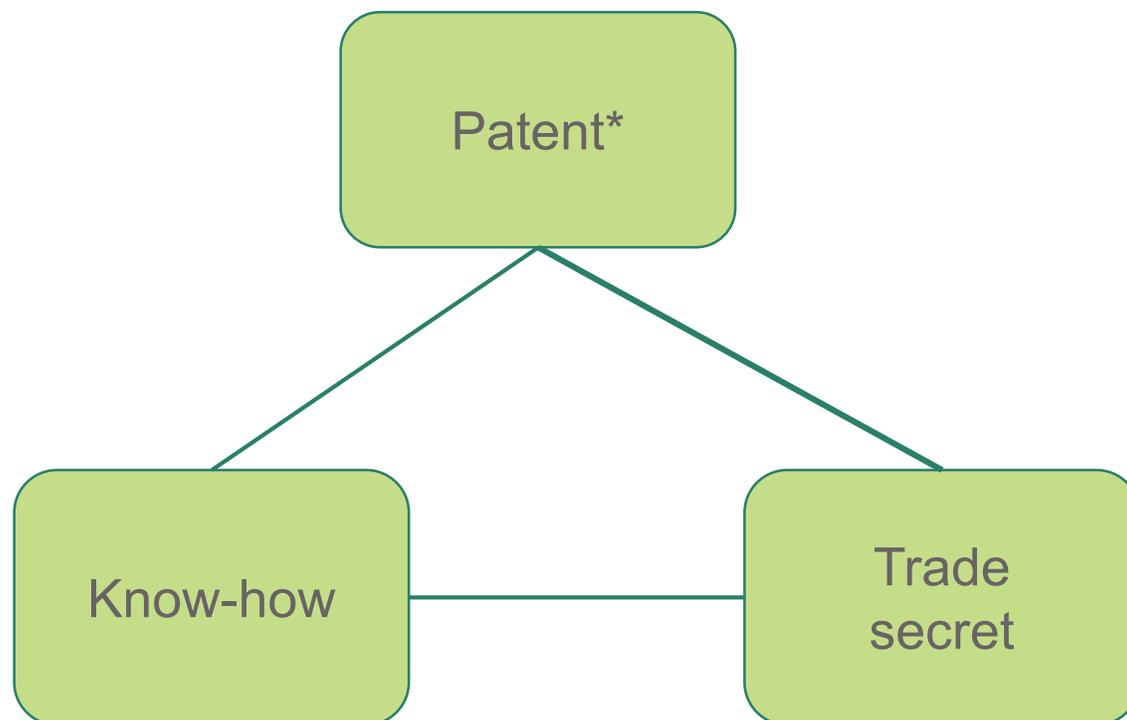
## The galvanic effect – effective and safe

- When in contact with fluids the noble metals create a galvanic effect
- The different electro potentials of the metals create a micro current
- Prevents microbial adhesion (gram positive/negative bacteria and fungi)
- Non-toxic, non-releasing mechanism
- Long lasting
- Effective and safe



# IP protection

"The holy trinity"



\*Current patent (2nd generation) valid until 2027/2029, 3rd generation filed

# Bactiguard coated products



	BIP Foley Catheters	BIP ETT, ETT Evac	BIP CVC	Bardex I.C/LubriSil I.C	OrthoSyn™
<b>Manufacturer</b>	Bactiguard AB	Bactiguard AB	Bactiguard AB	BD (BARD)	Vigilenz
<b>Regulatory approval</b>	CE	CE	CE	FDA	CE
<b>Duration of contact</b>	Permanent	Prolonged	Prolonged	Prolonged	Permanent
<b>Claims (in short)</b>	Reduction of bacteriuria, reduction of catheter-associated urinary tract infections (CAUTI), reduction of the use of antibiotics.	Reduction of microbial adhesion, prevention of ventilator-associated pneumonia (VAP).	Reduction of bacterial adhesion, reduction of Catheter-related bloodstream infections (CRBSI).	Clinically proven to reduce catheter-associated urinary tract infections. Dramatically reduces bacterial adherence and minimizes biofilm formation.	Reduction of bacterial adhesion, a primary step in the formation of biofilm on the surface of orthopaedic implants.

# Clinical evidence

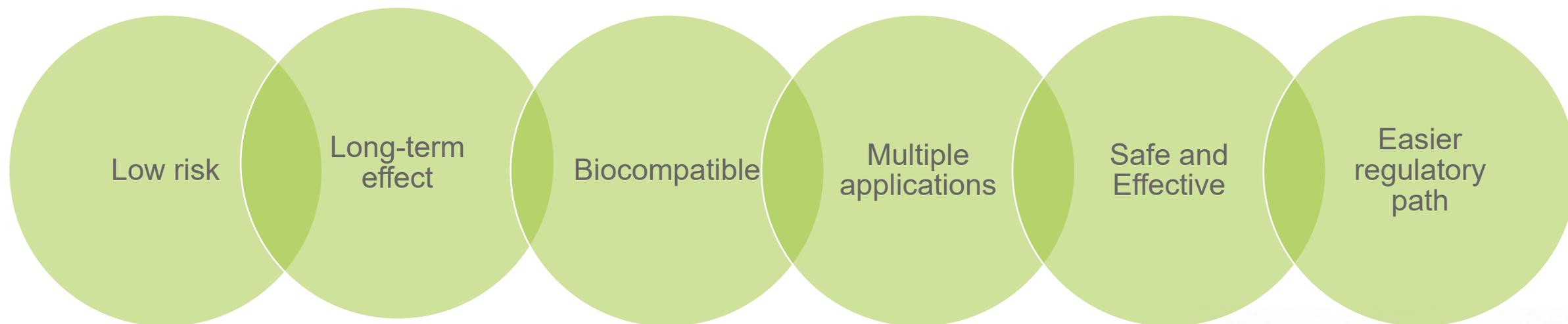
- **>170 million** Bactiguard coated catheters used since 1995
- **No adverse events** associated with the coating have been reported
- **> 40 clinical studies** (of which 31 are published) including over 100,000 patients
- **35%** weighted average reduction of symptomatic CAUTI in clinical studies, and in some studies over **90%**
- **Permanent catheter** Several reports of successful patient cases with permanent catheterization
- **52%** reduction of catheter related blood infections with BIP CVC and indications for decreased risk of thrombosis
- **67%** reduction of ventilator associated pneumonia with BIP ETT
- **Promising interim clinical data** on Bactiguard coated **trauma implants**



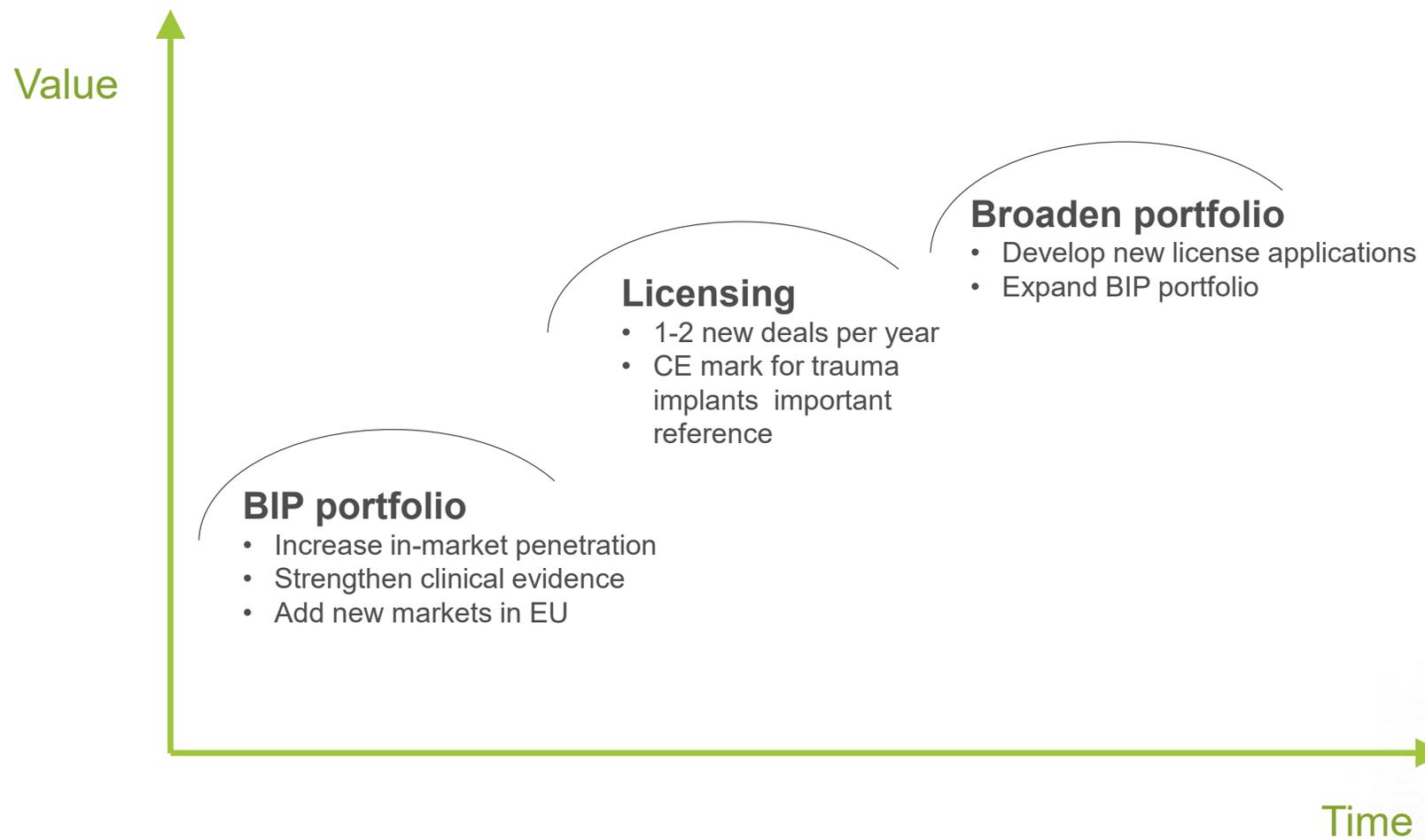
# Benefits of a non-toxic, stable technology

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## Infection prevention



# Growth strategy



# Financial targets

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- Average sales growth of 20% per annum for a 5-year period, with 2015 as the base year – starting point MSEK 118.5
- EBITDA margin of at least 30% at the end of the 5-year period (by 2020)
- Equity ratio of at least 30%
- Over time uphold a dividend policy of 30-50% of net profit, taking into consideration the financial position of the Company. Bactiguard is currently in an expansion phase and will prioritize expansion before dividend



# Concluding remarks

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- Important milestone for Bactiguard
- Zimmer Biomet a major, global player in orthopedics
- Confirms the value of the Bactiguard technology in a new application and global context
- Up-front license fee of USD 3 million at signing
- USD 2 million in additional payments contingent on U.S. regulatory clearance
- Royalties on net sales following commercialization
- Common vision of improving patient outcomes and quality of life

# More information available at [www.bactiguard.se](http://www.bactiguard.se)

For questions and additional information, please contact:



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