

# Innovating for the healthcare needs of tomorrow

Year-end presentation February 18, 2016



# Combating healthcare associated infections and antibiotic resistance is a shared commitment

"We encourage infection control via improved hygiene, vaccination, and preventive treatments to help reduce the number of infections needing antibiotic treatment."

Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance on January 21, 2016 at the World Economic Forum in Davos



"Infection prevention is a crucial element when tackling antimicrobial resistance as it reduces the need for antimicrobials. We will support initiatives that strengthen infection prevention within our countries." Declaration of the G7 Health Ministers meeting in Berlin in October 2015



Global consumption of antibiotics increased by 30 percent between 2000 and 2010, from approximately 50 billion to 70 billion standard units, based on data from 71 countries.

CDDEP report "The State of the World's Antibiotics 2015" September 2015





## Antibiotic resistance from a Swedish point of view

"The modern healthcare system is already showing cracks. There is a risk that people, already affected by the most multi-resistant infections, may not undergo bone marrow transplantation since the risk of dying during such an intervention is far too high. All unnecessary antibiotics must be removed from all sectors and we need to reduce the spread of multi-resistant bacteria."

Otto Cars, Professor at Department of Medical Sciences, Infectious Diseases at University of Uppsala

"Resistance against the last line of antibiotics has already been found in Sweden, which is worrying. This event is expected, as several other countries have already reported similar findings. Although at the moment it doesn't mean an increased risk for healthcare, it is still a worrying sign for the future and something that we will keep an eye on."



Otto Cars
Professor at Department of
Medical Sciences,
Infectious Diseases at
University of Uppsala





# Our key priorities

## **Key priorities**

- Drive sales of our own BIP product portfolio
- Develop new license businesses
- Secure refinancing of the bond loan

### **Achievements in 2015**

- Doubled sales of BIP product portfolio
- Entered license agreement in new therapeutic area
- Secured refinancing of the bond loan
- Strengthened the clinical evidence
- Product approval for China



# Highlights in the fourth quarter

- Product approval for China, followed by initial order in Q1
- Major initial order from India
- ✓ New license agreement for orthopaedic implants.
- Secured refinancing of bond loan
- ✓ Adjusted additional order from C.R. Bard
- Revised financial targets
- Changed accounting principles regarding territorial fees



## Market update

## Focus on select markets and expanding the business



### **EUROPE**

- Entering new markets
- Strengthening the team
- Tender management
- Reference sites

### **MEA**

- Expand the business
- Build KOL network
- Participating in tenders

### China

Preparations for launch

### **LATIN AMERICA**

- Focus on Brazil, Chile and Mexico
- Evaluations ongoing in Brazil & Chile
- Turn evaluations into repeat business



### **INDIA**

- Launch activities ongoing
- Clinical trials at six sites



#### Bactiguard in the world

- Direct sales
- Countries with distribution agreements
- Countries with exclusive licensing deals (C.R. Bard)
- Production facilities



## China and India



### China

- Product approval for Foley catheters
- First order for 100 000 catheters
- Preparations for launch
- Deliveries will start from Q1 2016

### India

- Clinical study involving 1 000 patients at six sites
- First order of 50 000 Foley catheters
- Market introduction at major urology and critical care conferences





## Licensing business

### **Current agreements**

## C.R. Bard

- Successful partnership since 1995
- Exclusive distributor of Bactiguard-coated Foleys in the US, Japan, UK and Ireland
- More than 150 million catheters sold to date
- Generating stable annual revenues

## **Vigilenz Medical Devices**

- Entering new therapeutic area
- Bactiguard-coated orthopaedic trauma implant sets
- Infection preventive and tissue friendly properties
- Covering the Asean markets
- Milestone driven project phase, followed by royalty payments

## **Strategy**

- Add license agreements in new therapeutic areas
- Exclusivity based on application or geography
- Value based pricing model



# The clinical evidence is getting stronger

**150 million** Foley catheters have been used since 1995

35% of weighted average reduction is proven in clincial studies of symptomatic CAUTI (catheter associated urinary tract infections), and in some studies up to 70%

**50%** reduction of catheter related blood stream infections with Bactiguard's central venous catheter

67% reduction of ventilator associated pneumonia with Bactiguard's endotracheal tube

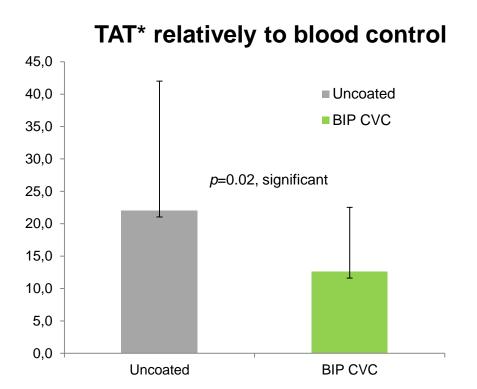
Fabrellas and Tincu two new clinical studies, conducted in Spain and Romania, show that Bactiguard-coated catheters reduce hospital acquired infections and are cost-effective

Recently published study indicates that Bactiguard's coating may reduce the risk of thrombosis





# Ex Vivo assessment of Blood Compatibility - BIP CVC: Vafa Homann et al. 2015



Problem	Catheter related Thrombosis – develops in around 4% of the patients and is a life threatening condition
Methods	Blood from 23 healthy volunteers was examined for compatibility with BIP CVC and standard catheter in the Chandlers-loop model
Primary outcome	BIP CVC showed less TAT = less activation of coagulation = lower thrombotic risk than non-coated CVC
Other	BIP CVC showed no hemolysis, while another anti-infective CVC* showed extensive hemolysis. Thus, BIP CVC is both anti-infective and tissue-friendly.

\*TAT= Thrombin-Anti-Thrombin complex, depends on activation of coagulation and is used as marker for thrombotic risk



\*Chlorhexidine Silver Sulfadiazine CVC

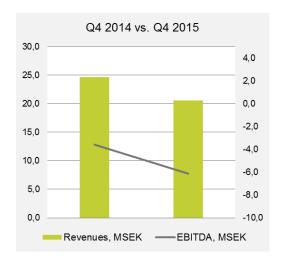
# **Highlights**

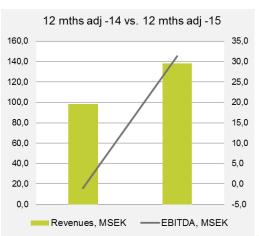
### Fourth quarter (Oct-Dec 2015)

- Revenues of MSEK 20.6 (24.7), minus 17% compared to 2014 (lower deliveries to C.R. Bard)
- EBITDA of MSEK -6.1 (-3.6), adjusted MSEK -4.8

### Full year (Jan-Dec 2015)

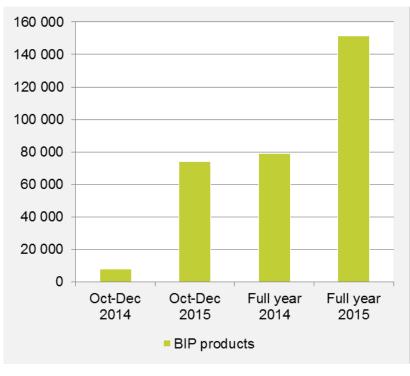
- Revenues of MSEK 138.5 (98.3), plus 41% compared to 2014 (additional MSEK 20 order C.R. Bard)
- EBITDA of MSEK 20.2 (-5.4),
  15% margin. Adjusted MSEK 31.4,
  23% margin







# **Supplied products**



- 74 000 BIP products supplied in Q4 2015 compared to approx.
  8 000 during Q4 2014
- For the full year 2015, 152 000 BIP products were supplied compared to 79 000 for the full year 2014, an increase of approx. 92%



# Change of accounting principle

### **Territorial fees**

- Territorial fees will be accounted for as Sales of BIP products at product delivery
- Previously, territorial fees were accounted for as revenues at contract signing
- The new principle will establish a more direct link between product deliveries, revenues and cash flow
- This increases transparency and improves the possibilities for shareholders to analyze the company's annual earnings capacity

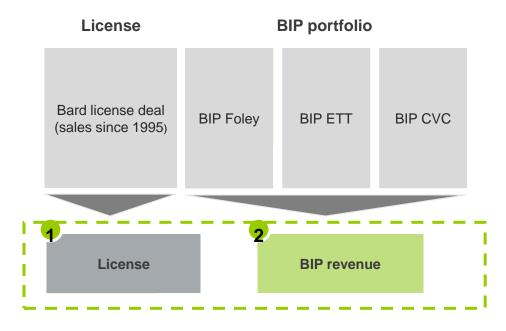
#### Effect:

- Positive effect of approx.
   MSEK 34 on profit for 2015
- Positive effect of approx.
   MSEK 4.7 on profit in Q4
- Negative effect on equity 2015 of MSEK 42
- All volumes delivered will generate revenue going forward



## Revenue streams

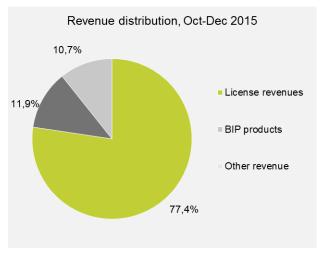
#### Two revenue streams in the income statement

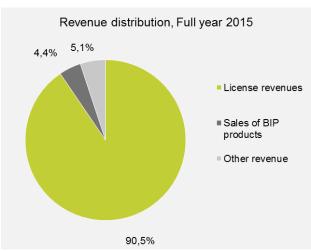


From a product perspective Bactiguard has two lines of business; Licenses and the BIP portfolio, acknowledged in the accounts as two revenue streams (after implementing change in accounting principle)



## **Income distribution**





MSEK	Oct-Dec	Oct-Dec	Full year
WISER	2015	2014	2015
License revenues	15,9	20,2	125,3
Sales of BIP products	2,4	0,3	6,1
Other revenue	2,2	4,2	7,0
Total Revenues	20,6	24,7	138,5



## License revenues from C.R. Bard

					mes)	derlying vo	nues (und	License reve
Of which		Full year	Q4	Q3	H1	Q2	Q1	(SEKm)
currency effect	7	82,7	20,5	21,3	40,9	19,3	21,6	2013
MSEK 5		89,8	20,2	24,3	45,3	22,8	22,5	2014
		105,3	15,9	36,8	52,6	25,8	26,8	2015
Of which	7		·				•	
currency effect	A						enues	License reve
MSEK 20		Full year	Q4	Q3	H1	Q2	Q1	(SEKm)
		82,7	20,5	21,3	40,9	19,3	21,6	2013
Of which	]	89,8	20,2	24,3	45,3	22,8	22,5	2014
currency effect	<b>\</b>	125,3	15,9	56,8	52,6	25,8	26,8	2015

- Part of the additional order from Bard in Q3 used in Bard's regular production affecting ordered volume in Q4
- Full year license revenue increased by 17% on underlying volume, including currency effect
- Total license revenue for the full year increased by 40 % including currency effect



# **Key figures**

Key figures	Oct-Dec 2015	Oct-Dec 2014	Full year 2015	Full year 2014
Revenues, SEKm	20,6	24,7	138,5	98,3
EBITDA, SEKm	-6,1	-3,6	20,2	-5,4
EBITDA margin, %	-30%	-15%	15%	-5%
EBITDA <sup>1</sup> , SEKm	-4,8	-2,3	31,4	-1,0
EBITDA margin <sup>1</sup> , %	-23%	-9%	23%	-1%
Operating profit, SEKm	-14,4	-11,3	-12,7	-35,5
Net profit for the period, SEKm	-19,3	-15,3	-26,5	-110,7
Operating cash flow <sup>2</sup> , SEKm	-25,6	-27,6	-32,5	-54,0

<sup>&</sup>lt;sup>1</sup>EBITDA adjusted for non-recurring costs

MSEK	Q4	Jan-Dec
EBITDA	-6,1	20,2
Provision for doubtful accounts	1,3	1,3
Non-recurring costs		9,9
Adjusted EBITDA	-4,8	31,4

- EBITDA (Q4) MSEK -6.1,
- EBITDA (Full year) MSEK 20.2 (15%), adjusted EBITDA MSEK 31.4 (23%).
- Net profit (Q4), MSEK -19.3, negatively affected by lower revenue from C.R. Bard and by market valuation of bond.
- Net profit full year MSEK -26.5 an improvement by MSEK 84.2 from 2014
- Operating cash flow for Q4, MSEK -25.6 including cash flow from investing activities of MSEK -3.0
- Full year operating cash flow MSEK -32.5 including interest payments on bond of MSEK 15.2



<sup>&</sup>lt;sup>2</sup>Cash flow from operating activities after investments and changes in working capital

# Financial flexibility and strength

Q2 -14

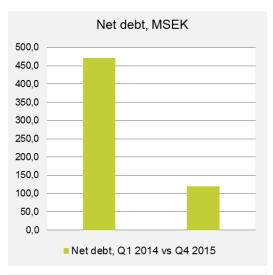
- Share issue of MSEK 20 in April
- Set off issue of MSEK 222.5 in June
- Share issue of MSEK 240 in connection with IPO

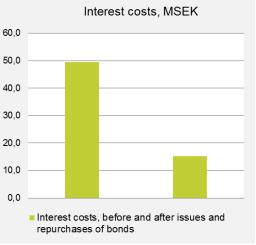


Q2 -14 - Q4 15 Repurchase of bonds, nominal value MSEK 89.5



- Equity ratio of 62 %
- Net debt of MSEK 120
- Cash position of MSEK 22.1
- Nominal value outstanding bond MSEK 138
- Annual interest costs on bond going forward until maturity, MSEK 15.2 (compared to MSEK 50 prior to IPO)
- Refinancing of bond loan December 2016 will significantly reduce annual interest costs at maturity.







# **Financial targets**

- Average sales growth of 20% per annum for a 5-year period, with 2015 (adjusted for the additional order from C.R. Bard) as the base year
- EBITDA margin of at least 30% at the end of the 5-year period
- 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 dividends



# **Concluding remarks**

- Antibiotic resistance and healthcare associated infections is still at the top of the political agenda
- There is a great and steadily increasing need for infection prevention
- Final product approval and first order from China
- Initial order from India
- Doubled the sales of our own product portfolio
- Entered a new license agreement for orthopaedic implants, a new therapeutic area
- Secured refinancing of the bond loan
- The clinical evidence for the technology is getting even stronger
- Focus on sales and improved cost efficiency to secure positive earnings and cash flow

"2016 will be an interesting year"



## More information is available on our website www.bactiguard.se

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# Bactiguard has an important role to play

## **Preventing healthcare associated infections**



# **Questions**

