



ANNUAL REPORT 2016

# Bactiguard<sup>®</sup>

Coating for infection protection



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## More than doubled volume



The sales trend of our own portfolio of infection prevention products (BIP) for the healthcare sector was strong and unit volumes more than doubled.

### Breakthrough in China and India

Following the product approval at year-end 2015/2016, China has grown to become Bactiguard's largest market and approx. 200 000 urinary catheters were delivered during the year. Training and sales activities aimed at hospitals have been intense.

India has, at the same time, emerged as our second largest market, to which Bactiguard delivered approx. 100 000 urinary catheters during the year. A large number of hospitals have tested our product and several have started using them on a regular basis.

### Expansion in Europe

By entering into partnership with leading suppliers to the healthcare sector in new markets, Bactiguard is gradually expanding its presence in Europe. In December, the Company entered into an exclusive partnership for Germany and Switzerland and earlier in the year, distribution agreements were signed for Finland, Greece, Poland and Austria.



### New clinical study with strong results

# ↓ 90% CAUTI

A new independent and randomized clinical study at the King Fahad Hospital in Saudi Arabia confirms that Bactiguard coated Foley catheters reduce the incidence of catheter associated urinary tract infections for patients in intensive care by 90 percent.

## Key ratios 2016

Revenues	128,3 MSEK
EBITDA	15,1 MSEK
Total assets	632 MSEK
Equity ratio	62 %
Earnings per share	- 0.81 SEK

### Bond loan refinanced

Bactiguard's bond loan matured in December 2016. The outstanding nominal amount of SEK 138 million and accrued interest was paid in full. The refinancing solution of in total SEK 150 million, consisting of a bank loan of SEK 100 million and a loan from the company's main shareholders of SEK 50 million, will substantially reduce the company's interest expenses.

### Inauguration of Bactiguard's new headquarters



The Minister of Enterprise and Innovation Mr. Mikael Damberg cut the ribbon and officially inaugurated Bactiguard's new headquarters and production facility in Tullinge, south of Stockholm, in March 2016.



### Tools to support prevention of healthcare associated infections

Two new tools were launched in order to reach our vision of establishing a new standard of care for the prevention of healthcare associated infections: Bactiguard Academy, a digital platform for training own personnel and distributors and BIP CIP (Bactiguard Clinical Implementation Programme) a tool for training healthcare professionals and thereby reducing infections associated with urinary catheter treatment.





Bactiguards CEO Christian Kinch with Sweden's Minister for Enterprise and Innovation Mikael Damberg.

Bactiguard invited the Swedish Minister for Enterprise and Innovation to inaugurate our new headquarters and production facility.

” *It's a revenge for life science in Sweden. There was a time when all we talked about was cutbacks and businesses that moved out of Sweden and the failure to develop things, said the Minister for Enterprise and Innovation Mikael Damberg. Therefore I feel a sense of pride seeing Bactiguard's headquarters and operations, he continued.*

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**Bactiguards mission is to save lives. We save lives and improve the quality of life for patients all over the world by reducing the risk of infection. I can therefore with pleasure and pride say that 2016 in many ways was a good year for Bactiguard.**

We exceeded by a wide margin the goal of doubling the volume of products sold in our own portfolio and we made progress in the license area. However, we were not able to fully turn this into a strong profitability. Compared to the previous year, revenues and profit were lower, as 2015 was positively affected by a major one-off order from C.R. Bard to build safety stock. Adjusted for this effect, the underlying growth was 8 percent.

In early 2016, we set up three main priorities: to increase sales of our own portfolio, further develop our existing licensing business and sign at least one new contract, and refinance the bond loan.

The sales trend of our own portfolio of infection prevention products for the healthcare sector has been strong. We delivered close to 420 000 units in 2016, a significant increase from the approximately 150 000 units we delivered in the previous year. Thereby we, by far, surpassed the tough goal we set at the beginning of 2016 i.e. to double the volume of the previous year.

After 5 years of waiting, we finally got the long-awaited product approval in China and this market has already evolved into our largest after deliveries of 200 000 urinary catheters during the year. During 2017 we will strengthen the organisation in China in order to increase our presence by focusing on the leading hospitals in the most important regions together with our distributor.

India has emerged as our second largest market and we delivered close to 100 000 urinary catheters there during the year. We encounter great interest in infection prevention from healthcare providers and during 2017 we will expand our regional distributor network, to be able to access this large country and better reach more patients.

Establishing Bactiguard in the major European markets is one of our top priorities and, in December of 2016, we entered an exclusive partnership for Germany and Switzerland with Roeser, one of Germany's leading suppliers to the healthcare sector. We believe strongly in the German market and expect that a breakthrough there will have positive effects on other European markets. Earlier in the year we signed distribution agreements for Poland and Austria, where sales are developing favorably. Meanwhile work continues to establish partnerships in several major European markets.

The Middle East did not live up to our expectations and deliveries were significantly lower in 2016 than the year before. We still have a strong market position and will continue developing our business, for example by signing a new distribution agreement for Egypt, the most populous country in the Middle East. In a few years, we see that the Egypt market can become one of our largest in the region.

In Sweden, our home market, we have made progress and increased our presence in the major hospitals. During the year, we won tenders for the Halland, Kronoberg, Blekinge, Värmland and Kalmar counties. Our central venous catheter (CVC) has become standard of care for ICU patients at the Lund University Hospital and the Stockholm County Council has just announced a public tender for urinary catheters where infection prevention is listed as a requirement and we see more and more regions going the same way.

We have a product portfolio that is very well adapted to the needs of intensive care patients, where infection rates are high and patients are seriously ill. Together with specialists at the Karolinska University hospital we have developed tools to reach our vision of establishing a new standard of care in preventing healthcare associated infections. The cost of treating patients with healthcare associated infections is very high, which means that there are also major socioeconomic gains to be made by preventing them.

The level of activity in developing both new and ongoing license businesses has been high. We did not quite reach the goal of signing a new contract during the past year, but in early February this year we entered a new, interesting therapeutic area, namely advanced vascular injection catheters for drug deliveries to vital organs. Several other interesting projects and dialogs are ongoing primarily within orthopedic implants. Where infections cause major complications. Through these different projects we see that our technology has the potential to add value to many different application areas and that bodes well for the future.

At the beginning of December, we completed our third priority, the refinancing of our bond loan which was then repaid in full. The refinancing solution consists of loans totaling SEK 150 million, at terms which will substantially reduce Bactiguard's interest expenses going forward.

During 2017 our main priorities will essentially remain the same, namely to double sales of our own product portfolio and develop new licensing businesses. This year has started with several positive events and I look forward to an equally positive and eventful year ahead where we will be able to save more lives and improve the quality of life for many more patients.

Christian Kinch  
CEO



## FACTS

### **Catheter associated urinary tract infections (CAUTI)**

are the most frequent healthcare associated infections (HAI), a large proportion of which is caused by indwelling urinary catheters. It comprises around 30% of all HAI.<sup>2</sup> These infections can result in serious complications such as urosepsis, which lead to patient suffering as well as increased mortality and healthcare costs.

### **Catheter-related bloodstream infection (CRBSI)**

also known as Central Line Associated Bloodstream Infections (CLABSI), are defined as the presence of bacteremia originating from an intravenous catheter. They are one of the most frequent, lethal, and costly complications of central venous catheterization and the most common cause of nosocomial bacteremia<sup>3</sup>. According to the World Health Organization, one case of CRBSI can cost up to USD 56 000 to treat. The US Center for Disease Control estimates that between 12% to 25% of patients who acquire CRBSI die<sup>4</sup>.

### **Ventilator Associated Pneumonia (VAP)**

is a common and very serious healthcare associated infection (HAI) of the respiratory tract that can affect patients using certain medical devices, such as endotracheal tubes. It is the second most common nosocomial infection in the ICU, and estimated to occur in up to 25% of patients.<sup>5,6,7</sup> It is associated with increasing the number of days the patients need to stay in the hospital by up to 25 days and the mortality directly attributable to VAP is estimated to be as high as 30-50 %<sup>8,9</sup>.

### **Surgical Site Infections (SSI)**

are among the most common HAI<sup>10</sup>. SSIs occur whenever there is a break in the skin due to surgery and can take up to 30 days to appear. The percentage of SSIs per 100 surgical procedures varied from 0.6% to 9.5% depending on the type of procedure. They are associated with longer hospital stays, additional surgical procedures, treatment in intensive care units and higher mortality<sup>11</sup>.



*The WHO estimates the annual financial losses due to HAI at approximately €7 billion in Europe, including direct costs only, and reflecting 16 million extra days of hospital stay. For the USA, the estimation is USD 6.5 billion.*

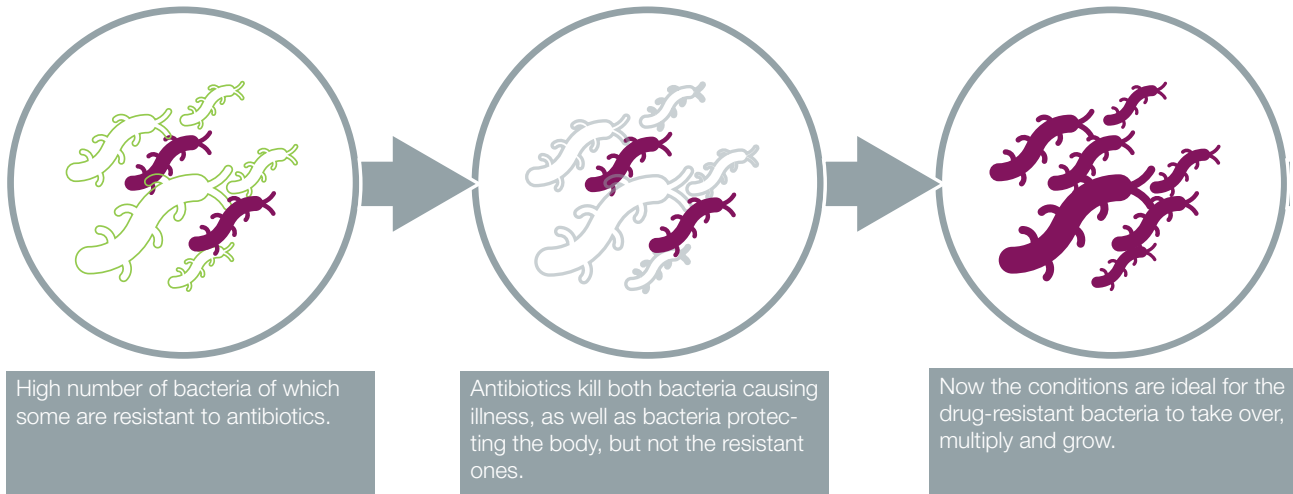
## Healthcare associated infections

**Healthcare-associated infections (HAI) are infections that patients acquire while receiving medical or surgical treatments. HAIs can occur from bacteria either inside the body or due to external factors, such as personnel, other patient's and visitors, equipment, medical devices or the healthcare environment.**

For patients, HAIs mean more complications, more antibiotic use, or even mortality. For healthcare providers, HAIs not only decrease patient's quality of life but also lead to excess burden on already limited staff resources. Overall, the healthcare systems suffer from increased economic consequences (due to increased length of stay and treatment), including the spread of antimicrobial resistance. Approximately 20–30% of HAI are preventable by strict hygiene and control programs<sup>1</sup>.

Some of the most common infections are CAUTI, CRBSI, VAP and surgical site infections. ■

## How antibiotic resistance develops



## Antibiotic resistance

**Healthcare-associated infections and antimicrobial resistance are among the most serious global threats. A large proportion of deaths that occur due to healthcare-associated infections are a direct result of multidrug resistant bacteria. An influential British report, *The Review on Antimicrobial Resistance*, estimates that globally 700 000 people die each year from infections caused by bacteria that are drug-resistant. By the year 2050, it is estimated that as many as 10 million people are at risk.**

Antimicrobial resistance is a crisis that must be managed with the utmost urgency. As the world enters the ambitious new era of sustainable development, we cannot allow hard-won gains for health to be eroded by the failure of our mainstay medicines.

Dr Margaret Chan, Director General, World Health Organization

Antimicrobial resistance (AMR) develops when microbes evolve to become resistant to the action of drugs. Resistance happens because antimicrobials put selection pressure on microbe populations; microbes survive through genetic change, which leads to antibiotics becoming less effective over time, or even useless.

Although AMR is a naturally occurring process, today it is a threat because of two main reasons: the first is that use of antimicrobials has increased so rapidly in the last few decades that microbes are exposed to a much larger number and greater concentration of antimicrobials, increasing their chances of developing re-

sistance; second, there are a very few new drugs under development to replace the ones that have already become ineffective due to resistance.

To address this issue, the United Nations General Assembly convened a high-level meeting in New York in September 2016, where world leaders signalled an unprecedented and coordinated approach to curb the spread of infections that are resistant to antimicrobial medicines. They agreed on a common resolution to tackle this serious threat. This was only the fourth time a health issue has been taken up by the UN General Assembly (the others were HIV, noncommunicable diseases, and Ebola).

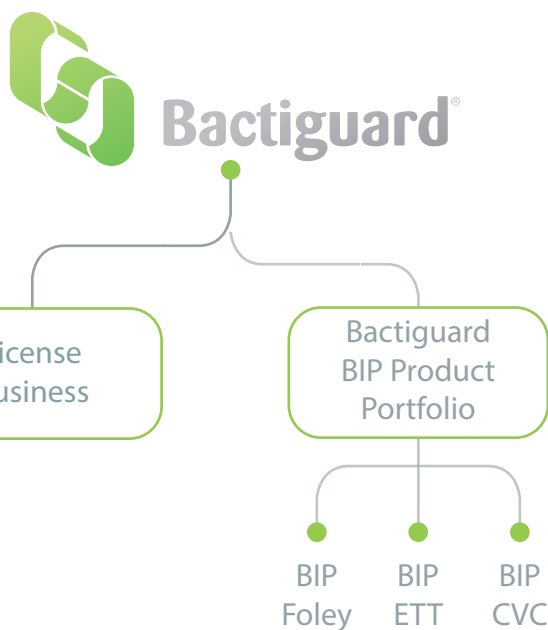
Antimicrobial resistance is not just a problem in low and middle income countries: 2016 also witnessed the death of a woman in Nevada, U.S. due to a superbug that was resistant to all 26 antibiotics available in the U.S. including those developed as a last resort against bacterial infection.<sup>12</sup> Although patients in the U.S. have died from superbug infections before (with the CDC estimating 23 000 deaths annually due to multidrug-resistant infections), many of those infections were discovered too late or, in the case of low income countries, newer and more expensive antibiotics are not available. However, the Nevada case was different in that resistance was discovered early in the treatment, but even the drugs that are usually used as last line of defence failed to work. ■

**B**actiguard is a Swedish medical device company. Our mission is to save lives. We reduce the high economic burden of healthcare associated infections, reduce the use of antibiotics and thereby the spread of multi-resistant bacteria. To achieve our mission we provide infection protection solutions that reduce healthcare associated infections caused by medical devices.

The company was established in 2005 and is expanding its geographical footprint with focus on markets in Europe, Middle East, China and India. We currently have 60 employees worldwide and are headquartered in Stockholm with production facilities in Sweden and in Malaysia.

Bactiguard has a two revenue streams: our license business and our own product portfolio BIP (Bactiguard Infection Protection). The license business is related to the use of Bactiguard's technology and means that other medtech companies sell Bactiguard-coated products under their own brand name (for example CR Bard).

Bactiguard's own product portfolio of indwelling urinary catheters, endotracheal tubes and central venous catheters prevents nosocomial infections in the urinary tract, the respiratory tract and in the bloodstream. ■



## Our Vision

**Our vision is to define a global standard of care to prevent healthcare associated infections caused by medical devices. This can only be achieved in close collaboration with academia, healthcare providers and policy makers. Bactiguards technology plays a key part in this, but several other areas need to be adressed.**

- Increased awareness of HAIs and their impact on antibiotic resistance
- Measure the incidence of infections and understand the mechanism behind them
- Implement effective preventive measures in the daily clinical setting
- Create clear guidelines and incentives for a more cost efficient healthcare.

## History of Bactiguard

The technology is based on a hundred-year-old patented Swedish innovation by Gustav Dahlén. He was awarded the Nobel Prize in physics in 1912 and is the man behind the successful AGA lighthouse system. Dahlén resolved the critical task of applying thin layers of metals to glass during the development process of the lighthouses. Thereafter the technology was further developed, first by Dahlén's pupil Carl Axel Bergström and later by his protégé Billy Södervall, who is the innovator behind the Bactiguard technology. In 1994 Bactiguard-coated urinary catheters were approved by the FDA for commercialization in the US market, where they are sold by CR Bard under the brand names Bardex IC and Lubrisil IC.



## How does it work?

Bactiguard's technology is well-proven, effective and tissue friendly. It is based on an extremely thin layer of noble metals, which is applied to medical devices and prevents bacteria from colonizing on the surface. This contributes to significantly reducing the number of healthcare associated infections. The technology can be applied to almost any type of materials which are commonly used for medical devices.

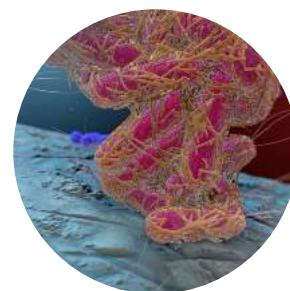
The patented coating is a noble metal alloy of gold, silver and palladium which is applied to the surface of medical devices. The composition of metals and their different electro potentials create a galvanic effect, referred to as a 'micro current' which prevents bacterial adhesion and biofilm formation. The coating is firmly attached to the surface of the device, which means that the effect is long lasting. The amount of noble metals is very low and not released in any toxic or pharmacological quantities, which makes the technology both tissue-friendly and safe for patients.

The Bactiguard coating is unique in the way that it effectively reduces the adhesion and growth of microbes, while at the same time being tissue friendly. More than 160 million Bactiguard coated products have been used in clinical practice since 1995 with no reported adverse events related to the coating. Bactiguard coated products have been used in a large number of clinical studies and evaluations (1986-2017) involving over 100,000 patients.

Through innovative technology, Bactiguard provides clinically proven, practical and cost effective solutions for infection control, which in turn contribute to higher patient safety, lower mortality, reduced healthcare costs and less use of antibiotics. ■

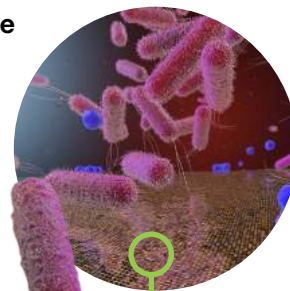
### Uncoated surface

Bacteria begin to adhere to the surface. When enough bacteria have developed, they form a biofilm. If they begin to disperse, there is an increased risk of infection.



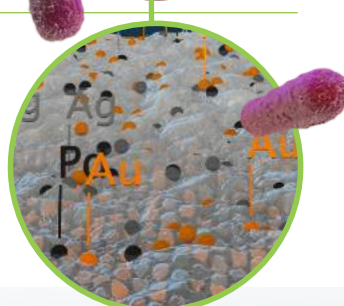
### Bactiguard coated surface

Less bacteria adhere to the Bactiguard coated surface, preventing biofilm formation and subsequent infection.



### Galvanic effect

The three noble metals in the Bactiguard coating - gold, silver and palladium cause a galvanic effect. The micro current prevents bacteria from adhering to the surface.



## Intellectual property

The patented Bactiguard technology is protected by a trinity:

- **Patent:** The current patent is in force until 2029 in the US and 2027 in other countries, and covers a combination of noble metals deposited on the surface of a device, the coating process and most medical devices attainable by the process.
- **Know how:** In order to make the coating attach to the underlying material and accomplish the desired anti-infective effect, the device has to be pre-treated and coated in a certain way, depending on the basic material of the device.
- **Trade secrets:** The patent and know how are complemented by company secrets, and the coating recipe is a well-kept and valuable company secret.

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Södervall is developing Bactiguard technology

1994

FDA 510k

1995

Patent in the US

2005

Bactiguard AB founded

1990

Partnership with CR.Bard

2008

Launch of BIP Foley Catheter

2013

Launch of BIP ETT & BIP CVC

2014

Share listed on Nasdaq Stockholm

2014

Relocation to new, integrated headquarters

2016

Launch of BIP ETT Evac

Bactiguards headquarters are located at Alfred Nobels Allé, close to Karolinska University Hospital

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av Dahlén, Swedish Nobel Prize laureate in Physics. The technology behind the AGA house system, which Bactiguard's technology is based on, is from.



## Positioned for growth

**Antibiotic resistance has been featured prominently in the global debate during 2016:**

- **The United Nations General Assembly held a rare high-level meeting to tackle the issue where all 193 members agreed on a common resolution to combat antibiotic resistance bacteria.**
- **The death of a patient in the US, in September 2016, due to a superbug that resisted all available antibiotics received widespread media attention.**
- **China and India came to the forefront in the battle to reduce resistance, two markets where Bactiguard also became very active during the year.**

Increased awareness of the consequences of antibiotic resistance has resulted in greater demand for infection prevention solutions for healthcare. Growth in the segment is driven by a desire to reduce both the number of healthcare associated infections and related costs. This means that Bactiguard is in a good position to grow the business. ■



Bactiguard Sales Team

### Sales

**Bactiguard is represented in approximately 40 countries, primarily through partnerships with distributors, with focus on Europe, China, India, and the Middle East. In Sweden, we have our own sales force which promotes our products and solutions to hospitals, elderly and primary care providers. There is growing interest in Bactiguard's products and we are gradually seeing that infection prevention is included as a separate category in public tenders.**

The product portfolio is well suited to the needs of patients in intensive care units (ICU), where infection rates are high and patients are severely ill. The cost of treating patients in ICUs is much higher than in other units so there are considerable economic gains to be made by preventing infections.

To support growth, the sales and marketing function was strengthened during the year, with more regional sales managers, who actively train and provide sales and marketing expertise to our distributors. ■



## Knowledge leads to success

**Our partners and distributors represent Bactiguard daily. We have therefore developed Bactiguard Academy, an e-learning tool. The purpose of Bactiguard Academy is to provide all our representatives with the most effective tools to help us achieve our vision in the best possible way. Bactiguard Academy gives our partners the understanding how our technology and solutions reduce the risk of healthcare-associated infections and antimicrobial resistance. Thus, they have a greater chance of success in their sales efforts. When our partners succeed, so do we.**

Bactiguard Academy is an e-learning platform that allows the training of our partners in an efficient manner. They can improve their skills and have easy access to the latest information available. Through a unique login, our partners can access training modules, which among other subjects include: healthcare-associated infections and antimicrobial resistance, the Bactiguard technology, product training, clinical evidence, proven processes for conceptual sales and successful procurement procedures.

Training of our own staff and partners has been a major focus in 2016 and will continue to be so in 2017. We firmly believe that an in-depth understanding contributes to sales success. Our ambition is that our partners should be an asset to their customers, as a source of information for them to be able to save lives and improve patients' quality of life by delivering the best health care possible.

The digital training is supplemented by physical training sessions, where in-house expertise from product development and clinical affairs contribute as well as external speakers from the healthcare sector. Our goal is that everyone who represents us will complete the training every year, and become a "Certified Bactiguard Ambassador." ■



**BACTIGUARD  
ACADEMY** 

### CERTIFIED AMBASSADOR

THIS CERTIFICATE IS PROUDLY  
PRESENTED TO:

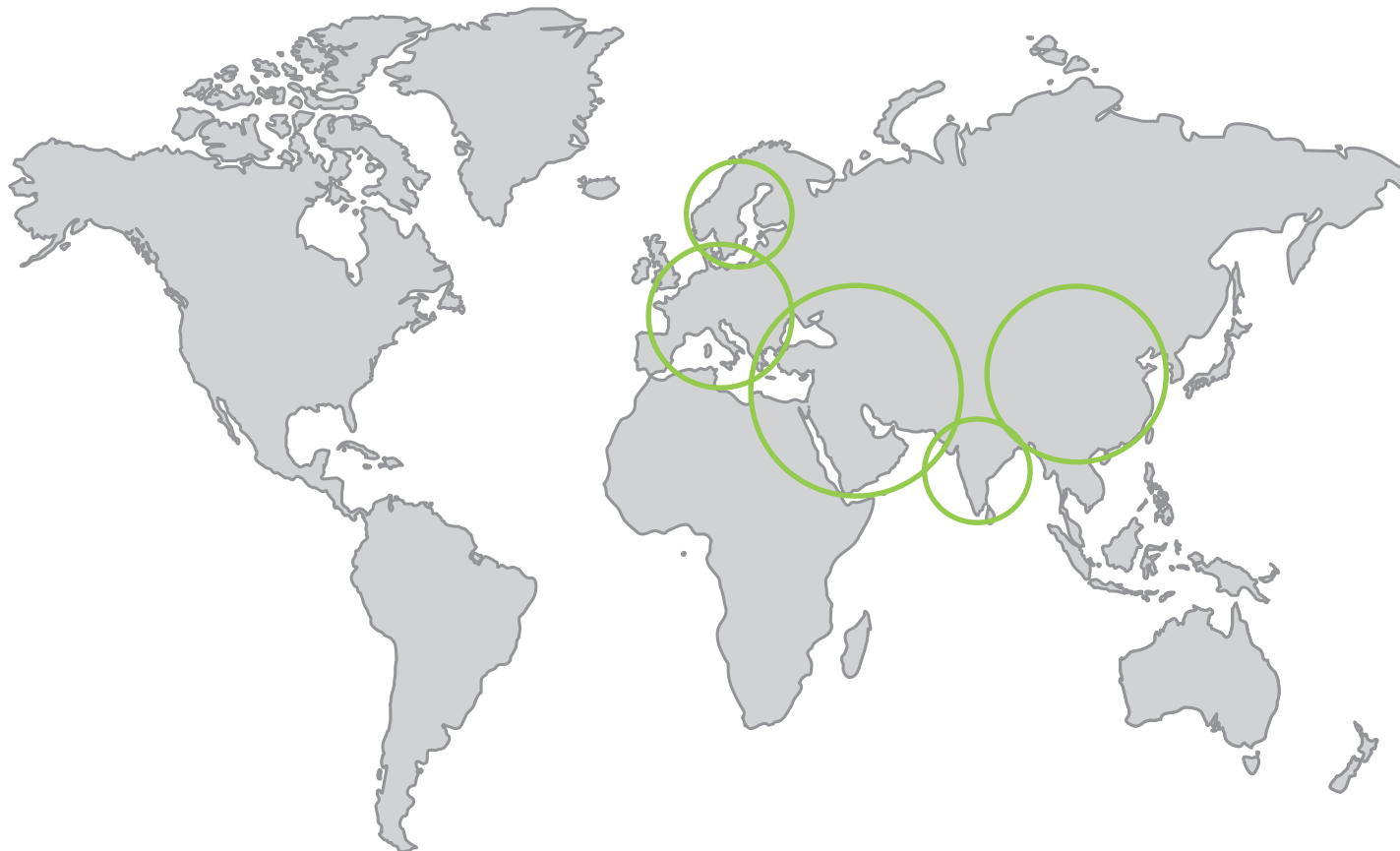
**JANE DOE**

For successfully completing all required training for Bactiguard Academy



Bactiguard Academy training of Chinese partner Jian An in July 2016





## Europe

One of our top priorities has been to establish Bactiguard in the major European markets and, in December, we entered an exclusive partnership with Roeser for Germany and Switzerland. Roeser is a leading supplier to hospitals and primary care facilities in Germany, an advanced market featuring some of the most prominent healthcare providers in Europe. Germany can therefore serve as a reference in other major markets. In order to support our partners in the best possible way, we invest in expertise and capacity. Earlier in the year, we signed distribution agreements for Poland and Austria, where sales have developed favourably. Meanwhile, our work to establish partnerships in several other major markets in Europe continues. ■



## Sweden

2016 was a break-through year in our home market, with an increasing interest in infection prevention, and we are increasing our presence region by region. We won tenders for the Kronoberg and Blekinge regions, as well as the counties of Kalmar, Värmland and Halland. Our newly introduced central venous catheter (CVC), has now become standard of care for ICU patients at Lund University Hospital.

In mid-December, the upgraded endotracheal tube was launched and we received a first order from the intensive care unit at Lund University Hospital. The interest in this product is substantial as ventilator acquired pneumonia is the most common infection in Swedish ICUs and solutions to address it are scarce.

In early 2017, the Stockholm County Council announced a tender for urinary catheters, where infection prevention is listed as a requirement and we see more and more regions moving in the same direction. ■



## China

2016 started off with the positive news that the long-awaited product approval in China was finally secured, after a more than five-year process. This resulted in large orders and product deliveries and China has now become Bactiguard's single largest market. Training activities for the staff of our distributor and sales activities aimed at hospitals have been intense since the summer. China is a vast country, with some 20 000 hospitals, where initial efforts have been aimed at the leading hospitals in the most important regions. Given the problem with increasing antimicrobial resistance and the authorities' determination to reduce antibiotic consumption, we see a great potential in the Chinese market. ■

## India

India, the single largest antibiotics-consuming country in the world, has emerged as our second largest market. During this first year, we have participated in major congresses for specialists, established dealers in several metropolitan areas and initiated deliveries to end customers. A large number of hospitals have evaluated our product and some 15 hospital groups have started using it on a regular basis, but it takes time to turn positive evaluations into recurring orders. In 2017, we will therefore expand our distribution network with more regional distributors for a wider reach and higher market penetration.

The clinical study involving a total of 1000 patients at six different hospitals has reached the half-way point. In early 2017, we will file our CVC and ETT for registration. Once approved, these products will create further potential and demand as blood stream infections and pneumonia are frequent, with high levels of mortality, particularly in the ICUs. ■



## Middle East and Africa

The Middle East is where Bactiguard first established a major footprint. Due to the political and economic situation in the region sales did not live up to our expectations during the year.

However, we have a strong market portion and are long term in our approach. One of the major highlights was the lifting of international economic sanctions against Iran, the second-largest country in the Middle East, where Bactiguard established presence a couple of years ago. This will make it easier to conduct business. The continuous development and market penetration in Kuwait is also positive.

In January 2017, Bactiguard signed a distribution agreement for Egypt, the most populous country in the Middle East. The product registration process has been initiated and the launch is planned for the second quarter of 2017. Within a few years, we see that Egypt can become one of our largest markets in the region. ■

## Our Bactiguard Infection Protection (BIP) products

Bactiguard's BIP products prevent infections in the urinary tract, the respiratory tract and in the bloodstream. Approximately two thirds of all healthcare associated infections occur in these three areas of the body, and medical devices cause an overwhelming majority of them.

The current product portfolio consists of indwelling urinary catheters (BIP Foley Catheter), endotracheal tubes (BIP Endotracheal Tube) and central venous catheters (BIP Central Venous Catheter), all with the Bactiguard coating, which prevents bacterial adhesion and colonization on the devices. Through these three product areas we address the most common infections in ICU patients: CAUTI, CRBSI and VAP. ■



### Infection Prevention Urinary Catheter – BIP Foley Catheter

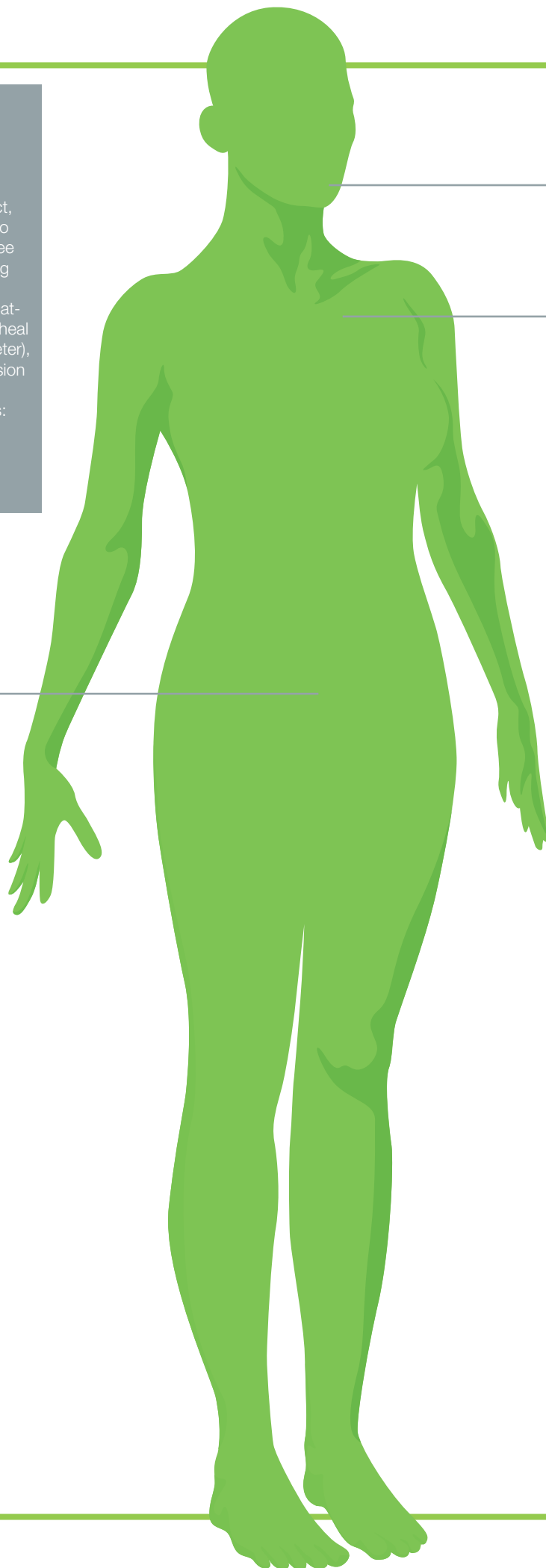
**Bactiguard coated Foley catheters have been used by over 160 million patients to date, which makes our technology market leading in this application area.**

Urinary catheters are used for drainage and irrigation of the bladder, or for collecting and measuring patient urine. Catheter associated urinary tract infections (CAUTI) account for a large proportion of HAIs and can result in serious complications such as urosepsis, which lead to patient suffering as well as increased mortality and healthcare costs.<sup>12,13</sup> Groups at risk include for example the critically ill and patients with urological malignancies and neurological diseases.

The Bactiguard Infection Protection Foley Catheter (BIP Foley Catheter), is an indwelling urinary catheter with Bactiguard coating which is proven to significantly reduce bacteriuria, symptomatic urinary tract infections and the use of antibiotics. In addition to the Bactiguard coating, they also have a hydrophilic coating to reduce friction between the catheter surface and urethra.

During 2016 a study at the King Fahad Hospital in Saudi Arabia confirmed that BIP Foley catheters significantly reduce the risk for CAUTI for patients in intensive care units, a strategically important patient group for Bactiguard due to their high exposure to infections<sup>14</sup>.

In early 2017, another independent clinical study conducted in Hong Kong confirmed that BIP Foley catheters reduce symptomatic catheter associated urinary tract infections and that the effect is even more pronounced among long-term users.<sup>15</sup> ■







## Infection Prevention Central Venous Catheter – BIP CVC

**Central venous catheters with infection preventive properties are an established mean of treatment in many parts of the world. The BIP CVC is designed to offer the best protection against infections, without causing any adverse reactions.**

Central venous catheters are used to administer drugs and intravenous solutions, and to sample blood. Catheter related bloodstream infections (CBRSI) also known as Central Line Associated Bloodstream Infections (CLABSI) can lead to serious complications, causing patient suffering as well as increased mortality and healthcare costs. The market for coated CVCs is well established in many parts of the world, and Bactiguard can offer not only an effective solution but also a safe one.

The Bactiguard Infection Protection Central Venous Catheter, BIP CVC, reduces the risk of microbial adhesion and colonization. Bactiguard coated CVCs have been shown to reduce catheter-related infections in high-risk patients by up to 52%.<sup>16</sup>

Use of BIP CVC has also indicated improved blood compatibility properties in terms of lower risk of thrombosis compared to standard CVCs. In the same ex vivo study, BIP CVC was also shown to be non-hemolytic compared to other coated CVCs.<sup>17</sup> ■



## Infection Prevention Endotracheal Tube – BIP ETT

**The unique combination of subglottic secretion drainage and the Bactiguard coating on the new endotracheal tube, BIP ETT Evac, is designed to offer the best protection against VAP available on the market.**

Endotracheal tubes are intended for use in airway management by oral or nasal intubation of the trachea. They are used to secure an open airway during anesthesia or when intubation is necessary as part of standard medical care. Ventilator associated pneumonia (VAP) is a common and very serious healthcare associated infection of the respiratory tract that can affect patients using endotracheal tubes. It is associated with increasing the time patients need to stay in the hospital by up to 25 days<sup>18</sup> and the mortality directly attributable to VAP is estimated to be as high as 30-50 %<sup>19,20</sup>.

The Bactiguard Infection Protection Endotracheal Tubes (BIP ETTs) reduce the risk of respiratory infections. During 2016 we launched BIP ETT Evac – the first and only endotracheal tube available that has double protection against VAP through both subglottic secretion drainage and the infection preventing noble-metal alloy coating against bacterial colonization on the device surface.

BIP ETTs have been shown to effectively reduce microbial adhesion to the device by up to 98%<sup>21</sup> in microbiological in vitro studies. In addition, a clinical study on 100 patients comparing a standard endotracheal tube with BIP ETT concluded that the Bactiguard coating reduced the incidence of VAP by 67%.<sup>22</sup> ■

## Clinical studies

The company's products have a major impact on people's lives and health. Therefore, we continuously conduct studies both in Sweden and internationally alongside doctors, nurses and other healthcare professionals. All our studies follow international and local laws, regulations and ethical principles. All studies are approved by Bactiguard management, ethical committees in hospitals as well as relevant authorities. We consistently make careful selection of partners among researchers and Contract Research Organizations (CRO) and patients whom we believe can benefit from our technology. All studies are performed in accordance with good clinical practice, Bactiguard quality systems and written Standard Operating Procedures (SOP). The results of the studies are documented and evaluated carefully. Routine safety monitoring is carried out on all our products in all markets in accordance with prevailing laws and procedures. ■



## Life is like a box of chocolates



**One morning in early 2016 we received a visit to our headquarters in Tullinge, Sweden. A happy couple was standing in our reception with a big bouquet of flowers and a box of chocolates.**

However, the story begins in 2015 when Bactiguard was contacted by a customer whose friend in Poland was living with multiple sclerosis (MS). She had heard of Bactiguard and felt that our urinary catheter would suit her friend's needs. She wanted to buy a package of catheters directly and send them to Poland.

The couple standing at our reception in the beginning of last year was the same customer and her partner who had contacted Bactiguard back in 2015. They were here to say thank you from their friend in Poland, because her urinary tract problems decreased which made her life better. Saying thanks with hand-delivered flowers and a box of Polish chocolates.



Nurse Anna with Ingrid

## Improving patients quality of life

**Ingrid is a sociable woman with a lot of things going on. She has made a great effort since her partner Sven suffered a stroke and had to use an adult diaper. Five years ago, when he instead received an indwelling catheter, she hoped life would get easier. It didn't. Sven contracted the bacteria *Pseudomonas aeruginosa* after a while, which colors the urine purple and spreads a strong, characteristic odor in the room. He became an "odour patient".**

who immediately made the decision to prescribe Sven the Bactiguard catheters instead of the traditional ones.

With the catheter Sven had before changing to Bactiguard's it started to smell after just a few days even after the catheter was flushed clean. With Bactiguard's catheter, Sven was odor free for a whole month and therefore it was prescribed that the catheter should now be changed at one month intervals. "For the doctor it was obvious that the patient's relatives should not have to live with the kind of odour problems that they had" says urology nurse Anna Johansson.

However, both she and Ingrid perceive that there is a lack of knowledge in the municipality regarding the huge difference that infection prevention catheters can do to increase the quality of life for patients and relatives

"But I'm not giving up now that I know that we can avoid the odor" says Ingrid and hopes that her story can help others when they find out that here is a way to overcome the odour problem. ■

\*Ingrid and Sven are fictional names

**„The smell was horrible. I couldn't stand that smell and neither could the grandchildren. They told their parents that the smell was horrible at grandma's and Sven's"** says Ingrid.

Ingrid stopped inviting friends over. It could perhaps have been possible the first day after the catheter was flushed clean. She avoided taking Sven out to town even though he loved going out to eat. Sven himself was not aware of the odor, it was only the people around him. Ingrid suffered.

"The last few years have been difficult. I was close to leaving him and moving out because of the odour."

When Ingrid now sits in the urologist's office in Oskarshamn and talks to the urology nurse, Anna Johansson, the situation is different.

"Sven still has a catheter – but it doesn't smell at all now!" Ingrid says. It was one of Anna's colleagues who, during a conversation, suggested that the patient should try a BIP Foley Catheter. Anna discussed it with the doctor



BIP CIP educational event at Bactiguard headquarters

## Launching BIP CIP - a major step towards our vision of defining a new standard of care

**Bactiguard’s vision is to define a universal standard of care to prevent healthcare associated infections caused by medical devices. We aim to accomplish this together with a variety of stakeholders that include decision makers, academia and the healthcare sector. Our technology and products are one part of the solution; but surveillance to measure the level of healthcare associated infections, preventive actions such as hygiene routines, training of staff and adequate treatment are all vital to reduce the number of HAIs.**

Better knowledge of the proper treatment of patients requiring catheters is one way of reducing catheter-related urinary tract infections, which can occur when bacteria migrate into the body through the catheter. Bacteria colonize the catheter and form biofilm which gives them the optimal environment to grow. Biofilm also protects bacteria from the body’s immune system and antibiotics.

With the aim of reducing these infections, Bactiguard has developed an educational material, our Clinical Implementation Program (BIP CIP) in collaboration with Karolinska University Hospital, represented by two experts: Helena Thulin, PhD, who

works as urology nurse at the urology department and Märta Lauritzen, also a urology nurse and head of the urotherapy department.

“When I train other healthcare professionals I often speak about the difference between infections which occur during the catheterization procedure and those which occur during the time of treatment. Infections may either arise when we inadvertently insert bacteria into the patient’s urinary tract during catheterization, which is at times avoidable if the catheterization procedure is carried out with utmost care. Or, infections can be caused by bacteria in the urinary tract forming a biofilm on a catheter which results in an infection,” explains Helena Thulin.

Today, catheter care is managed by a variety of different professionals, from nurses, to urotherapists and other caregivers. All with varying levels of education and knowledge on the importance of correct handling of catheters to avoid infections.

“The cooperation with Bactiguard is a great example of how healthcare can work together with businesses to ensure good quality care. We have contributed our expertise and experience in patient care; Bactiguard has the knowledge on the most appropriate communication methods and the channels to disseminate the material,” continues Märta Lauritzen. ■



Helena Thulin and Märta Lauritzen filming instruction video for BIP CIP





# Exploring new opportunities

**Bactiguard's strategy is to develop both new and ongoing license businesses. The level of activity has been intensified in the past year and in February 2017 we entered a new, interesting therapeutic area.**

**The Bactiguard technology for infection protection is well-proven, effective and tissue friendly and can be applied to almost any surface and material commonly used for medical devices. The clinical evidence is strong, showing that the coating reduces the number of healthcare associated infections in an effective and tissue friendly manner, by preventing bacterial adhesion and biofilm formation.**

The Bactiguard coating consists of the noble metals; gold, silver and palladium. It is applied to the surface of the device by a patented, wet chemical process that ensures uniformity and firm bonding regardless of the type of product. This means that the original product properties such as thickness, appearance and shape are not affected.

The coating is firmly attached to the surface of the device, which means that the effect is long lasting. There is no increased risk of thrombosis in vascular applications and the coating does not trigger immune reactions. The amount of noble metals is very low and not released in any toxic or pharmacological quantities, which makes the technology both tissue-friendly and safe for patients. ■

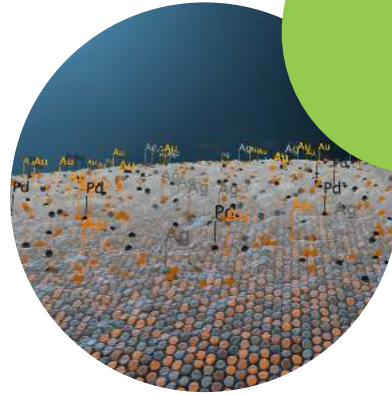
## Potential applications

The coating process is adjustable and can be scaled up, which means that the coating can be applied to many different types of materials and products. A new material or alloy is always tested, as every material has a unique composition. Bactiguard has successfully coated several types of titanium, titanium alloys and stainless steel as well as latex, silicone, polymers, ceramics and non-woven materials. The process validation is based on distinct process steps, to enable repeatability and reproducibility.

There are no special packaging requirements for Bactiguard coated products, which are sterilized by standardized methods. There are also no requirements to implement specific handling routines for Bactiguard coated products, which often is the case with other infection prevention technologies. ■

### Materials coated today:

Latex  
Silicone  
PVC  
Polyurethane (PU)  
Titanium



Aluminium  
Stainless Steel  
Copper  
Magnesium  
Zirconium

Glass  
Ceramics  
Textiles  
Zeolites  
Silica

Polypropylene (PP)  
Polystyrene(PS)  
Polyaryletherketone (PEEK)  
Polyimide (PI)  
Polyester

Nylon  
Nonwoven  
Polymethylmethacrylate  
Ethylvinylacetat (EVA)  
Teflon (PTEE)  
Elastomers (PDMS)



## Current license collaborations

Bactiguard has a long term, successful and profitable partnership with C.R Bard, a global manufacturer and supplier of medical devices and the leading provider of urinary catheters to hospitals in the US. In 1994, Bactiguard-coated Foleys were approved for use by the US FDA, through a 510(k) registration. C.R Bard markets these products in the US, Japan, UK, Ireland, Canada and Australia under the brand names Bardex IC and Lubrisil IC. They account for a significant portion of C.R Bard's sales of urology products and, to date, more than 160 million catheters have been used by patients, primarily in the US and Japan.

In 2015, Bactiguard signed a license agreement with Vigilenz Medical Devices, a Malaysian manufacturer and supplier of medical devices, for using the Bactiguard coating on orthopedic trauma implants in the South-East Asian market to prevent healthcare associated infections. Clinical trials have been initiated at two sites, including the University hospital in Kuala Lumpur, and the regulatory process is also well under way. We see considerable potential in further exploring new business opportunities in permanent and semi-permanent implants, given the infection preventive and biocompatible properties of the

Bactiguard coating.

In February 2017, Bactiguard and Smartwise Sweden AB (a privately-owned innovation company) entered a joint development project for advanced, Bactiguard-coated vascular injection catheters.

The license agreement opens a completely new area of application. Through advanced injection systems, pharmaceuticals and other forms of therapy can be targeted at damaged tissue of vital organs, following for example stroke or heart attack. High doses of chemotherapy can also be injected into cancer tumours. Delivering drugs and other therapies to vital organs is a complicated and delicate form of intervention, where the anti-infective and tissue friendly properties of the Bactiguard coating can reduce the risk of infections, thrombosis and allergic reactions for critically ill patients. The product is currently in the pre-clinical development phase, and it is expected that it will take three to five years it is approved for clinical use.

The Bactiguard technology has the potential to add value to many different applications and we will continue to explore new opportunities. ■

# We save lives

**Bactiguard's mission is to save lives. We save lives and improve patients' quality of life by preventing health care associated infections, which is a serious socioeconomic problem and constitute a threat to global public health.**

Bactiguards technology reduces the need for antibiotics by preventing the infection before it occurs. If there is no infection, no treatment is required. We contribute to combatting the spread of multiresistant bacteria, which is a consequence of too frequent and incorrect usage of antibiotics and may result in a situation where it is no longer possible to treat certain infections.

In line with Bactiguard's mission to save lives, decrease the cost burden on healthcare systems and reduce antimicrobial resistance, we engage with a variety of stakeholders to ensure that we are a company that contributes to a sustainable socioeconomic development. ■

## Code of conduct

Bactiguard aims at being a reliable partner that inspires confidence and delivers high quality and safe products to its customers. In order to ensure that we consistently act in a homogeneous and responsible manner there is a code of conduct which all employees, distributors, suppliers and collaboration partners are expected to comply with.

The code of conduct includes guidelines on how the company should manage its daily operations in an ethical, social, environmental and generally sustainable manner.

## Quality assurance

The company's operations are defined and certified in accordance with ISO standard 13485. Both the management and employees adhere to well-defined standard processes, referred to as Standard Operating Procedures (SOPs). The processes include production, case management and continuous improvements of operations.

## Waste management

Bactiguard's noble metal alloy coating consists of gold, silver and palladium. The coating is very thin and does not affect the product's other properties such as thickness, appearance and

stiffness. Neither is any special waste management required for Bactiguard's products, which are treated in the same manner as standard catheters and endotracheal tubes. This means that the products are handled as other medical waste, which is later burnt and thereafter handled in accordance with customary procedures at the waste station. The noble metals in the Bactiguard coating are not destroyed during combustion at the waste stage. The metals are captured in the filters during purification of the flue gases at the combustion plant. The metals end up in the fly ash from the combustion, which are taken care of and finally deposited in a closed system in accordance with the rules that apply for this type of waste and are not discharged in surface water.

## Production process

The coating process during production at Bactiguard is water-based and does not use organic solvents. A very small amount of noble metals is used in the coating process. The equivalent of a wedding ring (approximately 10 g) of metal is enough to coat approximately 400,000 catheters. All residual waste from the production is taken care of for recycling or destruction in accordance with provisions of the Swedish Environmental Protection Agency. ■



## Global Sepsis Alliance

Bactiguard is a proud sponsor of the World Sepsis Day, initiated by the Global Sepsis Alliance. Every year on September 13, countless events aimed at raising awareness of sepsis are organized all over the world. Sepsis is the primary cause of death from infection. Sepsis, or blood poisoning, is more common than heart attack and claims more lives than any form of cancer. Every year 25 million people suffer from sepsis and 8 million of them die. Despite this fact, very few people have ever heard of it. Bactiguard's mission is to save lives. Therefore it is important for us to help spreading the knowledge that the death toll can be reduced with better hygiene, better prevention, early detection, and better treatment. ■





Anna Messing Eriksson, Urology Department at Karolinska University Hospital receives Bactiguards research award by Nina Nilsson, SVP Sales & Marketing, Bactiguard.

## Research awards

During 2016, Bactiguard decided to institute three new research awards, to premier, inspire and stimulate research addressing healthcare associated infections. The awards were announced at the annual congresses for Nordic urotherapists (UTF) and the Swedish Urology Congress. The winners at UTF were Maria Akay, nurse at Danderyds Hospital for developing an e-learning module for catheter care and Karin Älvemyr, district nurse in Lund for her educational efforts in primary care aiming to prevent catheter-related urinary tract infections. Anna Messing Eriksson at Karolinska University Hospital and Dr Jon Forsberg from University Hospital in Linköping received their awards at the Urology Congress later during the year. ■



*Many thanks to Team Bactiguard for the opportunity to do what I love, travel the world and play tennis. It would not have been possible without you.*  
Mikael Ymer

## Good To Great Tennis Academy

**At Bactiguard, we value health, whether it is preventing infections or promoting a healthy lifestyle.**

Since 2012, Bactiguard has been a proud team sponsor of Good to Great Tennis, founded by Magnus Norman, previous winner of the Davis Cup and Master Series, and former tennis players Nicklas Kulti and Mikael Tillström. We are proud to have our own team, Team Bactiguard. By supporting elite youths in tennis, we aim to contribute to strengthening the development of future tennis talent in Sweden and at a global level. Most importantly, we aim to inspire both youth and adults to invest in their health and sports. ■

## Together we create job satisfaction

**Our employees are the key to the company's success. Bactiguard is a growing company characterized by innovation, entrepreneurship and diversity in which our core values form the basis of how we act and work.**

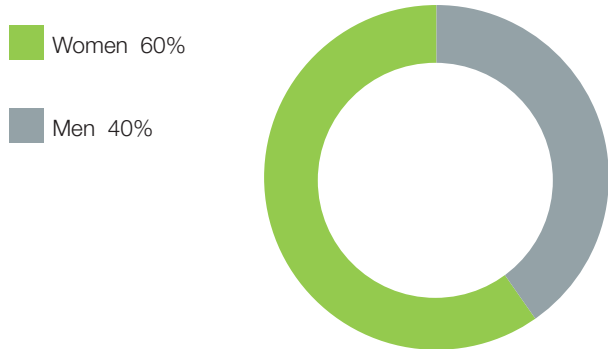
Bactiguard currently has approximately 60 employees, primarily located at our headquarters and production facility in Sweden and our production plant in Malaysia, but also in other regions. Among our employees we have a diversity of nationalities, languages, and expertise that spans a variety of areas, among others research and development, production, marketing and sales. In 2016 approximately half the employees were women, and women in leadership positions amounted to 50%.

We work together and each employee has individual goals. By doing this we create an environment where our employees feel job satisfaction and commitment. Our work is characterized by empathy, respect and communication all of which form the basis of our daily work along with our core values.

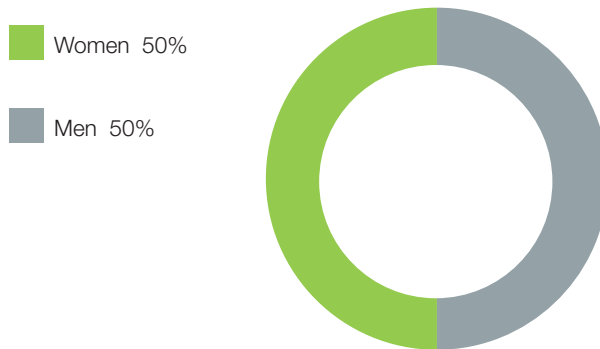
All our employees undergo a company-wide training program. This program includes among other things a general orientation of the company's operations and processes, rules and regulations, quality and safety issues. Individual goals are set in relation to the company's overall goal and are revised once a year in an individual appraisal meeting between an employee and his/her closest manager. ■



### Gender distribution



### Management positions



We have more than ten different nationalities from across all continents represented among our employees, and a balanced gender distribution. Half of the company's managers are women.







# samhall

## A valuable partner

Bactiguard assumes corporate social responsibility by, among other things, investing in local production. The collaboration agreement with Samhall, means that Samhall's employees are responsible for manufacturing the company's high technology products at the headquarters in Stockholm. Samhall is a state owned company which has been commissioned to create job opportunities for people with functional impairments. With approximately 20,000 employees, Samhall is Sweden's largest employer. Samhall is also a member of the international collaboration organization Workability International, which aims to ensure that the skills of people with functional impairments are utilized in the best possible manner. ■

### Our Core Values

Our daily operations are influenced by the company's core values:

- Long term partnership
- Trust and responsibility
- Creativity
- Responsiveness
- Resourcefulness

All embraced by:

- Empathy
- Respect
- Communication







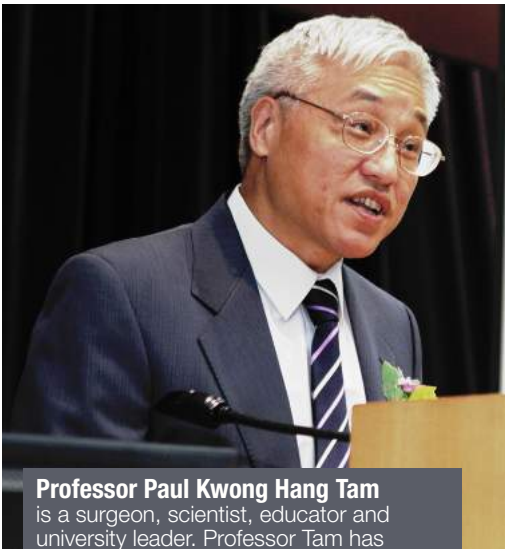
Photo: Ulf Sibom

**Chairman Professor Kenneth Chien** received a Presidential appointment as a Professor to Karolinska Institutet, in 2013. Professor Chien was previously the Charles and Elizabeth Ann Sanders Professor in the Department of Stem Cell and Regenerative Biology at Harvard University. During 2005-2009, he was appointed as Scientific Director of the Cardiovascular Research Center at Massachusetts General Hospital in Boston.



**David S. Finn, M.D.** is Assistant Medical Director for Primary Care Transformation at the Massachusetts General Hospital, in Boston. Medical Director, Dr. Finn is also the Massachusetts General Hospital, Executive Health Services as well as Instructor in Medicine at Harvard Medical School.

**Bactiguard Scientific Advisory Board**, with experts from three continents (Asia, Europe and USA) has been designed to engage leading international physicians and researchers who have a deep knowledge within a specific field, such as cardiology and surgery. One of the most important assignments is to clearly identify the patient groups who will benefit the most from Bactiguard's technology within a wide range of medical devices, and to present additional clinical evidence to position the technology as the standard for an advanced, academic and efficient health care. The Chairman for Bactiguard Scientific Advisory Board is Professor Kenneth Chien.



**Professor Paul Kwong Hang Tam** is a surgeon, scientist, educator and university leader. Professor Tam has been Chair of Pediatric Surgery at the University of Hong Kong since 1996 and Li Shu-Pui Professor in Surgery since 2013. He was the Vice President for Research (2003-2015) and is currently Provost and Deputy Vice Chancellor of the University of Hong Kong.



**Professor Staffan Holmin** is the Söderberg Professor of clinical neuroimaging at Karolinska Institutet. He is also consultant in endovascular neurointervention and vice chairman of the Neuroradiology Department at Karolinska University Hospital in Stockholm, Sweden.

# Board of Directors' Report

The Board of Directors and Chief Executive Officer of Bactiguard Holding AB (publ) hereby present their annual report and consolidated financial statements for the 2016 financial year.

## Operations

Bactiguard is a Swedish medtech company with a global presence. The company offers an infection protection solution that prevents healthcare associated infections caused by medical devices. By preventing infections, the company contributes to reduced usage of antibiotics and consequently the spread of multi-resistant bacteria, which is a growing problem worldwide. Bactiguard saves lives, shortens the duration of treatment, increases patient safety and thereby results in significant cost savings for healthcare and society.

Operations are conducted primarily in Sweden and Malaysia and include research and development, production, marketing, and sales.

Bactiguard's product portfolio, Bactiguard Infection Protection (BIP) covers medical devices within three areas; the urinary tract, respiratory tract and bloodstream.

Bactiguard has ISO 13485 certification, and EC certification for the BIP Foley Catheter (indwelling urinary catheters), BIP ETT (endotracheal tube) and BIP CVC (central venous catheters) product portfolios. The products are CE marked.

## Group structure

The Group includes Bactiguard Holding AB and its wholly-owned subsidiary Bactiguard AB which in turn owns subsidiaries. All operative activities were conducted in the Bactiguard AB Group.

## Revenues, volumes and earnings

### Revenues

Group revenues for the full-year were TSEK 128,342 (138,463). The decrease in revenues is mainly explained by lower License revenues. Excluding the effect of an additional non-recurring order from C.R. Bard in 2015 of approximately TSEK 20,000, revenues have increased by approximately 8 % compared to the previous year.

License revenues for the full-year 2016 contained a positive currency effect resulting from a strong development of the dollar rate during the year compared to the previous year of approx. TSEK 1,600.

Revenue from Sale of BIP products has increased compared to the previous year, which is the result of a strong increase in delivered products in 2016. Other revenues have also increased due to a positive exchange rate impact (USD and EUR) for 2016.

Bactiguard has the following revenue streams:

- License revenues are revenues from sales of products through licencing agreements. In 2016 these revenues relate to the Group's licencing agreement with C.R. Bard for Foley catheters in the USA, Japan, Great Britain, Ireland, Canada and Australia as well as licencing agreements with Vigilenz Medical Devices for orthopaedic implants with Bactiguard's coating, which covers the Southeast Asia ASEAN region.
- The Sale of BIP products relates to BIP Foley Catheters, BIP ETT and BIP CVC.
- Other revenues are mainly related to exchange rate differences

and other operating revenues.

### Volumes

Approximately 418,000 products were delivered for the full-year 2016, compared to approximately 152,000 for the full-year 2015.

### Earnings

Operating profit for the full-year totalled TSEK -18,268 (-12,666). The change TSEK -5,602 compared to the previous year is explained by a reduction in revenues of TSEK 10,121 and by lower operating costs of TSEK 4,519. The change in revenues is mainly the result of lower License revenues of TSEK 22,309 and higher revenues related to the Sale of BIP products of TSEK 9,625.

The increase in Raw material and necessities compared to last year of TSEK 7,895 is a result of expenses related to the Sale of BIP products, but also of other production-related one-off costs. Other external expenses have declined by TSEK 9,586 compared to the full-year 2015 which was burdened by non-recurring costs of TSEK 6,560 (of which the majority are attributable to consulting support in a strategic marketing project). Personnel costs also contain a non-recurring item in 2015 of TSEK 4,618 attributable to severance pay for the former CEO, which mainly explains the decrease of TSEK 7,123 from the full-year 2015 to 2016. For the rest, the decrease in personnel costs is attributable to the fact that the organisation has been reduced by 8 persons (average number of employees), mainly as a result of changes related to relocation of production from the facility in Markaryd to Tullinge in 2016.

Net financial items amounted to TSEK -13,065 (-18,304) for the full-year. Effects of market valuation of the bond loan are recognised as financial items in the income statement. The market valuation impacted net financial items positively for 2016 by TSEK 4,140 (2,602).

Consolidated net profit for the full-year 2016 was TSEK -26,851 (-26,501).

### Financial position

The consolidated equity ratio was 62 % as per 31 December 2015 (62 % as per 31 December 2015). Equity amounted to TSEK 390,328 (417,443 as per 31 December 2015).

Cash and cash equivalents for the Group totalled TSEK 15,645 as per 31 December 2016, which was a decrease of TSEK 6,474 compared to 31 December 2015. Net debt totalled TSEK 134,355 (120,021).

Total assets for the Group were TSEK 632,074 (676,246) as per 31 December 2016. The largest asset item in the balance sheet relates to technology associated with the Bactiguard product portfolio which as per 31 December 2016 totalled TSEK 236,612 (260,418).

Accounts receivable (short and long-term) have decreased by TSEK 13,834 as per 31 December 2016 compared to 31 December 2015, of which the net effect can be explained by provisions for bad debts of TSEK 12,171 with corresponding changes in short-term liabilities and without impact on earnings, for the change of distributor for Brazil, Argentina and Chile.

## Financial overview

The Group's financial performance condensed TSEK	01/01/2016 – 31/12/2016	01/01/2015 – 31/12/2015	01/01/2014 – 31/12/2014	01/01/2013 – 31/12/2013	01/01/2012 – 31/12/2012
<b>Group</b>					
Revenues	128,342	138,463	98,294	123,895	92,782
Net sales	118,736	131,420	93,528	120,399	89,968
EBITDA <sup>1</sup>	15,107	20,184	-5,352	39,630	9,278
EBITDA margin <sup>2</sup> , %	12	15	-5	32	10
Operating profit/loss	-18,268	-12,666	-35,483	10,792	-18,570
Profit before tax	-31,333	-30,970	-115,841	-6,139	-77,452
Profit after tax	-26,851	-26,501	-110,737	-3,774	-65,222
Total assets	632,074	676,246	811,128	717,230	703,632
Operating cash flow <sup>3</sup>	-19,822	-32,456	-53,977	-54,151	-62,526
Earnings per share <sup>4</sup> , SEK	-0.81	-0.80	-4.43	-0.19	-3.26
Operating cash flow per share <sup>5</sup> , SEK	-0.60	-0.97	-2.16	-2.71	-3.13
Number of shares at period-end <sup>6</sup>	33,302,373	33,302,373	33,302,373	20,000,000	20,000,000
Weighted average number of shares <sup>6</sup>	33,302,373	33,302,373	25,007,242	20,000,000	20,000,000
Equity ratio, %	62	62	55	11	12
Net debt	134,355	120,021	90,422	479,544	459,086
Average number of employees	57	65	58	52	39

The consolidated figures are stated in accordance with accounting policies stated in note 2.

1 Earnings before interest, taxes, depreciation and amortisation.

2 EBITDA/Revenues

3 Cash flow from operating activities after investments and changes in working capital

4 Earnings for the period/weighted average number of shares during the period, issue-adjusted

5 Operating cash flow/weighted average number of shares during the period, issue-adjusted

6 Adjusted for split

The bond loan Bactiguard issued in December 2011 with an original nominal amount of MSEK 450, with an annual rate of 11 % and a duration of 5 years, matured on 12 December 2016. The entire outstanding nominal amount of MSEK 138 and accrued interest were then paid. The refinancing solution comprised a bank loan of MSEK 100 with duration until 31 December 2017 as well as a loan from the company's main shareholders of MSEK 50 with duration until 30 June 2018. The loans carry a base interest rate of Stibor 90, but no less than 0 %, and a margin of 3.5 %.

### Investments

Investments in property, plant and equipment for the year totalled TSEK 961 (5,744) and are mainly related to investments in the production facility.

Investments in intangible assets totalled TSEK 6,450 (5,921) for the year and are primarily related to capitalised development expenditures.

No investments in financial assets took place during the year.

### Cash flow

Operating cash flow (cash flow from operating activities after investments and changes in working capital) totalled TSEK -19,822 (-32,456) of which interest payments on the bond loan totalled TSEK 15,180 (15,180).

Total cash flow for the full-year was negative at TSEK -7,822 (-83,283). The comparative figure for last year included repurchase of bonds amounted to TSEK 50,827 in total (equivalent to

nominal TSEK 50,500).

### Key events during the year

- Following the product approval of Bactiguard's infection protection urinary catheters in China, the first order of 100,000 catheters was received in January, corresponding to an order value of more than MSEK 3.
- A laboratory study, published in the Journal of Biomedical Material, conducted by scientists at the Karolinska Institute and Bactiguard, shows that Bactiguard's coating may reduce the risk of thrombosis. A previous clinical study shows that Bactiguard's infection protection central venous catheters reduce the number of bloodstream infections by 50 %. In the new study, it was observed that the coating applied to the catheter's surface may also prevent thrombosis.
- In February Bactiguard won a tender, to supply urinary catheters to the Swedish region Halland. The tender entailed a framework agreement starting on 1 October 2016, which enabled Region Halland as of this date to purchase Bactiguard's infection protection urinary catheters.
- The Minister of Enterprise and Innovation Mikael Damberg cut the blue ribbon and officially inaugurated Bactiguard's new headquarter and production facility in Tullinge, south of Stockholm, in March 2016.
- In April 2016, Bactiguard received a European research grant, aimed at developing a new generation of vascular access catheters, with new bio-smart materials for medical devices. The



technology will be developed in a project financed by Vinnova and Innovative UK. The research grant within the European programme Eurostars amounts to more than MSEK 6, of which Bactiguard's share is approximately MSEK 4 over a period of two and a half years.

- Many spinal cord injured patients use indwelling suprapubic catheters. A large share of these patients suffer from recurring urinary tract infections requiring antibiotic treatment which has a negative impact on their quality of life. In order to reduce the number of infections and suffering of these patients, Bactiguard initiated in May 2016 a clinical study in collaboration with the Centre for Spinal Cord Injury, Sweden's leading clinic for spinal cord injured patients, at Rehab Station Stockholm.
- In connection with Bactiguard Holding AB's annual general meeting on 19 May 2016, the industry experience of the Board of Directors was strengthened through the election of Marie Wickman-Chantereau as new board member. She works as a business area manager in specialist care in Stockholm at Aleris and adjunct professor of plastic surgery at the Karolinska Institute, Stockholm.
- In May 2016 the executive management in Bactiguard was offered an opportunity to invest in the company by purchasing a sizeable number of shares. Other members of the senior management were also offered the opportunity to purchase shares. The transaction was enabled by the two main shareholders Christian Kinch and Thomas von Koch, who offered the management to purchase a total of 751,013 shares of series B, corresponding to a value of approximately MSEK 9.2.
- The initial order from India, which was received in December 2015, consisted of some 50,000 infection protection urinary catheters (BIP Foley Catheters). The second order consisted of some 60,000 BIP Foley Catheters and was delivered in its entirety in the third quarter, which generated revenues of approximately MSEK 2.
- The duration for the credit facility of MSEK 100 which Bactiguard received as a loan commitment in November 2015 was extended in August 2016 to 31 December 2017. Other conditions did not change.
- In September 2016 Bactiguard started a new clinical study with the aim of reducing the risk of catheter associated urinary tract infections and the use of antibiotics in patients undergoing prostate cancer surgery at the well renowned Martini-Klinik of the University Medical Center Hamburg-Eppendorf. The Martini-Klinik, is specialized in prostate cancer diagnosis and treatment and is today the number one prostate cancer centre in the world in terms of the number of radical prostatectomies annually – with over 2,200 surgeries in 2015. The institute is focused on providing value-based care, where quality of life aspects for patients are at the centre of attention.
- In October 2016, a conducted, independent and randomized clinical study confirmed that Bactiguard coated urinary catheters reduce the number of catheter associated urinary tract infections among patients in Intensive Care Units (ICUs). The study was conducted at King Fahad Hospital in Saudi Arabia and included 60 patients at ICUs who were catheterized for at least 3 days. The incidence of catheter associated urinary tract infections was 90 % lower for patients with Bactiguard's catheters (BIP Foley), compared to patients with standard silicone

catheters. The study was published in Urology Annals.

- In November Bactiguard received a second order from the distributor in China, Jian An Pharmaceuticals. The order was for 100,000 BIP Foley catheters, which was the same quantity as the initial order received in early 2016. The order was delivered in the fourth quarter of 2016 and generated sales revenue of approximately MSEK 3.
- The bond loan Bactiguard issued in December 2011 with an initial nominal amount of MSEK 450, an annual interest rate of 11 % and a duration of 5 years, matured on 12 December 2016. The entire outstanding nominal amount of MSEK 138 and accrued interest were paid. The refinancing solution comprises a bank loan of MSEK 100 with duration until 31 December 2017 as well as a loan from the company's main shareholders of MSEK 50 with duration until 30 June 2018. The loans carry an interest rate of Stibor 90, but no less than 0 %, and a margin of 3.5 %. Bactiguard's interest expenses will decrease significantly through this refinancing.
- In December, Bactiguard entered into partnership with Roeser Medical GmbH ("Roeser") and signed an exclusive distribution agreement for Germany and Switzerland. At the same time, an order for products worth some EUR 400,000 was placed, the majority of which will be delivered throughout 2017.

### **Future expectations**

Preventative measures are a priority of both the World Health Organization (WHO), the World Economic Forum, health ministers in the G7 countries and governments across the globe. The increased awareness of the consequences of antibiotic resistance has resulted in greater demand for infection prevention solutions for healthcare, which also contributes to good conditions for Bactiguard's infection protection products and coating. Growth within this segment is managed by both a desire to reduce the number of healthcare associated infections and reduce the costs which can be related to these. This means that Bactiguard has good conditions to strengthen its position in existing markets and at the same time establish itself in new markets.

### **Research and development**

Company research and development activities are focused on developing new products, and increasing knowledge of the problem of healthcare associated infections.

### **Personnel**

The average number of employees in the Group for the year was 57 (65) employees.

### **Guidelines for remuneration to senior management**

The Board of Directors proposes that the 2017 AGM decides on the following guidelines for remuneration and other employment terms for senior management (unchanged compared to the decision of the 2016 AGM).

### **Guidelines**

Senior management includes the CEO and other executives within Bactiguard, and the Board of Directors, to the extent they retain remuneration for assignments other than as directors.

## Shareholding as per 31 December 2016

Shareholders	Total series A shares	Total series B shares	Total shares	% of capital	% of votes
Christian Kinch with family and company	2,000,000	7,440,977	9,440,977	28.3	39.6
Thomas von Koch and company	2,000,000	7,440,878	9,440,878	28.3	39.6
Handelsbanken Fonder AB	–	1,212,688	1,212,688	3.6	1.7
Försäkringsaktiebolaget, Avanza Pension	–	778,860	778,860	2.3	1.1
Swedbank Försäkring	–	729,902	729,902	2.2	1.1
Ståhlberg, Jan	–	582,544	582,544	1.7	0.8
Cancerfonden - Riksföreningen Mot	–	559,415	559,415	1.7	0.8
Fröafall Invest AB	–	516,000	516,000	1.5	0.7
Rugfelt, Johan	–	401,632	401,632	1.2	0.6
Sargas Equity AB	–	364,090	364,090	1.1	0.5
<b>Total, largest shareholders</b>	<b>4,000,000</b>	<b>20,026,986</b>	<b>24,026,986</b>	<b>72.1</b>	<b>86.6</b>
Total, other	–	9,275,387	9,275,387	27.9	13.4
<b>Total number of shares</b>	<b>4,000,000</b>	<b>29,302,373</b>	<b>33,302,373</b>	<b>100.0</b>	<b>100.0</b>

Bactiguard shall have levels of remuneration and terms that are necessary in order to recruit and retain senior managers with the skills, competencies and experience required to achieve the company's operational targets. The total remuneration paid to senior managers shall be competitive, reasonable, and designed for this purpose.

Senior managers shall be offered a fixed salary that is competitive in market conditions and which shall be determined based on the individual's responsibilities and experience. Review of the fixed salary shall be made annually for each calendar year.

Senior managers may, from time to time, be offered variable remuneration that is adjusted to market conditions. Such variable remuneration shall be designed for the purpose of promoting long-term value creation in Bactiguard and be related to predetermined and measurable criteria. Any variable remuneration shall be limited to 50 % of the fixed annual salary. In designing variable remuneration for senior managers that is paid in cash, the Board of Directors shall consider imposing reservations that (i) make payment of a portion of such remuneration conditional to that the performance to which earning such remuneration is based shall be sustainable over time (ii) provide the company the opportunity to recall any such remuneration that has been paid based on information that is later found to be obviously false.

### Pensions

Senior managers are entitled to retirement solutions that are adjusted to market conditions. Defined contribution retirement plans shall be preferred.

### Benefits

Other benefits may include access to a company car, healthcare contribution and other common benefits. Other benefits may not constitute a significant portion of the total remuneration.

### Severance pay

On termination of senior managers by the company, the notice period for such termination may not exceed 6 months. Any severance pay may not exceed the amount of a single year's fixed salary.

### Incentive programme

When the Board of Directors finds it appropriate, company senior managers shall also be offered participation in long-term share or share price-related incentive programmes that shall ensure long-term commitment to the development of the company. Determination of any such share or share price-related incentive programme shall be made by the Board of Directors.

The Board of Directors will evaluate on an annual basis whether a long-term incentive programme should be proposed at the AGM, and if this is the case, whether the proposed long-term incentive programme should comprise transfer of shares in the company.

These guidelines shall apply to agreements that are entered subsequent to the AGM, and to all changes made to existing agreements after that time. The Board of Directors shall be entitled to depart from the above guidelines when, in the assessment of the Board of Directors in a specific case, there are special reasons therefore.

### Environmental impact

The Group engages in notifiable activities under the Swedish Environmental Code (environmentally hazardous activities and health protection) and to the Swedish Work Environment Authority (use of contagions in risk group 2).

The notifiable activities concern portions of the production process and the research and development the company conducts

### The Bactiguard share

Trade in the Bactiguard share was started at Nasdaq Stockholm with the ticker symbol "BACTI."

The closing price for listed B shares as per 30 December 2016 was SEK 16,90 with a market capitalisation of TSEK 562,810.

Share capital in Bactiguard as per 31 December 2016 was TSEK 833 allocated to 29,302,373 series B shares each carrying a single vote (29,302,373 votes) and 4,000,000 series A shares, each with ten votes (40,000,000 votes). The total number of shares and votes in Bactiguard as per 31 December 2016 was 33,302,373 shares and 69,302,373 votes.

For the company's series A shares the duty to give prior option of purchase applies in accordance with § 15 of the articles of association, but for the rest there are no restrictions on transferability for these shares.

### Significant risks and uncertainty factors

Bactiguard Holding's operations and profits are affected by several external factors. The company continually engages in a process of identifying all risks that may arise and assessing how each of these risks shall be managed. The company is primarily exposed to market related risks, operational related risks and financial risks. The risks Bactiguard is exposed to are addressed separately below.

### Financial risk management and financial instruments

Through its activities, the Group is exposed to various types of risk. The Group has a comprehensive risk management programme that concentrates on minimising potential unfavourable effects on financial results. The company's Board of Directors is ultimately responsible for the exposures, management and follow-up of the Group's risks. The frameworks that apply to the exposures, management, and follow-up of financial risks are set by the Board of Directors and revised annually. The Board of Directors has delegated responsibility for daily risk management to the company's CEO, who in turn has delegated this to the company's CFO. The Board of Directors is able to decide on temporary departures from these established frameworks.

Financial risks are described in note 4.

### Macroeconomic risk

Weak economic performance and high national debt may cause both public and private customers to experience difficulty in obtaining financing. As well, this may have a negative impact on some countries' ability and political willingness to invest in and allocate public resources to healthcare. Bactiguard maintains market presence in many geographic markets for the purpose of minimising any country-specific portion of the combined macroeconomic risk.

### Regulatory risk

As manufacturer of medical devices, Bactiguard's operations are subject to requirements and standards that are determined by the regulatory authorities for each of the markets where Bactiguard is represented. Regulatory processes in various countries may cause a risk of delays in the launching process of products in these countries. Bactiguard works with its local distributors and regulatory advisors to minimise these risks.

### Technology risk

The medtech industry is generally characterised by swift technological changes and continuous progress in industrial know-how, which continually brings new products and improved treatment methods. Bactiguard has obtained patents in many of the countries in which the company operates in order to protect its technology, and has applied for patents in additional countries. Additionally, Bactiguard has taken several other measures to ensure that company-unique knowledge (such as application and manufacture of the Bactiguard coating) is not disclosed to any competitor.

### Liquidity risk

Liquidity risk is defined as the risk of not having access to cash assets or credit available to cover payment commitments, including interest payments and amortisation. Liquidity risk is especially significant in the event large unanticipated payment commitments arise. Lack of liquidity to cover large payment commitments can have a negative impact on Bactiguard's operations and its financial position. As per 31 December 2016, the Group has liquidity amounting to TSEK 45,645, including approved bank overdraft facilities of TSEK 30,000. The liquidity risk is monitored on a monthly basis through rolling forecasts of 3 months which evaluate the liquidity situation and is the base of taking relevant measures (financial or operational).

After refinancing of the company's bond loan was completed, the company has continued to work actively on ensuring a long-term financing solution at market conditions which is expected to be in place before maturity of existing loans.

The management deems that current liquidity levels will be sufficient to manage the company's commitments for the coming year.

### Parent company

Revenues consist of invoiced group-wide costs (management fees). The parent company has received interest on its receivables from group companies during 2016. Company costs primarily relate to financial expenses of which the interest due on the bond loan is the single largest item. No investments have been made during 2016.

### Proposed appropriation of profit

#### Parent company

The following retained earnings are at the disposal of the Annual General Meeting (SEK)

Retained earnings	24,344,035
Share premium reserve	473,016,706
Profit/loss for the year	-29,662,488
	<b>467,698,253</b>

The Board of Directors proposes that the profits be distributed as carried forward	467,698,253
	<b>467,698,253</b>

In regard to the Group's and parent company's profit and financial position in general, further reference is made to the following financial statements. All amounts are expressed in thousands of Swedish krona (TSEK), unless otherwise specified.

The Corporate Governance Report for fiscal year 2016 is available on page 28.



# Corporate Governance Report 2016

Bactiguard Holding AB (publ) ('Bactiguard' or 'the company') has prepared this Corporate Governance Report in compliance with Chap.6 § 6 of the Swedish Annual Accounts Act and Chap.10 of the Swedish Code of Corporate Governance ('the Code').

In addition to the principles for corporate governance required by law or other applicable legislation, at Bactiguard corporate governance is based on internal documents such as the articles of association, the Board of Directors' work plan and CEO instruction, and policies and guidelines, as well as external rules such as the Nasdaq Stockholm Rules and regulations for Issuers and the Code. In 2016, the company has not made any deviations from the Code.

## Shares and shareholders

The Bactiguard series B share is listed on Nasdaq Stockholm. At year-end, the total number of shares was 33,302,373 (of which 4,000,000 non-listed series A shares) and the number of shareholders was 2,632. Page 26 contains a list of the company's biggest shareholders as per 31 December 2016.

## General Meetings

The shareholders' right to decide on matters affecting Bactiguard is exercised at the general meeting in accordance with the Swedish Companies Act and is the company's highest decision making organ. The rules that control conducting general meetings are found in the Swedish Companies Act, the Code, and the company articles of association §§ 10–12.

All shareholders registered in the share registry as of the record date and who have provided timely notice of their intention to participate in the general meeting are entitled to participate therein and vote their full shareholding. There are no limitations as to the number of votes shareholders may exercise at the general meeting. Notice for convening the general meeting is published for shareholders on the company's website and announced in Post- och Inrikes Tidningar. Simultaneously with publication of the notice, the company advertises this information in the newspaper Dagens Industri. Shareholders wanting to have a matter considered at the general meeting shall request so in writing to the Board of Directors. Such matters shall be brought for consideration at the general meeting if the request was submitted to the Board of Directors no later than seven weeks prior to the meeting. All shareholders are entitled to ask questions to the company regarding matters on the agenda for the general meeting, and in relation to the company and the Group's financial position.

An annual general meeting ('AGM') shall be held in Stockholm, Huddinge or Botkyrka within six months of the closing date for the financial year. The company's financial year begins on 1 January and closes 31 December. The AGM determines issues including adopting the company's annual report, appropriation of the company's profit or loss, and discharging the board members and the CEO from liability. The AGM also appoints board members and auditors, and determines the establishment of a nomination committee, fees for the Board of Directors and auditors, and guidelines for determining salaries and other remuneration to the CEO and other senior managers. Resolutions by the general meeting are normally passed by simple majority vote, except where the Swedish Companies Act imposes requirements for a higher portion of the shares and assigned votes represented at the general meeting, for example, resolutions regarding amendment of the company's articles of

association. The general meeting has not authorised the Board of Directors to repurchase company shares.

## The Articles of Association

Bactiguard's articles of association are published in full on the Bactiguard website, [www.bactiguard.se](http://www.bactiguard.se). Changes to Bactiguard's articles of association are made in accordance with the provisions of the Swedish Companies Act. Bactiguard's articles of association stipulate that the Board of Directors shall consist of not less than three and no more than seven members. The board members are elected by the AGM for one year at a time. The company articles of association do not contain any special provisions on appointment or dismissal of board members.

## Nomination committee

At the 2016 AGM, rules were adopted for appointment of members to the Nomination committee for the 2017 AGM. These rules, as adopted, provide that the Nomination committee shall be formed by the chairman of the Board of Directors contacting the three largest shareholders (by votes) as per ownership statistics on 31 August, who each shall be entitled to appoint one member to serve together with the chairman of the Board of Directors on the Nomination committee. For the 2017 AGM, the Nomination committee consists of Jan Lombach, Chairman, (appointed by KK Invest AB, a company controlled by Christian Kinch), Thomas von Koch (appointed by Bactiguard B.V., a company controlled by Thomas von Koch), Christian Brunlid (appointed by Handelsbanken Fonder AB) and Stanley Brodén (Chairman of the Board of Directors).

## Board of Directors

The Board of Directors is the highest management organ of the company, standing under the authority of the general meeting. The Board of Directors is, inter alia, responsible for the company's organisation and management of the company's affairs, ensuring that the company's organisation is designed to adequately control the company's accounts, financial management and other economic conditions. The Board of Directors shall continually assess the company's financial position. The Board of Directors shall primarily address comprehensive and long-term issues, and other issues of unusual character or great significance to the Group and the company.

The Board of Directors' work shall follow a written work plan that shall ensure that the Board of Directors is fully informed and that all control related aspects of the company's operations are addressed. Pursuant to the work plan, the Chairman of the Board of Directors is responsible for monitoring and discussing the developments of Bactiguard in regular contacts with the CEO. The Chairman of the Board of Directors shall also perform duties such as ensuring that the Board of Directors receive continual information from the CEO as necessary to monitor the company's financial position, financial planning and development, and that an annual assessment of the work of the Board of Directors is conducted. In addition to the specific responsibility of the Chairman of the Board of Directors, the Board of Directors has not allocated its areas of responsibility in any way, other than that stipulated in the instructions for the audit and remuneration committees.

The work plan of the Board of Directors stipulates that the Board of Directors shall, in a 12 month cycle, address at least the following areas of importance for the company; accounting and auditing issues; market and market analyses; risk identification; strategy; organisation; assessment of the Board of Directors and the CEO and the system for internal control; and the company's capital structure. The Chairman of the Board of

Directors is responsible for the annual evaluation of the work of the Board of Directors.

During 2016 the Chairman conducted a written survey evaluation with all board members comprising of 15 different aspects of the work of the Board of Directors. The Chairman of the Board of Directors has presented results of the evaluation to both the Board of Directors and the Nomination committee.

During 2016 the Board of Directors held a total of 9 meetings where minutes were recorded. All board members attended all board meetings. In 2016 the work of the Board of Directors was characterised by focus, long-termism and perseverance in terms of the work on increasing the sale of BIP products and winning new licencing deals. The Board of Directors has also continued its work on ensuring long-term stable financing as a basis for the company's continued development. During the year the Board of Directors also increased its focus on strengthening the management structure for securing delivery of the development the Board of Directors wants to see.

In 2016 the Board of Directors has comprised Stanley Brodén (Chairman), Mia Arnhult, Peter Hentschel and Christian Kinch and from the 2016 AGM Marie Wickman-Chantereau as well. Additional information on the board members is available on page 31.

#### **Board Committees**

The Audit committee is tasked with monitoring the company's financial reporting and the effectiveness of internal controls and risk management in the company, and internal audits as necessary. The committee shall also monitor and review the auditor's independence and impartiality, and especially follow whether the auditor provides other services than purely auditing services to the company. The committee also contributes proposals to the general meeting for adoption regarding the appointment of auditors. Since the audit committee's re-establishment in February 2016, the committee comprises the board members Mia Arnhult (Chairman), Stanley Brodén and Peter Hentschel. All members were present at meetings during 2016.

The Remuneration committee shall support the Board of Directors with proposals, advice, and preparation in regard to issues of remuneration principles for the CEO and other senior managers and individual remuneration to the CEO in accordance with remuneration principles. These principles include the relationship between fixed and any variable remuneration, and the relationship between performance and remuneration, the general terms for any bonus and incentive programme, and the general terms for non-monetary benefits, pension, notice of termination and severance pay. The Board of Directors is also responsible as a whole for establishing remuneration levels and other employment terms for the CEO. Share-related incentive programmes for group management are, however, adopted only by the AGM. The committee shall also; support the Board of Directors in monitoring the system through which the company complies with publication requirements stipulated by legislation, market regulations and the Code in regard to information related to remuneration of the CEO and other senior managers; monitor and assess any ongoing or concluded incentive programs for variable remunerations to the CEO and/or other senior managers; evaluate compliance with the guidelines for remuneration to the CEO and other senior managers adopted by the AGM as well as the current structure and levels of remuneration. In 2016 the remuneration committee comprised the board members Stanley Brodén (Chairman) and Peter Hentschel. All members were present at meetings during 2016.

#### **Chief Executive Officer**

The CEO is appointed by the Board of Directors and is responsible for the daily administration of the company's operations in accordance with the instructions and regulations of the Board of Directors. The CEO also functions as the Chairman of the management making all decisions in consultation with other managers. Christian Kinch was the company's CEO in 2016. Additional information on the CEO is available on page 30.

#### **Internal controls and risk management activities regarding financial reporting**

As the company's financial system is designed to ensure that entering agreements and payment of invoices, and similar, must follow the decision processes, and the signatory and authorisation procedures provided in internal steering documents, the company has a basic control structure to counteract and prevent the risks identified by the company. In addition to these control structures, a series of additional control activities are conducted to further discover and correct any errors and deviations. Such control activities consist of follow-up at various levels in the organisation, for example, follow-up and review by the Board of Directors regarding their formal decisions; review and comparison of income items and account settlement; and approval of the accounting of business transactions with the finance department. In accordance with its work plan, the Board of Directors conducts an annual review of these internal controls and also, annually, performs risk identification and establishes risk mitigation measures. The auditor is invited to a board meeting to present its auditing measures in regard to internal control.

The division and delegation of responsibility have been documented and communicated in internal steering documents established for the Board of Directors and the company, such as; the work plan of the Board of Directors, the CEO instruction, and the delegation of authority, authorisation procedure and other internal steering documents, such as the financial handbook. All internal steering documents are maintained up-to-date on a regular basis, to reflect legislative changes or revision of reporting standards. Bactiguard has established an organisation for the purpose of ensuring that all financial reporting is correct and efficient.

The internal steering documents define responsibilities and daily interactions between the positions involved so that all necessary information and communication reach all persons as necessary. The group management receives weekly and monthly financial information regarding the company and its subsidiaries in regard to developments of upcoming investments and liquidity planning. The company's communication policy is designed to ensure that publication of all information, both internal and external is made correctly and at the appropriate time for all occasions.

Monitoring is conducted continuously at all levels of the organisation. The Board of Directors regularly assesses the information which the company's senior management and auditors submit. In addition, the Board of Directors conduct annual follow-up of previous risk assessments and any measures implemented therefore. The Board of Directors' monitoring of developments in internal controls and ensuring that measures are taken in regard to any shortcomings or suggestions that arise are particularly important.

#### **Internal audit**

Considering the scope of the company's operations and the organisational structure at large, the Board of Directors has not found any reason to implement an internal auditing unit. The Board of Directors has assessed that the monitoring and review programme described above are sufficient, in combination with the external audits, to maintain effective internal controls in regard to the financial reporting.

## Group management



**Johan Rugfelt**  
COO

**Cecilia Edström**  
Senior Vice President  
Sales & New Business

**Christian Kinch**  
VD

**Fredrik Järsten**  
CFO

**Nina Nilsson**  
Vice President Marketing

### Christian Kinch

Born 1966  
CEO

**Education:** Studies at the Stockholm School of Economics.

**Other assignments:** Board member of Swecare Aktiebolag and SWIB Holding AB (holding company for Smartwise Sweden AB and Procella Therapeutics AB). Owner and board member in KK Consult AB.

**Background:** Founder of Kinchard AB and Netpharma AB and assignments within the Group.

**Shareholding in the company:** 2,000,000 shares series A (legal entity) and 7,440,977 shares series B (direct, family and legal entity).

### Johan Rugfelt

Born 1967  
COO (Chief Operating Officer)

**Education:** BSc Business and Economics, Stockholm School of Economics.

**Other assignments:** –

**Background:** Assignments within McKinsey, Bain, SEB, Business Sweden and within the Group.

**Shareholding in the company:** 401,632 shares of series B (own).

### Cecilia Edström

Born 1966  
Senior Vice President Sales & New business

**Education:** BSc Business and Economics, Stockholm School of Economics.

**Other assignments:** Board member of Nordic Public Affairs AB.

**Background:** Various roles within SEB, Scania AB and TeliaSonera AB.

**Shareholding in the company:** 216,948 shares of series B (own).

### Fredrik Järsten

Born 1967  
CFO (Chief Financial Officer)

**Education:** BSc Business and Economics, Stockholm School of Economics.

**Other assignments:** Chairman of the Board of Directors of Terroir Suisse AB, board member and CEO of Fredrik Järsten Konsult AB.

**Background:** Assignments within SEB Enskilda, Lazard, Litorina Kapital as well as within the Aleris Group.

**Shareholding in the company:** 121,632 shares of series B (own, legal entity).

### Nina Nilsson

Born 1977  
Vice President Marketing

**Education:** Diploma in Marketing from IHM Business School. Studies in medical education, Karolinska Institutet

**Other assignments:** –

**Background:** Several assignments within international marketing and sales for Johnson & Johnson, programme coordinator at the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU).

**Shareholding in the company:** 84,632 shares of series B (own).





**Stanley Brodén**

Born 1951

Board member since 2015.

**Education:** Economic studies at Linköping University. MiL's Management training.

**Other assignments:** Chairman of the Board of Directors of Frösunda Omsorg AB in Stockholm. Industrial Adviser to EQT.

**Shareholding in the company:** 50,000 shares of series B (legal entity).

*Independent in relation to the company and group management and the company's largest shareholders.*



**Mia Arnhult**

Born 1969

Board member since 2014 and chair of the audit committee.

**Education:** Degree in Business finance and trade law, Lund University.

**Other assignments:** Chairman of the Board of Devyser Holding AB and Devyser AB. Board director of Odd Molly International AB (publ), Footway Group AB (publ), M2 Capital Management AB and Suburban Properties Stockholm AB and partner in Utvecklingsbolaget Persson & Persson i Stockholm HB, a trading partnership. Board member and CEO of M2 Gruppen AB, CEO of Locellus AB and Arnhult Invest AB.

**Shareholding in the company:** 50,000 shares series B (own) and 516,000 shares series B (legal entity).

*Independent in relation to the company and group management and the company's largest shareholders.*



**Marie Wickman-Chantreau**

Born 1955

Board member since 2016.

**Education:** M.D and Med. DR., Associate Professor of Plastic Surgery, Karolinska Institutet Stockholm.

**Other assignments:** Business area manager Specialist care Stockholm, Aleris. Member of EURAPS Scientific Committee and board member Kvinvest AB.

**Shareholding in the company:-**

*Independent in relation to the company and group management and the company's largest shareholders.*



**Peter Hentschel**

Born 1949

Board member since 2015.

**Education:** Civil Engineer, Chemistry – Chalmers University of Technology. Studies in corporate economics at Gothenburg University.

**Other assignments:** Chairman of the Board of Directors of Reapplix Aps and board member of Lumina Adhesives AB.

**Shareholding in the company:** 50,000 shares of series B (own).

*Independent in relation to the company and group management and the company's largest shareholders.*



**Christian Kinch**

Born 1966

CEO of the Group since June 2015 and during the period 2005 to March 2014. Chairman of the board from March 2014 to June 2015.

**Education:** Studies at the Stockholm School of Economics.

**Other assignments:** Board member of Swecare Aktiebolag and SWIB Holding AB (holding company for Smartwise Sweden AB and Procella Therapeutics AB). Owner and board member KK Consult AB.

**Shareholding in the company:** 2,000,000 shares series A (legal entity) and 7,440,977 shares series B (direct, family and legal entity).

*Not independent in relation to the company and the group management or the company's larger shareholders.*

## Condensed consolidated income statement

Amounts in TSEK	Note	2016	2015
Net sales	5, 6	118,736	131,420
Other revenues	5	9,606	7,043
<b>Total</b>		<b>128,342</b>	<b>138,463</b>
Raw material and consumables		-15,797	-7,902
Other external expenses	7, 8	-46,701	-56,287
Personnel costs	9	-45,819	-52,942
Depreciation and amortisation	14, 16–21	-33,375	-32,850
Other operating expenses		-4,848	-1,078
Profit participations in associates	23	-70	-70
<b>Total operating expenses</b>		<b>-146,610</b>	<b>-151,129</b>
<b>Operating profit/loss</b>		<b>-18,268</b>	<b>-12,666</b>
<b>Profit/loss from financial items</b>			
Financial income	10	9,735	2,657
Financial expenses	11	-22,800	-20,961
<b>Total</b>		<b>-13,065</b>	<b>-18,304</b>
<b>Profit before tax</b>		<b>-31,333</b>	<b>-30,970</b>
Taxes for the period	12	4,482	4,469
<b>Net profit/loss for the year</b>		<b>-26,851</b>	<b>-26,501</b>
<b>Attributable to:</b>			
Shareholders of the parent		-26,851	-26,501
Earnings per share, SEK		-0.81	-0.80

## Condensed consolidated statement of comprehensive income

Amounts in TSEK	2016	2015
Net profit/loss for the year	-26,851	-26,501
Other comprehensive income:		
<i>Items that will be reclassified to profit or loss for the year</i>		
Translation differences	-264	1,146
Other comprehensive income, after tax	-264	1,146
<b>Total comprehensive income for the year</b>	<b>-27,115</b>	<b>-25,355</b>
<b>Attributable to:</b>		
Shareholders of the parent	-27,115	-25,355
Total earnings per share, SEK	-0.81	-0.76

## Condensed consolidated statement of financial position

Amounts in TSEK	Note	31/12/2016	31/12/2015
<b>ASSETS</b>			
<b>Non-current assets</b>			
<b>Intangible assets</b>			
Goodwill	13	226,292	226,292
Technology	14	236,612	260,418
Brands	15	25,572	25,572
Customer relationships	16	11,728	12,908
Capitalised development expenditure	17	16,562	12,062
Patents	18	1,021	1,272
<b>Total</b>		<b>517,787</b>	<b>538,524</b>
<b>Property, plant and equipment</b>			
Improvements, leasehold	19	16,133	17,917
Machinery and other technical plant	20	5,659	7,412
Equipment, tools and installations	21	3,937	5,432
<b>Total</b>		<b>25,729</b>	<b>30,761</b>
<b>Financial assets</b>			
Accounts receivable	25	16,170	6,012
Investments in associates	23	1,228	1,298
<b>Total</b>		<b>17,398</b>	<b>7,310</b>
<b>Total non-current assets</b>		<b>560,914</b>	<b>576,595</b>
<b>Current assets</b>			
Inventory	24	15,144	11,687
Accounts receivable	25	27,642	51,634
Other current receivables		3,025	4,620
Prepaid expenses and accrued income	26	9,704	9,591
Cash and cash equivalents	27	15,645	22,119
<b>Total</b>		<b>71,160</b>	<b>99,651</b>
<b>Total assets</b>		<b>632,074</b>	<b>676,246</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity attributable to shareholders of the parent</b>			
<b>parent</b>			
Share capital	28	833	833
Translation differences		88	352
Other capital contribution		675,690	675,690
Retained earnings including net profit for the year		-286,283	-259,432
<b>Sum equity attributable to shareholders of the parent</b>		<b>390,328</b>	<b>417,443</b>
<b>Total equity</b>		<b>390,328</b>	<b>417,443</b>
<b>Non-current liabilities</b>			
Advance payments from customers		18,207	-
Debt to shareholders	29	50,000	-
Deferred tax liability	12	30,285	34,767
<b>Total</b>		<b>98,492</b>	<b>34,767</b>
<b>Current liabilities</b>			
Liabilities to credit institutions	29	100,000	-
Bond loan	29	-	142,140
Accounts payable		4,896	4,017
Other current liabilities		3,835	3,996
Accrued expenses and deferred income	31	34,523	73,883
<b>Total</b>		<b>143,254</b>	<b>224,036</b>
<b>Total liabilities</b>		<b>241,746</b>	<b>258,803</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>632,074</b>	<b>676,246</b>



## Condensed consolidated statement of changes in equity

Equity attributable to shareholders of the parent					
Amounts in TSEK	Share capital	Other capital contributions	Translation reserve	Retained earnings including net profit for the year	Total equity
<b>Opening balance 1 January 2015</b>	833	675,690	-794	-232,931	442,798
<b>Comprehensive income</b>					
Profit/loss for the year	-	-	-	-26,501	-26,501
Other comprehensive income:					
Translation differences	-	-	1,146	-	1,146
Total other comprehensive income, after tax	-	-	1,146	-	1,146
<b>Total comprehensive income</b>	-	-	1,146	-26,501	-25,355
<b>Transactions with shareholders</b>					
Total transactions with shareholders	-	-	-	-	-
<b>Closing balance 31 December 2015</b>	833	675,690	352	-259,432	417,443
<b>Opening balance 1 January 2016</b>	833	675,690	352	-259,432	417,443
<b>Comprehensive income</b>					
Profit/loss for the year	-	-	-	-26,851	-26,851
Other comprehensive income:					
Translation differences	-	-	-264	-	-264
Total other comprehensive income, after tax	-	-	-264	-	-264
<b>Total comprehensive income</b>	-	-	-264	-26,851	-27,115
<b>Transactions with shareholders</b>					
Total transactions with shareholders	-	-	-	-	-
<b>Closing balance 31 December 2016</b>	833	675,690	88	-286,283	390,328

## Condensed consolidated statement of cash flows

Amounts in TSEK	2016	2015
<b>Cash flow from operating activities</b>		
Net profit/loss for the year	-26,851	-26,501
Adjustment for non-cash flow items:		
Depreciation	33,375	32,850
Market valuation bond loan	-4,140	-2,602
Other non-cash items	-6,268	-3,653
	<b>-3,884</b>	<b>94</b>
Increase/decrease inventory	-3,416	-2,628
Increase/decrease accounts receivable	-803	-4,747
Increase/decrease other current receivables	370	141
Increase/decrease accounts payable	933	-7,371
Increase/decrease other current liabilities	-5,611	-6,280
<b>Cash flow from operating activities</b>	<b>-8,527</b>	<b>-20,885</b>
<b>Investing activities</b>		
Investments in intangible assets	-6,450	-5,921
Investments in property, plant and equipment	-961	-5,744
<b>Cash flow from investing activities</b>	<b>-7,411</b>	<b>-11,666</b>
<b>Operating cash flow</b>	<b>-19,822</b>	<b>-32,456</b>
<b>Financing activities</b>		
Amortisation of debt	-138,000	-50,827
Borrowings	150,000	-
<b>Cash flow from financing activities</b>	<b>12,000</b>	<b>-50,827</b>
Cash flow for the year	-7,822	-83,283
Cash and cash equivalents at start of year	22,119	105,147
Exchange difference in cash and cash equivalents	1,348	255
<b>Cash and cash equivalents at end of year</b>	<b>15,645</b>	<b>22,119</b>

## Condensed parent company income statement

Amounts in TSEK	Note	2016	2015
Net sales		–	–
Other operating revenues	5	7,563	7,036
<b>Total</b>		<b>7,563</b>	<b>7,036</b>
Other external expenses	7, 8	-3,207	-2,752
Personnel costs	9	-7,121	-12,750
<b>Total</b>		<b>-10,328</b>	<b>-15,502</b>
<b>Operating profit/loss</b>		<b>-2,765</b>	<b>-8,466</b>
<i>Profit/loss from financial items</i>			
Interest income and similar items	10	4,431	5,275
Interest expenses and similar items	11	-31,328	-27,674
<b>Total</b>		<b>-26,897</b>	<b>-22,399</b>
<b>Profit/loss after financial items</b>		<b>-29,662</b>	<b>-30,865</b>
Taxes for the period	12	–	–
<b>Net profit/loss for the year</b>		<b>-29,662</b>	<b>-30,865</b>

## Statement of comprehensive income

Amounts in TSEK	2016	2015
Net profit/loss for the year	-29,662	-30,865
Other comprehensive income	–	–
<b>Total comprehensive income</b>	<b>-29,662</b>	<b>-30,865</b>



## Condensed parent company balance sheet

Amounts in TSEK	Note	2016	2015
<b>ASSETS</b>			
<b>Non-current assets</b>			
<b>Financial assets</b>			
Shares in Group companies	22	384,574	384,574
Receivables in Group companies		213,515	315,200
<b>Total</b>		<b>598,089</b>	<b>699,774</b>
<b>Current assets</b>			
<b>Current receivables</b>			
Receivables from group companies		22,395	12,977
Other current receivables		–	–
Prepaid expenses and accrued income	26	243	1,457
<b>Total</b>		<b>22,638</b>	<b>14,434</b>
<b>Cash and cash equivalents</b>	27	<b>1,118</b>	<b>16,052</b>
<b>Total current assets</b>		<b>23,756</b>	<b>30,486</b>
<b>Total assets</b>		<b>621,845</b>	<b>730,260</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
<b>Restricted equity</b>			
Share capital	28	833	833
<b>Total</b>		<b>833</b>	<b>833</b>
<b>Non-restricted equity</b>			
Retained earnings		497,360	528,225
Profit/loss for the year		-29,662	-30,865
<b>Total</b>		<b>467,698</b>	<b>497,360</b>
<b>Total equity</b>		<b>468,531</b>	<b>498,193</b>
<b>Non-current liabilities</b>			
Debt to shareholders	29	50,000	–
<b>Total</b>		<b>50,000</b>	<b>–</b>
<b>Current liabilities</b>			
Bond loan	29	–	225,259
Liabilities to credit institutions	29	100,000	–
Accounts payable		85	93
Other current liabilities		809	1,009
Accrued expenses and deferred income	31	2,420	5,706
<b>Total</b>		<b>103,314</b>	<b>232,067</b>
<b>Total liabilities</b>		<b>153,314</b>	<b>232,067</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>621,845</b>	<b>730,260</b>

## Changes in equity, parent company

Amounts in TSEK	Share capital	Restricted equity	Retained earnings including net profit for the year	Total equity
<b>Opening balance 1 January 2015</b>	833	–	528,225	529,058
<b>Comprehensive income</b>				
Profit/loss for the year	–	–	-30,865	-30,865
<b>Total comprehensive income</b>	–	–	-30,865	-30,865
Total transactions with shareholders	–	–	–	–
<b>Closing balance 31 December 2015</b>	833	–	497,360	498,193
<b>Opening balance 1 January 2016</b>	833	–	497,360	498,193
<b>Comprehensive income</b>				
Profit/loss for the year	–	–	-29,662	-29,662
<b>Total comprehensive income</b>	–	–	-29,662	-29,662
Total transactions with shareholders	–	–	–	–
<b>Closing balance 31 December 2016</b>	833	–	467,698	468,531

## Cash flow statement, parent company

Amounts in TSEK	2016	2015
<b>Cash flow from operating activities</b>		
Net profit/loss for the year	-29,662	-30,865
Adjustment for non-cash flow items:	-2,057	-3,893
	<b>-31,719</b>	<b>-34,758</b>
Increase/decrease other current liabilities and receivables	-7,400	6,691
<b>Cash flow from operating activities</b>	<b>-39,119</b>	<b>-28,067</b>
<b>Cash flow from investing activities</b>	<b>-</b>	<b>-</b>
<b>Financing activities</b>		
Amortisation of loan	-227,500	-
Borrowings	150,000	-
Change in receivables from group companies	101,684	-43,200
<b>Cash flow from financing activities</b>	<b>24,184</b>	<b>-43,200</b>
Cash flow for the year	-14,934	-71,267
Cash and cash equivalents at start of year	16,052	87,319
<b>Cash and cash equivalents at end of year</b>	<b>1,118</b>	<b>16,052</b>



# Notes

## NOTE 1 General information

Bactiguard Holding AB, corporate identity number 556822-1187, is a limited company registered in Sweden and domiciled in Stockholm. The address of the headquarters is Box 15, 146 21 Tullinge. The operations of the company and its subsidiaries (‘the Group’) are conducted in south Stockholm (headquarters and production facilities) and in Malaysia (production facilities). The operations cover research and development, production, marketing and sales of the company’s products and technical solutions.

## NOTE 2 Significant accounting policies

The consolidated financial statements for Bactiguard Holding AB have been prepared in accordance with International Financial Reporting Standards (IFRS) as approved by the EU and the interpretations of the IFRS Interpretations Committee (IFRIC) as per 31 December 2016.

In addition, the Group applies the Swedish Annual Accounts Act and the Swedish Financial Reporting Board’s recommendation RFR 1 ‘Supplementary rules for Group accounting’.

Items in the consolidated financial statements have been prepared on a cost basis, except for certain financial instruments which are stated at fair value. The functional currency of the parent company is the Swedish krona, which is also the presentation currency of the Group. All amounts are specified in thousands unless otherwise stated. The significant accounting policies which have been applied are described below.

### New and amended standards and interpretations that enter into force in 2016

New or amended standards and new interpretations have not had any significant impact on the Group’s financial reports of 2016.

### New and amended standards and interpretations that have not yet entered into force

New and amended standards and interpretations that have been issued but which enter into force for the financial year starting after 1 January 2017 have not yet been applied by the Group. The new and amended standards and interpretations determined to have an impact on the consolidated financial reporting for the period they are applied for the first time are described below.

Standards	Shall be applied for the financial year starting:
IFRS 9 Financial Instruments	1 January 2018 or later
IFRS 15 Revenue from contracts with customers	1 January 2018 or later
IFRS 16 Leases	1 January 2019 or later

IFRS 9 Financial instruments issued on 24 July 2014 and shall replace IAS 39 Financial Instruments: Recognition and Measurement. The standard is issued in phases where the version issued in July 2014 replaces previous versions.

IFRS 9 contains new principles on how financial assets should be classified and valued. The company’s purpose of the holding of the asset (i.e. the company’s ‘business model’) and the financial asset’s contractual cash flows are decisive for which valuation category a financial belongs to.

The new standard also contains new rules for impairment testing of financial assets which entails that the previous ‘incurred loss method’ is replaced by a new ‘expected loss method.’

The aim of the new rules for hedge accounting is that the company’s risk management should be reflected in the accounting. The standard entails greater opportunities to hedge risk components in non-financial items and for more types of instruments to be included in a hedging relationship. Furthermore, the quantitative requirement for efficiency no longer remains. IFRS 9 is applicable to the financial year which starts on 1 January 2018 and it has been adopted by the EU. The management’s assessment is that application of IFRS 9 may impact the recognised amounts in the financial reporting in respect to the consolidated financial assets and liabilities. Management has not yet conducted a detailed analysis of the impact resulting from application of IFRS 9 and can therefore not quantify this.

IFRS 15 Revenue from contracts with customers was issued on 28 May 2014 and shall replace IAS 18 Revenue and IAS 11 Construction contracts. IFRS 15 entails one model for revenue recognition for almost all revenue arising from contracts with customers, except lease contracts, financial instruments and insurance contracts. According to IFRS 15, the basic principle for revenue recognition is that a company should recognise revenue to depict the transfer of promised goods or services to customers, by an amount which the company expects to receive in exchange for the goods or services. Revenue is recognised when the customer obtains control over goods or services. There is significantly more guidance in IFRS 15 for specific areas and the disclosure requirements are extensive. IFRS 15 applies to the financial year starting on 1

January 2018 or later with previous application being permitted. The standard has been adopted by the EU. Management has not yet conducted a detailed analysis of the impact resulting from application of IFRS 15 and can therefore not quantify this.

IFRS 16 Leases was issued on 13 January 2016 and shall replace IAS 17 Leases. IFRS 16 introduces a ‘right of use model’ and for the lessee it largely entails that all leases should be recognised in the balance sheet, therefore classification in operational and financial leases should not be conducted. Leases with a leasing period which is 12 months or shorter and leases which amount to smaller values are exceptions. In the income statement depreciation is recognised on assets and interest expenses on liabilities. The standard contains more extensive disclosure requirements compared to the current standard. IFRS 16 does not entail any real differences compared to IAS 17 for lessors. IFRS 16 applies to the financial year which starts on 1 January 2019 with earlier application permitted, provided that IFRS 15 is applied simultaneously. The standard has not been adopted by the EU yet. Management has not yet conducted a detailed analysis of the impact resulting from application of IFRS 16 and can therefore not quantify this.

The management assesses that other new or amended standards and new interpretations, which have not entered into force, are not expected to have any material impact on the Group’s financial reports when they are applied the first time.

### Accounting policies for the parent company

#### Amended accounting policies

The amendments to RFR 2 have not had any material impact on the parent company’s financial reports for 2016.

#### Amendments to RFR 2 which have not yet entered into force

The amendments to RFR 2 Accounting for Legal Entities which enter into force as of 1 January 2017 mainly refer to the following areas:

IFRS 7 Financial instruments: Disclosures  
Increased disclosure requirements for legal entities in order to clarify the signification of ‘starting point of cost value in accordance with the Swedish Annual Accounts Act.’ Covers the accounting policies for financial instruments, principles for hedge accounting and principles for derecognition from the balance sheet. Larger companies should also provide disclosures on derivative instruments which are not valued at fair value as well as disclosures on outstanding loans which are convertible or associated with right of option for subscription or similar securities. The amendment will entail extended accounting policies.

The management assesses that other amendments to RFR 2, which have not entered into force, are not expected to have any material impact on the parent company’s financial reports when they are applied the first time.

### Consolidated financial statements

The consolidated financial statements cover the parent company Bactiguard Holding AB and those companies over which the parent company has direct or indirect control (subsidiaries). Control involves the entitlement to directly or indirectly design strategies of a company in order to obtain economic benefits. In determining whether control exists, any shareholder agreements or potential voting shares that may be utilised or converted without delay shall be considered. Control normally exists when the parent company directly or indirectly holds shares representing more than 50 % of the votes.

Subsidiaries are consolidated in the financial statements as of the acquisition date, and are excluded from consolidation as of the date when such control ceases.

Group profit and components of other comprehensive income are attributable to the parent company’s owners and to holdings without control, even when this leads to negative value of the holding without control.

The accounting policies for subsidiaries have been amended, when necessary, to ensure consistent application of the Group’s accounting policies. All intra-group transactions, dealings and unrealised gains and losses attributable to intra-group transactions have been eliminated when preparing the consolidated financial statements.

### Transactions with holdings without control

Changes to the parent company’s share of a subsidiary that do not lead to a loss of control are recognised as equity transactions (that is, as transactions with the Group’s owners). Any difference between the amounts with which the holding without control is adjusted and the fair value of the paid or received compensation is recognised immediately in equity and allocated to the parent company’s owners.

### Loss of control

If the parent company loses control over a subsidiary, the gain or loss is measured at the time of disposal as the difference between:

- i) the total of the fair value for the compensation received and the fair value of any remaining holding, and

ii) the previous carrying amount for the subsidiary's assets (including goodwill), and liabilities, and any holding without control.

### Business combinations

#### Business combinations are recognised using the acquisition method.

The cost of business combinations is carried at fair value on the acquisition date, and is measured as the sum of the fair value on the acquisition date for the assets paid, any incurred or assumed liabilities, and the equity interest issued in exchange for control of the acquired business. Acquisition-related costs are recognised in the income statement when they are incurred.

The identifiable acquired assets and assumed liabilities, and contingent assets are recognised at fair value on the acquisition date with the following exceptions:

- Deferred tax assets or liabilities and liabilities or assets attributable to the business combination agreements for remuneration to employees are recognised and valued in accordance with IAS 12 Income taxes and IAS 19 Employees benefits.
- Liabilities or equity instruments attributable to the acquired business' share-based allocations or to the exchange of the acquired businesses' share-based allocations against the acquiring entity's share-based allocations are valued on the acquisition date in accordance with IFRS 2 Share-based payment.
- Non-current assets (or disposal groups) classified as held for sale according to IFRS 5. Non-current assets held for sale and discontinued operations are measured according to the standard.

Contingent liabilities assumed in a business combination are recognised as though they are existing liabilities that are the result of past events, and whose fair value can be measured reliably.

For business combinations where the total purchase price, any holding without control, and fair value on the acquisition date of previous shareholding, exceeds the fair value of identifiable acquired net assets on the acquisition date, the difference is recognised as goodwill in the statement of financial position. If the difference is negative, this is recognised as a profit on an acquisition at a low price immediately in the income statement after testing the difference.

In every business combination, the previous holding without control in the acquired business is carried either at fair value or at the value of the proportional share of the holding without control in the identifiable net assets in the acquired business.

#### Participations in associated companies

Participations in associated companies are recognised using the equity method.

#### Goodwill

Goodwill arising from acquisition of subsidiaries is measured as the amount where the total purchase price, any holding without control and fair value on the acquisition date of previous shareholding exceeds the fair value on the acquisition date of the identifiable acquired net assets. Goodwill that arises during the acquisition of subsidiaries is recognised at cost less any accumulated impairments.

For impairment testing, goodwill is allocated to the cash generating units that are expected to benefit from synergies expected from combining operations. Goodwill shall be tested for impairment annually, or more often whenever events indicate that the carrying amount may not be recoverable. If the recovery value of a cash generating unit is determined to be lower than the carrying amount, the amount of write-down is allocated, first by reducing the carrying amount for goodwill attributable to the cash generating unit and then by the carrying amount for goodwill attributable to the other assets in the unit. A recognised impairment of goodwill cannot be reversed in a later period.

During the sale of a subsidiary, the remaining carrying amount for goodwill is included in the calculation of the capital gain or loss.

#### Operating segments

Operating segments are components of a company that engages in business activities from which it may earn revenues and incur expenses, whose operating profit/loss is audited regularly by the company's chief operating decision maker, and for which independent financial information is available. The company's reporting of operating segments matches the internal reporting to the chief operating decision maker. The chief operating decision maker is the function that assesses the operating segment's results and makes decisions on the allocation of resources. The company's assessment is that the group management is the chief operating decision maker.

The company is deemed to operate entirely within a single operating segment.

#### Revenues

Group revenues are mainly derived from license revenues and revenues from the sale of BIP products. Revenues are recognised at the fair value of the

compensation received or will be received, less VAT, discounts and similar deductions.

#### Sale of goods

Revenues from the sale of goods are recognised when the goods are delivered and ownership is transferred to the customer when all the following conditions have been fulfilled:

- Risks and benefits associated with the ownership of the goods have been transferred to the buyer
- The Group does not have any continued involvement in the regular management which is associated with ownership and nor does it have control over the sold goods
- Revenues and associated costs can be measured reliably
- It is probable that the economic benefits associated with the transaction will accrue to the Group.

The afore-mentioned entails that each agreement requires an analysis of the circumstances and conditions which impact the transaction.

#### Royalties

Group revenues from royalties are derived from license revenues. Revenues are recognised continuously on an accruals basis on the outcome of sales in accordance with the economic substance of the relevant agreement.

#### Sales of rights

When the Group concludes a distribution agreement with respect to rights for a geographic market and with a right to call the products, they are recognised as accounts receivable and deferred income by the amounts determined in the agreements. The timing of revenue recognition and deduction against deferred income takes place when the products are delivered.

#### Dividends and interest income

Dividends are recognised when the shareholder's right to receive payment has been established.

Interest income is recognised as revenue allocated over the duration using the effective interest method. The effective interest rate is the rate at which the present value of all future receipts and payments over the fixed rate period are equal to the carrying amount of the receivable.

#### Lease agreements

A finance lease agreement is an agreement that substantially transfers all the economic risks and rewards associated with ownership of an object from the lessee to the lessor. Other lease agreements are classified as operating lease agreements. The Group has only concluded operating lease agreements.

Leasing fees from operating lease agreements are charged on a straight-line basis over the lease term unless other systematic methods better reflect the economic utility of users over time.

#### Foreign currencies

Items in the individual financial statements of each group entity are presented in the currency of the primary economic environment in which each entity primarily operates (its functional currency). All amounts in the consolidated financial statements are translated to Swedish krona (SEK), which is the parent company's functional and reporting currency.

Foreign currency transactions in each entity are translated into the entity's functional currency according to prevailing exchange rates on the transaction date. On each balance sheet date, monetary items in foreign currency are translated at the exchange rate on the balance sheet date. Non-monetary items, carried at fair value in a foreign currency, are translated at the rate that existed when the fair value was determined.

Non-monetary items, carried at historical cost in a foreign currency are not translated.

Exchange rate differences are recognised in the income statement for the period in which they arise, except for transactions that are hedges that fulfil the conditions for hedge accounting of cash flows or for net investments, where the gain or loss is recognised in other comprehensive income.

In preparing these consolidated financial statements, foreign subsidiaries' assets and liabilities are translated to Swedish krona using the exchange rate on the balance sheet date. Revenue and cost items are translated to the average exchange rate for the period, unless the exchange rate has fluctuated significantly during the period, whereby the exchange rate on the transaction date is used instead. Any translation differences that arise are recognised in other comprehensive income and transferred to the Group's translation reserve. On disposal of a foreign subsidiary, such translation differences are recognised in the income statement as a part of the capital gain or loss.

Goodwill and changes to fair value that arise in the acquisition of a foreign business are treated as assets and liabilities of the operations and translated at the exchange rate on the balance sheet date.

### Borrowing costs

Borrowing costs that are directly attributable to the acquisition, construction or production of an asset that necessarily takes a substantial period of time to complete for its intended use or sale are included in the cost of the asset up to the time the asset is completed for its intended use or sale. Interest income from the temporary investment of such borrowings is deducted from the borrowing costs that are recognised in the asset's cost.

Other borrowing costs are recognised in the income statement in the period they arise.

### Employee benefits

Employee benefits in the form of salaries, bonus, paid vacation, paid sick leave, and similar, as well as pensions are reported as they are incurred. Pensions and other benefits after terminated employment are classified as defined contribution or defined benefit pension plans. The Group only has defined contribution pension plans.

### Defined contribution plans

The company pays fixed fees to a separate independent legal entity for defined contribution plans and has no liability to pay additional fees. Group earnings are charged for costs as the benefits are earned, which normally coincides with the date when the premiums are paid.

### Taxes

Tax expense is the sum of current and deferred tax.

#### Current tax

Current tax is measured as the taxable earnings for the period. Taxable earnings differ from the profit shown in the income statement, which includes non-taxable revenue and non-deductible expenses, and revenues and costs that were taxable or deductible in other periods. The Group's current tax liabilities are calculated applying the tax rates that have been decided or advised as of the balance sheet date.

#### Deferred tax

Deferred tax is recognised for all temporary differences that arise between the carrying amount of the assets and liabilities in the financial reports and the taxable amounts used when calculating taxable income. Deferred tax is recognised, using the balance sheet liability method. In principle deferred tax liabilities are recognised for all taxable temporary differences, and in principle deferred tax assets are recognised for all deductible temporary differences to the extent it is probable that the amounts can be utilised against future taxable profit. Deferred tax liabilities and tax assets are not recognised if the temporary difference is attributable to goodwill or if it arises from a transaction that is the first reporting of an asset or liability (that is not a business combination) and which, on the transaction date, does not affect reported or taxable income.

Deferred tax liabilities are recognised for taxable temporary differences attributable to investments in subsidiaries, except when the date for reversing the temporary differences can be controlled by the Group and it is probable that such a reversal will not take place in the foreseeable future. The deferred tax assets that are attributable to deductible temporary differences related to such investments shall only be recognised to the extent it is probable that the amounts can be utilised against future taxable profit and it is probable that these will be utilised in the foreseeable future.

The carrying amount for deferred tax assets is reviewed at the end of each reporting period and reduced to the extent it is no longer probable that sufficient taxable profit will be available to be utilised, wholly or partially, against the deferred tax assets.

Deferred tax is measured at the tax rates that are expected to apply for the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been decided or notified on the balance sheet date.

Deferred tax assets and tax liabilities are offset when they are attributable to income tax levied by the same authority and when the Group intends to settle the tax with a net amount.

#### Current and deferred tax for the period

Current and deferred tax is recognised as an expense or revenue in the income statement, except when the tax arises from transactions that are recognised as other comprehensive income or directly against equity. In such cases, the tax is also reported in other comprehensive income or directly against equity. For current and deferred tax that arises during reporting of business combinations, the tax effect should be recognised in the acquisition calculation.

### Property, plant and equipment

Property, plant and equipment is recognised at cost less accumulated depreciation and any accumulated impairments.

The cost consists of the purchase price, costs directly attributable to bringing the asset to the site and working condition for its intended use, and the esti-

mated cost of dismantling and removing the asset, and restoring the site where it is located. Additional costs are included only if the asset is recognised as a separate asset, when it is probable that the future economic benefits that can be attributed to the item will flow to the Group and the cost for the same can be measured reliably. All other costs for repairs, maintenance and additional fees are recognised in the income statement for the period they arise.

Depreciation of property, plant and equipment is written off so that the asset's value less the estimated residual value at the end of the useful life, is depreciated on a straight-line basis over the estimated useful life, which is assessed as:

Improvements, leasehold	5–15 years
Machinery and other technical plant	5 years
Equipment, tools and installations	5 years

Estimated useful life, residual values, and depreciation methods are retested at least at the end of each financial period, the effect of any changes to assessments is recognised prospectively.

The carrying amount for property, plant and equipment is derecognised in the statement of financial position when it is retired or disposed, or when no future economic benefits are expected from the use or retirement/disposal of the asset. The gain or loss that arises when the asset is retired or disposed, is the difference between any net revenue during disposal and the carrying amounts recognised in profit for the period when the asset is derecognised in the statement of financial position.

### Intangible assets

#### Separately acquired intangible assets

Intangible assets with a determinable useful life that are acquired separately are recognised at cost less accumulated depreciation and any accumulated impairments. Depreciation takes place on a straight-line basis over the asset's estimated useful life. Estimated useful life and depreciation methods are retested at least at the end of each financial year, the effect of any changes to assessments is recognised prospectively.

#### Internally generated intangible assets – Capitalised expenses for product development

Internally generated intangible assets that derive from the Group's product development are only recognised when the following conditions are met:

- It is technically feasible to complete the intangible asset so that it is available for use or sale,
- The company intends to complete the intangible asset and to use or sell it,
- Conditions are present to use or sell the intangible asset,
- The company demonstrates how the intangible asset will generate reliable future economic benefits,
- Adequate technological, financial, and other resources are available to complete development and to use or sell the intangible asset, and
- The expenses directly attributable to the intangible assets during its development can be measured reliably.

If no internally generated intangible assets can be recognised, then expenses for development thereof are recognised as a cost in the period when they are incurred.

After they are first recognised, internally generated intangible assets are carried at cost less accumulated depreciation and any accumulated impairments.

#### Intangible assets acquired in a business combination

Intangible assets acquired through a business combination are identified and recognised separately from goodwill when they meet the definition of an intangible asset and their fair value can be measured reliably. The cost of such intangible assets comprises their fair value on the acquisition date.

After they are first recognised, intangible assets acquired in a business combination are carried at cost less accumulated depreciation and any accumulated impairments in the same way as with separately acquired intangible assets.

#### Estimated useful life for intangible assets

Technology	15 years
Customer relationships	15 years
Patents	20 years
Capitalised expenses for product development	5 years
Brands	Indeterminable useful life

#### Disposals and retirements

An intangible asset is derecognised in the statement of financial position when it is retired or disposed, or when no future economic benefits are expected from the use or retirement/disposal of the asset. The gain or loss that arises when an intangible asset is derecognised in the statement of financial position, comprises of the difference between the payment received during the disposal and the asset's carrying amount, and is recognised in the income statement when the asset is derecognised from the statement of financial position.



### Impairment of tangible assets and intangible assets excluding goodwill

On each balance sheet date, the Group analyses tangible and intangible assets to determine whether there is evidence that these assets have decreased in value. If so, the asset's recovery value is measured to determine the value of any impairment. If it is not possible to determine the recovery value of an individual asset, the Group measures the recovery value of the cash generating unit to which the asset belongs.

Intangible assets with indeterminable useful life and intangible assets that are not yet finished for use shall be tested for impairment annually, or when there is evidence of loss in value.

The recoverable amount is the higher of the fair value less selling cost and its value in use. When measuring value in use, an estimate of the future cash flows is discounted to present value using the pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

If the recovery value of an asset (or a cash generating unit) is determined to be below the carrying amount, an impairment loss is recognised for the carrying amount of the asset (or the cash generating unit) to reflect the recovery value. The impairment loss is immediately recognised as an expense in the income statement.

When an impairment loss is reversed, the carrying value of the asset (or the cash generating unit) is revalued to reflect the increase in recovery value, but this increased recovery value may not exceed what the depreciated historical cost would have been if the impairment of the asset had not been recognised (or cash generating unit). Reversal of an impairment loss is recognised directly in the income statement.

### Financial instruments

Financial assets or liabilities are recognised in the balance sheet when the company becomes a party in the contractual terms of the instrument. A financial asset or a portion of a financial asset is derecognised from the balance sheet when the contractual rights are realised, mature or when the company loses control over it. Financial liabilities or portions of financial liabilities are derecognised in the balance sheet when the agreed obligation is performed or is extinguished in another manner.

On each balance sheet date, the company evaluates whether there is objective evidence that a financial asset or group of financial assets is impaired as a result of past events. Examples of such events include the significant deterioration in the financial position of the counterparty or failure to pay an amount which is due.

Financial assets and financial liabilities that are not measured at fair value through the income statement in a subsequent period, are recognised in the original period at fair value including transaction costs (which are added or deducted, respectively). Financial assets and financial liabilities that are measured at fair value through the income statement in the subsequent period, are recognised in the original period at fair value. In the subsequent period the financial instruments are measured at amortised cost or at fair value depending on the initial classification under IAS 39.

In the original period, financial assets or financial liabilities are classified as one of the following classes:

#### Financial assets

- Fair value through the income statement
- Loans and accounts receivable
- Investments held to maturity
- Financial assets available for sale

#### Financial liabilities

- Fair value through the income statement
- Other financial liabilities measured at amortised cost

### The fair value of financial instruments

The fair value of financial assets and financial liabilities is measured as follows:

The fair value of financial assets and liabilities that have standard conditions that are traded on an active market is measured in relation to the quoted market price.

The fair value of other financial assets and liabilities is determined according to generally accepted valuation models that are based on information obtained from observable current market transactions.

The carrying amounts of all financial assets and liabilities are deemed to be a reasonable approximation of their fair value, unless otherwise specifically stated in the following notes.

### Amortised cost

Amortised cost is the amount at which the asset or liability is measured at initial recognition, less principal repayments and plus or minus any accumulated

accruals using the effective interest method of the initial difference between the amounts received or paid and amounts to be received or paid on the due date and less depreciation. The effective rate is the interest rate at which, when discounting all estimated future cash flows over the expected maturity, results in the initial carrying amount of the financial asset or the financial liability.

### Offsetting financial assets and financial liabilities

Financial assets and financial liabilities are offset and recognised as a net amount in the balance sheet when there is a legal right to offset and when the intention is to settle the items on a net basis or to simultaneously realise the asset and settle the liability.

### Cash and cash equivalents

Cash and cash equivalents include cash assets and bank balances, and other short-term securities that are readily convertible to cash and are subject to an insignificant risk of changes in value. Classification as cash or cash equivalents requires that the maturity does not exceed three months from the date of the acquisition. Cash assets and bank balances are classified as 'Loans and accounts receivable' and these are carried at amortised cost. Since bank deposits are payable on demand, amortised cost equals the nominal amount. Short-term investments are classified as 'Held for trading' and are carried at fair value with value fluctuations recognised in the income statement.

### Accounts receivable

Accounts receivable are classified as 'Loans and accounts receivable' and these are carried at amortised cost. Accounts receivable with a maturity greater than 12 months are recognised as financial assets and are discounted. Receivables assessed as doubtful are deducted. Any impairments for accounts receivable are recognised as operating expenses.

### Accounts payable

Accounts payable are classified as 'Other financial liabilities' and these are carried at amortised cost. However, the expected maturity of accounts payable is short, so the liability is recognised at the nominal amount and is not discounted.

### Borrowing from credit institutions and other loans

Interest-bearing bank borrowings, bank overdraft, and other borrowings are classified as 'Other financial liabilities' and are carried at amortised cost. Any differences between the amount received (net transaction costs) and the repayment amount of the loan is recognised in the income statement over the borrowing period using the effective interest method.

### Bond loan

The corporate bond comprises a loan contract (a liability component) and an embedded derivative. The liability component is normally recognised at amortised cost and the embedded derivative is carried, under certain conditions, at fair value in the same way as a separate derivative instrument. The embedded derivative arises in that the bond repayment amount is determined by the Group's EBITDA for a specified future period. Rather than carry the liability component and the embedded derivative separately, the Group has chosen to carry the entire combined instrument (both the liability component and the embedded derivative together) at fair value. The value fluctuations that arise are recognised in the net interest income in the income statement. The combined instrument is classified as 'fair value through the income statement'.

The bond loan matured for payment in December 2016 and was then paid in its entirety.

### Derivative instruments

Currency forwards are used to hedge foreign currency flows. The hedge instrument is recognised separately at fair value in the balance sheet with the value fluctuations in the income statement. The Group has not used any derivative instruments during the year.

### Inventories

Inventories are carried at the lowest of cost or net realisable value. Cost is measured by first applying, the FIFO (First in, first out) method. Net realisable value is the expected sales price less expected costs necessary for completion and expected costs necessary for a sale.

### Provisions

Provisions are recognised when the Group has a legal or informal obligation based on past events, it is probable that an outflow of resources will be required to settle the obligation, and the amount can be reliably measured.

The amount reserved is the best estimate of the amount required to settle the existing obligation on the balance sheet date, considering the risks and uncertainties associated with the obligation. When a provision is measured by estimating the payments expected to be required to settle the obligation, the

carrying amount shall correspond to the present value of these payments.

When a part or all of the amount required to settle a provision is expected to be repaid by a third party, the reimbursement shall be separately reported as an asset in the statement of financial position when the realisation of income is virtually certain if the company settles the obligation and the amount can be reliably measured.

#### Accounting policies for the parent company

The parent company applies the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's Recommendation (RFR 2) Accounting for legal entities. The application of RFR 2 means that the parent company, to the extent possible, follows all the EU approved IFRS within the framework of the Swedish Annual Accounts Act and the Swedish Pension Obligations Vesting Act and considers the relationship between accounting and taxation. The changes in RFR 2.

The differences between the accounting policies of the parent company and the Group are described below.

#### Classification and format

The parent company's income statement and balance sheet follow the format specified in the Swedish Annual Accounts Act. The differences from IAS 1 Presentation of Financial Statements that were used in preparing the Group's financial statements are primarily recognising revenues and costs, non-current assets, equity, and the introduction of provisions as a separate item.

#### Subsidiaries

Shares in subsidiaries are recognised at cost in the parent company's financial statements. Acquisition-related costs for subsidiaries that are charged in the consolidated financial statements are included as a part of the cost for shares in subsidiaries.

#### Group contributions

A group contribution received by the parent company from a subsidiary is recognised using the same policies as regular dividends from that subsidiary, which entails that the group contribution is recognised as financial income.

Group contributions from the parent company to a subsidiary are recognised in the income statement as an appropriation.

#### Pensions

The parent company's pension commitments have been calculated and recognised based on the Swedish Pension Obligations Vesting Act. Applying the Swedish Pension Obligations Vesting Act is a prerequisite for tax deductibility.

#### Financial instruments

The parent company does not apply IAS 39 Financial instruments: Recognition and measurement. The parent company applies a method based on cost in accordance with the Swedish Annual Accounts Act.

#### Definitions for key ratios

##### Equity ratio

Equity and untaxed reserves (less deferred tax) in relation to the balance sheet total.

##### Net debt

Interest-bearing liabilities less cash and cash equivalents.

##### EBITDA

Earnings before interest, taxes, depreciation and amortisation.

##### EBITDA margin

EBITDA/revenue.

##### Earnings per share

Earnings for the period/weighted average number of shares during the period, issue-adjusted.

##### Operating cash flow

Cash flow from operating activities after investments and changes in working capital.

##### Financial income and expense

Financial income minus financial expense.

#### Alternative Performance Measures

The Company presents certain financial measures in the interim report that are not defined under IFRS. The Company believes that these measures provide useful supplemental information to investors and the company's management as they allow for the evaluation of the company's performance. Because not all companies calculate the financial measures in the same way, these are not always comparable to measures used by other companies. Therefore, these financial measures should not be considered as substitutes for measures as defined under IFRS.

The tables below present measures that are not defined under IFRS

#### EBITDA

Shows the company's earning power from ongoing operations irrespective of capital structure and tax situation and is meant to facilitate comparisons with other companies in the same industry.

	Group	
	2016	2015
Operating profit/loss	-18,268	-12,666
Depreciation and amortisation	33,375	32,850
EBITDA	15,107	20,184

#### Net debt

Is a measurement used to describe the group's indebtedness and its ability to repay its debt with cash generated from the group's operating activities if the debts matured today.

	Group	
	2016	2015
Interest-bearing liabilities	150,000	142,140
Cash and cash equivalents	-15,645	-22,119
Net debt	134,355	120,021

#### NOTE 3 Significant accounting estimates and assessments

The most significant assumptions concerning the future, and other important sources of uncertainty in estimations on the balance sheet date, which cause a significant risk for substantial adjustment to carrying amounts for assets and liabilities in the coming financial year are described below.

#### Revenue recognition

A basic condition for revenue recognition is that revenues from sales shall be recognised when the significant risks and rewards associated with ownership are transferred to the buyer. The assessment of when these risks and rewards are transferred requires review of each contract and circumstance under which each transaction is conducted. The quantified amounts which are assessed as revenues are recognised in note 5.

#### Impairment testing of goodwill and brands

The Group conducts impairment testing annually for goodwill and brand or whenever there is an indication they may be impaired, see note 13.

#### Assessment of provisions for doubtful accounts receivable

Accounts receivable are one of the most substantial items in the balance sheet and are recognised at their nominal amount net deductions for doubtful accounts receivable. Accounts receivable with a maturity of more than 12 months are discounted. Provisions for doubtful accounts receivable are therefore subject to accounting estimates and assessments. The Group conducts continual assessments of all outstanding accounts receivable. Provisions are made for past due receivables where payment appears less probable. 46 % of accounts receivable refer to territorial fees and correspond to deferred income and advance payments from customers of the same amount, i.e. these accounts receivable have not been recognised as income yet and any provision of them would reduce deferred income and not earnings. One of the largest accounts receivable pertaining to Iraq, which the company carefully follows given the economic and political situation in the country. See note 4 for additional information regarding credit risk.

#### Calculating deferred taxes

Deferred tax assets and deferred tax liabilities are balance sheet items that are subject to accounting estimates and assessments. Deferred tax is measured based on the temporary differences that arise between recognised and taxable values of assets and liabilities. Accounting estimates and assessments impact the recognised deferred tax amounts in that the carrying amounts of various assets and liabilities must be determined, and by the fact that forecasts regarding future taxable profit regarding utilisation of deferred tax assets also depend on these.

## NOTE 4 Financial risk management and financial instruments

Group 31/12/2015	Within 3 months	3-12 months	2-5 years	Later than 5 years	Total
Bond loan	–	153,180	–	–	153,180
Accounts payable	4,017	–	–	–	4,017
Bank overdraft	–	–	–	–	–
<b>Total</b>	<b>4,017</b>	<b>153,180</b>	<b>–</b>	<b>–</b>	<b>157,197</b>
<b>Group 31/12/2016</b>					
Debt to shareholders	535	1,337	50,880	–	52,752
Liabilities to credit institutions	1,069	102,674	–	–	103,743
Accounts payable	4,896	–	–	–	4,896
Bank overdraft	–	–	–	–	–
<b>Total</b>	<b>6,500</b>	<b>104,011</b>	<b>50,880</b>	<b>–</b>	<b>161,391</b>
<b>The parent company 31/12/2015</b>					
Bond loan	–	252,525	–	–	252,525
Liabilities to group companies	–	–	–	–	–
Accounts payable	93	–	–	–	93
<b>Total</b>	<b>93</b>	<b>252,525</b>	<b>–</b>	<b>–</b>	<b>252,618</b>
<b>The parent company 31/12/2016</b>					
Debt to shareholders	535	1,337	50,880	–	52,752
Liabilities to credit institutions	1,069	102,674	–	–	103,743
Accounts payable	85	–	–	–	85
<b>Total</b>	<b>1,689</b>	<b>104,011</b>	<b>50,880</b>	<b>–</b>	<b>156,580</b>

Through its activities, the Group is exposed to various types of risk. The Group's objective is to create a comprehensive risk management programme that concentrates on minimising potential unfavourable effects on financial results. The company's Board of Directors is ultimately responsible for the exposures, management and follow-up of the Group's risks. The frameworks that apply to the exposures, management, and follow-up of financial risks are set by the Board of Directors and revised annually. The Board of Directors has delegated responsibility for daily risk management to the company's CEO, who in turn has delegated this to the company's CFO. The Board of Directors is able to decide on temporary departures from these established frameworks. The financial risks Bactiguard is thus exposed to are addressed separately below.

### Liquidity and financing risks

Liquidity and financing risks involve the risk of not being able to meet payment obligations due to having insufficient liquidity or difficulties in obtaining external loans. The table above illustrates the Group's liquidity risks using a maturity analysis of financial liabilities. The amounts in these tables are not discounted values and they also contain, where applicable, interest payments, whereby these amounts cannot be reconciled against the amounts reported in the balance sheets. Interest payments are determined based on conditions which apply on the balance sheet date. Amounts in foreign currencies are translated to Swedish krona on the balance sheet date exchange rates.

The company manages liquidity and financing risks through continual monitoring of liquidity forecasts. After refinancing of the company's bond loan was completed, the company has continued to work to ensure a long-term financing solution at market conditions in accordance with the table above.

### Credit and counterparty risk

Credit risk refers to the risk that a counterparty in a transaction causes a loss to the Group by not fulfilling its contractual obligations. The Group's exposure to credit risk is primarily attributable to accounts receivable. To limit the Group's credit risk, every new customer is subjected to a credit analysis. The financial situation for existing customers is also continually monitored to identify warning signals at an early stage.

Accounts receivable are spread to a large number of customers where, however, a few of these represent a substantial amount of total accounts receivable. One of the largest accounts receivable pertaining to Iraq, which the company carefully follows given the economic and political situation in the country.

Accounts receivable are not concentrated to any single geographic area. No substantial concentration of credit risk. Sales of goods are only made to customers for which the credit risk is assessed as small. Bactiguard uses the Swedish Export Credits Guarantee Board's assessment of credit worthiness in each country. The greatest exposure to credit risk is identified in the carrying amount in the balance sheet for each financial asset respectively.

### Financial instruments

All financial instruments are classified based on measurement categories in accordance with IAS 39. The table below shows the Group's financial assets for each measurement category and the carrying amount and fair value for each item.

	31/12/2016		31/12/2015	
	Carrying amount	Fair value	Carrying amount	Fair value
<b>Financial assets</b>				
<i>Loans and accounts receivable:</i>				
Accounts receivable	43,812	43,812	57,646	57,646
Cash and cash equivalents	15,645	15,645	22,119	22,119
<b>Total financial assets</b>	<b>59,457</b>	<b>59,457</b>	<b>79,765</b>	<b>79,765</b>
<b>Financial liabilities</b>				
Long-term interest-bearing liabilities	50,000	50,000	–	–
Short-term interest-bearing liabilities	100,000	100,000	142,140	142,140
Accounts payable	4,896	4,896	4,017	4,017
Other liabilities	38,358	38,358	77,879	77,879
<b>Total financial liabilities</b>	<b>193,254</b>	<b>193,254</b>	<b>224,036</b>	<b>224,036</b>



## Contd. Note 4 Financial risk management and financial instruments

	31/12/2016			31/12/2015		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<b>Financial assets</b>						
Accounts receivable	–	–	16,170	–	–	6,012
<b>Total financial assets</b>	<b>–</b>	<b>–</b>	<b>16,170</b>	<b>–</b>	<b>–</b>	<b>6,012</b>
<b>Financial liabilities</b>						
Advance payments from customers	–	–	18,207	–	–	–
Bond loan	–	–	–	142,140	–	–
<b>Total financial liabilities</b>	<b>–</b>	<b>–</b>	<b>18,207</b>	<b>142,140</b>	<b>–</b>	<b>–</b>

### Measurement of financial instruments at fair value

Financial assets and financial liabilities measured at fair value in the balance sheet consist of non-current accounts receivable and the bond loan. The Group's other financial assets and financial liabilities are assessed as having carrying amounts that reasonably approximate their fair value. A measure of fair value based on discounted future cash flows, where a discount rate that reflects the counterparty's credit risk provides the most important input data, is seen as not showing a substantial difference compared to the carrying value.

The table above presents the Group's financial assets and liabilities measured at fair value and how they were classified in the fair value hierarchy. The different levels are defined as follows:

Level 1 – Quoted prices (unadjusted) in active markets for identical assets or liabilities that the company can access on the measurement date. A market is considered as active if transactions for the asset or liability take place with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 – Other input data than the quoted prices included in Level 1, which is directly or indirectly observable for the asset or liability.

Level 3 – Unobservable input data for the asset or liability.

### Bond loan

The bond was listed on the Nasdaq Stockholm and is traded through Carnegie, Nordea, Swedbank, SEB and others and is valued at market price. The bond matured and was repaid in its entirety on 12 December 2016.

### Accounts receivable

Non-current accounts receivable with maturity longer than 12 months have been discounted.

### Capital risk management

The Group's objective of managing capital is to ensure the Group's capability to continue its operations, in order to generate reasonable returns to the shareholders and benefit other stakeholders.

The Group monitors its capital structure based on its gearing ratio. The gearing ratio is determined as the net debt divided by EBITDA (Operating result adjusted for depreciation). Net debt is calculated as interest-bearing liabilities less cash and cash equivalents.

### Currency risk

Currency risk relates to the risk that the fair value or future cash flows fluctuate due to changes in exchange rates. The exposure for currency risk primarily derives from payment flows in foreign currencies, referred to as 'transaction exposure,' and from translating balance sheet items in foreign currency and during translation of foreign subsidiaries' income statements and balance sheets to the Group's presentation currency which is Swedish krona, referred to as 'currency exposure.'

The Group's outflows primarily consist of SEK and USD while the primary inflows are USD and EUR. The Group is thereby highly affected by changes in these currency exchange rates.

Under the Group's currency policy such transaction exposure can be reduced through the use of derivative instruments. Pursuant to the currency policy, the Group may use forward contracts, swaps and currency options. If such instruments are used, hedging should take place by 40-80 % of the forecasted cash flows in USD for the next twelve months. However, as of 31 December 2016 the Group held no (-) outstanding currency contracts.

The Group's consolidated profit is primarily affected by exchange rates which are mostly attributable to USD and EUR. Under the Group's finance policy, currency exposure shall not be hedged.

### Sensitivity analysis

Based on the year's revenues, cost, and currency structures, a general one percent point change in the exchange rate between SEK and USD would impact the Group's operating profit by approximately MSEK +/- 0.9 (1.1). A similar change to the rate of SEK in relation to the EUR (one percentage point) would impact the Group's operating profit by approximately MSEK +/- 0 (0.3).

### Interest rate risk

Interest rate risk relates to the risk that the fair value or future cash flows fluctuate due to changes in market rates of interest. The Group is primarily exposed to interest rate risk through its loan financing.

As the loan runs at an interest base of Stibor 90, however minimum 0 %, and an interest surcharge of 3.5 %, Bactiguard has no direct exposure to interest rate risk. The interest rate risk in a future scenario with external long-term loans should primarily be handled through the spread of fixed rate periods.

## NOTE 5 Revenues

	Group		Parent company	
	2016	2015	2016	2015
License revenues	102,983	125,292	–	–
Sales of BIP products	15,753	6,128	–	–
Exchange rate differences	4,199	3,716	–	–
Change in inventory of finished goods and products in progress	2,102	–	–	–
Other operating revenues	3,305	3,327	7,563	7,036
<b>Total</b>	<b>128,342</b>	<b>138,463</b>	<b>7,563</b>	<b>7,036</b>

### Intra-group purchases and sales

Intra-group purchasing in the parent company for 2016 was TSEK 7,563 (7,036) and purchases were TSEK 0 (-).

## NOTE 6 Segment reporting

### Group

The information reported to the chief operating decision makers as bases for distribution of resources and assessing segment profit, is not separated into different operating segments. The Group is therefore seen as a single operating segment.

Of the Group's total revenues, sales to C.R. Bard. represent 80 % (93 %). Net revenues totalled TSEK 118,736 (131,420) allocated to the following geographic markets: America 87 % (95 %), MEA 2 % (3 %), Asia (8 %) (0.5 %), Europe 3 % (1.5 %) of which Sweden 0.5 % (0.3 %).

Of the Group's total intangible and tangible assets of TSEK 543,516 (569,285), less than 1 % (1 %) are attributable to foreign companies.

### Parent company

No sales of goods were made in the parent company for the period.

**NOTE 7** Remuneration to auditors

	Group		Parent company	
	2016	2015	2016	2015
<b>Deloitte</b>				
Audit engagements	501	532	501	532
Audit-related services	118	276	62	160
Tax consultancy	22	27	22	-
Other services	-	-	-	-
<b>Total</b>	<b>641</b>	<b>835</b>	<b>585</b>	<b>692</b>
<b>Other auditors</b>				
Audit engagements	47	51	-	-
Audit-related services	-	-	-	-
Tax consultancy	-	-	-	-
Other services	-	-	-	-
<b>Total</b>	<b>47</b>	<b>51</b>	<b>-</b>	<b>-</b>

The audit assignment refers to fees charged for the statutorily required audit. The assignment includes auditing the annual accounts and financial statements, reviewing the administration of the Board of Directors and Chief Executive Officer, and the fees for audit advice provided to the company during the audit engagement. Other auditing services refer to quality assurance services and include a review of the Group's interim financial statements and review of projects funded by the EU.

**NOTE 8** Operating leases

On the balance sheet date, the parent company and the Group had outstanding commitments in the form of minimum lease fees for non-cancellable operating lease agreements, with due dates as below:

	Group		Parent company	
	2016	2015	2016	2015
Within 1 year	9,533	9,580	-	-
Between 1 year and 5 years	36,109	36,113	-	-
After more than 5 years	58,190	67,029	-	-
<b>Total</b>	<b>103,832</b>	<b>112,722</b>	<b>-</b>	<b>-</b>

The rental commitment is the largest portion of the amounts above.

Expenses for operating lease agreements for the year totalled TSEK 9,861 (8,716) for the Group and TSEK 18 (39) for the parent company.

**NOTE 9** Number of employees, salaries, other remuneration and social security costs**Employees**

	2016		2015	
	Number of employees	Of which men	Number of employees	Of which men
<b>Average number of employees</b>				
Parent company	3	2	4	3
Swedish subsidiaries	31	13	35	15
Foreign subsidiaries	23	8	26	11
<b>Group total</b>	<b>57</b>	<b>23</b>	<b>65</b>	<b>29</b>

	2016			2015		
	Salaries and other remuneration	Social security costs	Total	Salaries and other remuneration	Social security costs	Total
<b>Total salaries and other remuneration to employees</b>						
Parent company	4,814	2,755	7,569	8,271	4,412	12,683
- of which pension costs		1,153	1,153		2,145	2,145
Swedish subsidiaries	24,997	11,389	36,386	27,376	10,428	37,804
- of which pension costs		4,644	4,644		3,898	3,898
Foreign subsidiaries	3,326	493	3,819	3,190	490	3,679
- of which pension costs		-	-		-	-
<b>Group total</b>	<b>33,137</b>	<b>14,637</b>	<b>47,774</b>	<b>38,836</b>	<b>15,330</b>	<b>54,166</b>
- of which total pension costs		5,797	5,797		6,043	6,043

Salaries and remuneration to employees excludes consultant fees, i.e. not employees. Other personnel costs totalled net TSEK -1,955 (-1,224) including capitalised personnel costs of TSEK -3,484 (-3,946) for time spent on an ongoing project.

Severance pay of TSEK 4,171 for the former CEO is included in the parent company's total salaries and social security costs for last year.

**Contd. Note 9 Number of employees, salaries, other remuneration and social security costs**

**Board of Directors and senior management**

	2016		2015	
	Board of Directors	Senior management	Board of Directors	Senior management
<b>Gender distribution in Board of Directors and senior management</b>				
Men	3	5	3	7
Women	2	5	1	6
<b>Total</b>	<b>5</b>	<b>10</b>	<b>4</b>	<b>13</b>

The CEO, also board member, is included in the Board in the above table.

Remuneration and other benefits to senior management	2016				2015			
	Salaries/ Remuneration	Other benefits	Pension	Total	Salaries/ Remuneration	Other benefits	Pension	Total
Chief Executive Officer	2,159	–	522	2,681	4,791	–	1,576	6,367
Other senior management	14,183	62	2,361	16,606	11,483	–	1,992	13,475
<b>Total</b>	<b>16,342</b>	<b>62</b>	<b>2,883</b>	<b>19,287</b>	<b>16,274</b>	<b>–</b>	<b>3,568</b>	<b>19,842</b>

The CEO of Bactiguard Holding AB was employed for the year. No agreements regarding severance pay are in effect between the company and the current CEO or other senior management. Other senior management includes, in addition to group management, the Production and Purchasing Manager, two regional sales managers, the CFO, Clinical Research Manager and Product Development and Market Access Manager. The table above includes severance pay of TSEK 3,364 contracted last year with the previously employed CEO.

Board of Directors	2016				2015			
	Salaries/ Board fee	Other remuneration	Pension	Total	Salaries/ Board fee	Other remuneration	Pension	Total
Stanley Brodén, Chairman	417	58	–	475	122	–	–	122
Peter Hentschel, Board member	179	–	–	179	122	–	–	122
Christian Kinch, Board member (Chairman up to and including June 2015)	–	–	–	–	1,538	–	288	1,826
Mia Arnhult, Board member	179	58	–	237	186	–	–	186
Marie Wickman-Chantreau, Board member as of June 2016	117	–	–	117	–	–	–	–
Ulf Mattson, Board member up to and including May 2015	–	–	–	–	63	–	–	63
<b>Total</b>	<b>892</b>	<b>116</b>	<b>–</b>	<b>1,008</b>	<b>2,033</b>	<b>–</b>	<b>288</b>	<b>2,320</b>

Bonuses, included in the afore-mentioned salaries and remuneration to the Board of Directors and CEO totalled TSEK (-). Defined benefit plans do not form any portion of the total pension costs of the Group parent company. Other remuneration comprises fees for the chair of the audit and remuneration committees.

**NOTE 10 Financial income**

	Group		Parent company	
	2016	2015	2016	2015
Interest income	2	3	1	–
Interest income, group company	–	–	4,430	5,275
Market valuation of the bond loan	4,140	2,602	–	–
Exchange rate gains	2,418	52	–	–
Other financial income	3,175	–	–	–
<b>Total financial income</b>	<b>9,735</b>	<b>2,657</b>	<b>4,431</b>	<b>5,275</b>

All interest income is attributable to financial assets that are measured at their amortised cost.

**NOTE 11 Financial expenses**

	Group		Parent company	
	2016	2015	2016	2015
Interest expenses	15,233	19,145	25,798	27,365
Interest expenses, group company	–	–	–	–
Market valuation of the bond loan	–	–	2,859	–
Exchange rate loss	326	1,816	–	–
Other financial expenses	7,241	–	2,671	309
<b>Total financial expenses</b>	<b>22,800</b>	<b>20,961</b>	<b>31,328</b>	<b>27,674</b>

The largest share of interest expenses in the Group are attributable to the bond loan. The bank overdraft facilities have been measured at their amortised cost and the bond loan has been valued at market rate. Other financial expenses include fee for the loan commitment, the discount interest of non-current accounts receivables and financing costs related to production site in Tullinge.

## NOTE 12 Taxes

	Group		Parent company	
	2016	2015	2016	2015
Nominal tax (22 %)	6,893	6,813	6,526	6,790
Tax effect non-deductible expenses	-461	-429	-1	-
Tax effect non-taxable income	-	-	-	-
Tax effect of loss carry-forwards for which no deferred tax assets are reported	4,443	1,223	-	-
Tax effect for which no deferred tax loss carry-forwards are reported	-6,493	-3,137	-6,525	-6,790
<b>Total</b>	<b>4,482</b>	<b>4,470</b>	<b>-</b>	<b>-</b>

The Group has tax loss carry-forwards as per 31 December 2016 of TSEK -284,975 (-334,399) corresponding to the maximum deferred tax asset of TSEK 62,695 (73,568), of which TSEK 33,606 (33,606) is recognised as deferred tax assets and reduced deferred tax on intangible assets in connection with Bactiguard Holding AB acquired Bactiguard AB.

The Group has not recognised the effects of temporary differences related to the market valuation of the bond loan and tangible assets.

	Group		Parent company	
	2016	2015	2016	2015
Current taxes	-	-	-	-
Deferred taxes	4,482	4,469	-	-
<b>Total</b>	<b>4,482</b>	<b>4,469</b>	<b>-</b>	<b>-</b>

### Deferred tax

Temporary differences occur whenever the carrying amounts and taxable values of assets and liabilities differ. The temporary differences of the Group and parent company have resulted in deferred tax liabilities and deferred tax assets in regard to the following items:

	Group	
	2016	2015
<b>Deferred tax assets</b>		
Loss carry-forwards	33,606	33,606
<b>Total deferred tax assets</b>	<b>33,606</b>	<b>33,606</b>
<b>Deferred tax liabilities</b>		
Intangible assets	63,891	68,373
<b>Total deferred tax liabilities</b>	<b>63,891</b>	<b>68,373</b>
<b>Total net deferred tax liabilities</b>	<b>30,285</b>	<b>34,767</b>

The deferred tax assets occurred when Bactiguard Holding acquired Bactiguard AB as a reduction of deferred tax liabilities attributable to the acquired surplus value in intangible assets. The year's change to deferred tax liabilities is attributable to temporary differences related to depreciation of intangible assets.



## NOTE 13 Goodwill

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening acquisition value	226,292	226,292	–	–
<b>Closing accumulated acquisition value</b>	<b>226,292</b>	<b>226,292</b>	<b>–</b>	<b>–</b>
<b>Net carrying amount</b>	<b>226,292</b>	<b>226,292</b>	<b>–</b>	<b>–</b>

The carrying amount of goodwill is attributable to Bactiguard Holding's acquisition of Bactiguard AB.

### Impairment testing intangible assets with indeterminable useful life

Impairment testing of goodwill and brands with indeterminable useful life is conducted annually in the Group and, when indications arise of the necessity for impairment testing. Goodwill that arose in connection with a business combination was allocated on the transfer date to the cash generating units in the Group that were expected to obtain benefits of the combination. Bactiguard Holding has a single cash generating unit.

The recoverable amount for a cash generating unit is established based on estimations of value in use. These estimations are based on expected future cash flows identified in financial forecasts that were approved by the company management that cover a 5 year period. The assessment of future cash flows includes assumptions regarding primarily sales growth, operating margins and discount rates. The discount rate of 12.8 % (13.7 %) before taxes reflects specific risks tied to the asset. The forecasted operating margin was based on previous performance and the management's expectations of the market. Growth beyond the forecasted 5 year period is expected to be 1.5 % (1.5 %) per year, which matches the Group's long-term assumptions for inflation. These assumptions are in line with the previous year's impairment testing.

The assumptions of impairment testing follow the company's growth strategy which is divided into the following four phases;

#### Phase 1

- Stable revenues from the licencing agreement with C.R. Bard
- Development of the BIP portfolio

#### Phase 2

- Develops the BIP portfolio
- Sign distribution agreements with several countries
- Obtain product approval in several countries and initiate deliveries

#### Phase 3

- Expansion to new markets
- Obtain product approvals for several countries and initiate deliveries
- Additions to the existing BIP portfolio with new variants of current products
- Develop new products
- Sign two or three new licencing agreements in the next five years

#### Phase 4

- Sign additional licencing agreements
- Increase sales generated by the BIP portfolio
- Develop new products

Bactiguard is in a growth and build-up phase, with market expansion.

Investments have been made in the sales and marketing function, the product portfolio has been developed, and opportunities for new licencing deals have been investigated. The rewards of these investments are now expected to have greater impact.

Based on the assumptions presented above, the value in use exceeds the carried goodwill. Conducting sensitivity analyses of the above assumptions indicates that it requires greater changes to the assumptions (more than 10 % reduction in future cash flows, in combination with at least 4 percentage points increase in the discount rate) in order to cause any impairment requirement in regard to goodwill and brands. The impairment testing does not include any effects of potential future restructuring or future improvements to the bulk of assets. The forecast revenue is based on the present and existing condition of the assets.

## NOTE 14 Technology

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening acquisition value	357,100	357,100	–	–
<b>Closing accumulated acquisition value</b>	<b>357,100</b>	<b>357,100</b>	<b>–</b>	<b>–</b>
Opening accumulated depreciation	-96,683	-72,876	–	–
Depreciation for the year	-23,806	-23,807	–	–
<b>Closing accumulated depreciation</b>	<b>-120,488</b>	<b>-96,683</b>	<b>–</b>	<b>–</b>
<b>Net carrying amount</b>	<b>236,612</b>	<b>260,418</b>	<b>–</b>	<b>–</b>

The item technology includes Bactiguard's patented and unique coating technology which can be applied to a broad spectrum of products.

## NOTE 15 Brands

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening acquisition value	25,572	25,572	–	–
<b>Closing accumulated acquisition value</b>	<b>25,572</b>	<b>25,572</b>	<b>–</b>	<b>–</b>
<b>Net carrying amount</b>	<b>25,572</b>	<b>25,572</b>	<b>–</b>	<b>–</b>

The carrying amount for brands is attributable to Bactiguard Holding's acquisition of Bactiguard AB as Bactiguard was identified as an intangible asset. The brand is known, established and enjoys trademark protection for an indeterminate period in relevant markets where the company operates. The Group conducts impairment testing annually for the brand or whenever there is an indication that it may be impaired, see note 13.

**NOTE 16** Customer relationships

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening acquisition value	17,700	17,700	-	-
<b>Closing accumulated acquisition value</b>	<b>17,700</b>	<b>17,700</b>	-	-
Opening accumulated depreciation	-4,792	-3,612	-	-
Depreciation for the year	-1,180	-1,180	-	-
<b>Closing accumulated depreciation</b>	<b>-5,972</b>	<b>-4,792</b>	-	-
<b>Net carrying amount</b>	<b>11,728</b>	<b>12,908</b>	-	-

**NOTE 17** Capitalised development costs

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening acquisition value	14,433	8,796	-	-
Capitalisation for the year	6,153	5,637	-	-
<b>Closing accumulated acquisition value</b>	<b>20,586</b>	<b>14,433</b>	-	-
Opening accumulated depreciation	-2,371	-1,024	-	-
Depreciation for the year	-1,653	-1,347	-	-
<b>Closing accumulated depreciation</b>	<b>-4,024</b>	<b>-2,371</b>	-	-
<b>Net carrying amount</b>	<b>16,562</b>	<b>12,062</b>	-	-

Capitalised development costs refer to ongoing development projects. Depreciation is initiated when the project is completed.

**NOTE 18** Patents

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening acquisition value	2,559	2,274	-	-
Capitalisation for the year	297	285	-	-
<b>Closing accumulated acquisition value</b>	<b>2,856</b>	<b>2,559</b>	-	-
Opening accumulated depreciation	-1,287	-821	-	-
Depreciation for the year	-548	-466	-	-
<b>Closing accumulated depreciation</b>	<b>-1,835</b>	<b>-1,287</b>	-	-
<b>Net carrying amount</b>	<b>1,021</b>	<b>1,272</b>	-	-

**NOTE 19** Improvements, leasehold

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening acquisition value	20,382	15,976	-	-
Purchases	676	4,406	-	-
<b>Closing accumulated acquisition value</b>	<b>21,058</b>	<b>20,382</b>	-	-
Opening accumulated depreciation	-2,465	-164	-	-
Depreciation for the year	-2,460	-2,301	-	-
<b>Closing accumulated depreciation</b>	<b>-4,925</b>	<b>-2,465</b>	-	-
<b>Net carrying amount</b>	<b>16,133</b>	<b>17,917</b>	-	-

**NOTE 20** Machinery and other technical plant

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening acquisition value	13,482	14,131	-	-
Purchases	200	580	-	-
Sales/scrapping	-3,223	-	-	-
Exchange rate differences	318	-1,229	-	-
<b>Closing accumulated acquisition value</b>	<b>10,777</b>	<b>13,482</b>	-	-
Opening accumulated depreciation	-6,070	-4,369	-	-
Depreciation for the year	-2,146	-2,221	-	-
Sales/scrapping	3,217	-	-	-
Exchange rate differences	-119	520	-	-
<b>Closing accumulated depreciation</b>	<b>-5,118</b>	<b>-6,070</b>	-	-
<b>Net carrying amount</b>	<b>5,659</b>	<b>7,412</b>	-	-

**NOTE 21** Equipment, tools and installations

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening acquisition value	7,620	6,864	-	-
Purchases	85	1,260	-	-
Sales/scrapping	-	-504	-	-
Exchange rate differences	2	-	-	-
<b>Closing accumulated acquisition value</b>	<b>7,707</b>	<b>7,620</b>	-	-
Opening accumulated depreciation	-2,188	-660	-	-
Depreciation for the year	-1,582	-1,528	-	-
<b>Closing accumulated depreciation</b>	<b>-3,770</b>	<b>-2,188</b>	-	-
<b>Net carrying amount</b>	<b>3,937</b>	<b>5,432</b>	-	-

**NOTE 22** Shares in subsidiaries

	Parent company	
	31/12/2016	31/12/2015
Opening acquisition value	384,574	384,574
<b>Closing acquisition value</b>	<b>384,574</b>	<b>384,574</b>

Subsidiaries	Corp.ID. no.	Domicile	Share of equity %	Share of voting power %	Book value
Bactiguard AB	556668-6621	Stockholm	100	100	384,574
Bactiguard International AB	556754-7731	Stockholm	100	100	-
Bactiguard China Limited	1403452	Hongkong	100	100	-
Bactiguard Malaysia SDN. BHD.	970618-V	Malaysia	100	100	-
Bactiguard Singapore Pte. Ltd.	201135972E	Singapore	100	100	-
Bactiguard Israel Ltd.	514794247	Israel	100	100	-
Avisere Technology Private Ltd.	U72200WB2004PTC098738	India	99	99	-
<b>Total</b>					<b>384,574</b>

## NOTE 23 Shares in associates

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening balance 1 January	1,298	1,368	-	-
Investments	-	-	-	-
Participations in result of associates	-70	-70	-	-
<b>Closing balance</b>	<b>1,228</b>	<b>1,298</b>	-	-

The participations are related to 50 % ownership in BG Casil Ltd (Ahmedabad, India). The holding has been assessed as being immaterial for further disclosures.

## NOTE 24 Inventory

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Raw material	1,967	969	-	-
Products in progress	1,461	925	-	-
Finished goods	11,716	9,793	-	-
<b>Total inventory</b>	<b>15,144</b>	<b>11,687</b>	-	-

## NOTE 25 Accounts receivable

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Accounts receivable, gross	102,004	103,604	-	-
Provision for bad debts	-58,191	-45,958	-	-
<b>Total accounts receivable, net after provision for bad debts</b>	<b>43,812</b>	<b>57,646</b>	-	-

Of which non-current accounts receivable are TSEK 16,170 (6,012).

46 % (61 %) of accounts receivable refer to territorial fees and correspond to deferred income and advance payments from customers of the same amount and have thereby not impacted the income statement.

The management has assessed that the carrying amount for accounts receivable, net after provisions for bad debts, corresponds to the fair value.

Age analysis of accounts receivable	Group	
	2016	2015
Not due	18,443	11,615
Overdue 1–30 days	2,740	4,761
Overdue 31–90 days	744	617
Overdue > 90 days	80,076	86,611
of which provision for doubtful accounts receivables	-58,191	-45,958
<b>Total</b>	<b>43,812</b>	<b>57,646</b>

Provision for bad debts	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Opening balance	-45,958	-10,156	-	-
Provision for doubtful receivables	-12,233	-35,802	-	-
Realised loss	-	-	-	-
<b>Closing balance</b>	<b>-58,191</b>	<b>-45,958</b>	-	-

The company's assessment is that payment will be received for accounts receivable that are past due but not impaired. The assessment is confirmed by customer balance inquiries.

## NOTE 26 Prepaid expenses and accrued income

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Prepaid rent	2,549	2,497	-	-
Other items	7,155	7,094	243	1,457
<b>Total</b>	<b>9,704</b>	<b>9,591</b>	<b>243</b>	<b>1,457</b>

## NOTE 27 Cash and cash equivalents

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Cash and bank balances	15,645	22,119	1,118	16,052
<b>Total</b>	<b>15,645</b>	<b>22,119</b>	<b>1,118</b>	<b>16,052</b>



## NOTE 28 Share capital

Share capital in Bactiguard as per 31 December 2016 was TSEK 833 allocated to 29,302,373 series B shares each carrying a single vote (29,302,373 votes) and 4,000,000 series A shares, each with ten votes (40,000,000 votes). The total number of shares and votes in Bactiguard as per 31 December 2016 was 33,302,373 shares and 69,302,373 votes. The shares have a quotient value of SEK 0.025.

The disclosures are unchanged compared to 31 December of the previous year.

## NOTE 29 Loans and liabilities

	Group		Parent company	
	2016	2015	2016	2015
Liabilities to shareholders	50,000	–	50,000	–
Bond loan	–	142,140	–	225,259
Liabilities to credit institutions	100,000	–	100,000	–
<b>Total</b>	<b>150,000</b>	<b>142,140</b>	<b>150,000</b>	<b>225,259</b>

The company issued a bond loan at a nominal value of TSEK 450,000 carrying 11 % annual interest in December 2011. The bond loan had a duration of five years and thus matured on 12 December 2016. The entire outstanding nominal amount of MSEK 138,000 and accrued interest has been paid.

The refinancing solution comprises a short-term bank loan of TSEK 100,000 with duration until 31 December 2017 as well as a long-term loan from the company's principal shareholder of TSEK 50,000 with duration until 30 June 2018.

The loan runs at an interest base of Stibor 90, however minimum 0 %, and an interest surcharge of 3.5 %.

Bactiguard's interest expenses will decrease significantly by means of this refinancing.

## NOTE 30 Bank overdrafts

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Bank overdraft facilities granted	30,000	30,000	–	–
Unutilised bank overdrafts	30,000	30,000	–	–
<b>Utilised bank overdrafts</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>

## NOTE 31 Accrued expenses and deferred income

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
Accrued interest expenses	300	732	300	1,251
Accrued holiday pay	6,342	7,642	1,013	3,046
Deferred income	22,704	61,955	–	–
Other items	5,177	3,554	1,107	1,409
<b>Total</b>	<b>34,523</b>	<b>73,883</b>	<b>2,420</b>	<b>5,706</b>

Deferred income mainly refers to the sale of rights to sell BIP products in an agreed geographic market and is taken up as income during product delivery. The year's change in deferred income is related to product shipments and changes in the agreement.

## NOTE 32 Pledged assets and contingent liabilities

	Group		Parent company	
	31/12/2016	31/12/2015	31/12/2016	31/12/2015
<b>Pledged assets</b>				
Shares in subsidiaries	134,944	155,718	384,574	384,574
Floating charge	30,000	30,000	–	–
Pledged loans	–	–	–	180,000
<b>Total</b>	<b>164,944</b>	<b>185,718</b>	<b>384,574</b>	<b>564,574</b>

There are no contingent liabilities in effect.

### NOTE 33 Related party transactions

Transactions between the company and its subsidiaries, which are related to the company, have been eliminated in the consolidation, and disclosures regarding these transactions are therefore not provided in this note. Disclosures regarding transactions between the Group and other related parties are presented below.

Services and other transactions between companies within the Group are charged based on commercial principles. Bactiguard has a bank loan of TSEK 100,000 in which the board member – also CEO and principal shareholder – Christian Kinch as well as the principal shareholder Thomas von Koch (“the Principal shareholders”) have undertaken to, without compensation, stand surety for Bactiguard Holding AB’s obligations during the loan agreement. As a surcharge Bactiguard also has a loan directly from the Principal shareholders of TSEK 50,000 in which the credit has been issued without collateral and for the rest runs at corresponding commercial terms as the bank loan of TSEK 100,000.

Besides that stated above, neither Bactiguard nor its subsidiaries have provided loans, guarantees or guarantee commitments to or for the benefit of any board members or senior management in the Group. None of these people have had any direct or indirect participation in another business transaction with any company within the Group which is or was uncustomary in its nature or with respect to the conditions.

Details of remuneration and benefits for key individuals in a managerial position are provided in note 9.

### NOTE 34 Key events after the balance sheet date

- Bactiguard concluded a resale agreement and entered into a partnership with Heal Pharma for Egypt. The product registration process has started and the launch is planned for the second quarter of 2017.
- In February 2017 Bactiguard and Smartwise Sweden AB (Smartwise), established a joint development project for advanced, Bactiguard coated vascular injection catheters. At the same time a licencing agreement was concluded. In 2017 Smartwise will pay 2.5 million US dollar for the exclusive and global entitlement to the Bactiguard technology within this application area, followed by royalty payments when the products are commercialised. By means of the agreement with Smartwise, Bactiguard is developing the licencing business to comprise three different therapy areas, indwelling urinary catheters, orthopaedic implants and now advanced vascular injection catheters. Smartwise is owned by a group of private investors, including Christian Kinch and Thomas von Koch.
- A recently conducted, independent clinical study from Hong Kong confirmed that Bactiguard coated urinary tract catheters reduce the number of symptomatic catheter associated urinary tract infections and that the effect is even higher among long-time users.

### NOTE 35 Dividends

No dividends were issued during 2016 and no dividends are proposed to the 2017 AGM.

### NOTE 36 Proposed appropriation of profit

#### Parent company

The following retained earnings are at the disposal of the Annual General Meeting (SEK)

Retained earnings	24,344,035
Share premium reserve	473,016,706
Profit/loss for the year	-29,662,488
	<b>467,698,253</b>

The Board of Directors proposes that the profits be distributed

as carried forward	467,698,253
	<b>467,698,253</b>

## Signing the annual report

The Board of Directors and Chief Executive Officer hereby certify that these consolidated financial statements were prepared in accordance with the international financial reporting standards, as referenced in the European Parliament and of the Council regulation (EC) No. 1606/2002 of 19 July 2002 on the application of international accounting standards and provide a fair representation of the parent company's and the Group's operations, financial position and performance and describe the material risks and uncertainties facing the parent company and group companies.

Stockholm 18 April 2017

Christian Kinch  
*CEO and Board member*

Stanley Brodén  
*Chairman*

Peter Hentschel  
*Board member*

Marie Wickman-Chantereau  
*Board member*

Mia Arnhult  
*Board member*

Our auditor's report was submitted on 18 April 2017.

Deloitte AB

Kent Åkerlund  
*Certified Public Accountant*

# AUDITOR'S REPORT

## To the general meeting of the shareholders of Bactiguard Holding AB (publ) corporate identity number 556822-1187

### Report on the annual accounts and consolidated accounts

#### Opinions

We have audited the annual accounts and consolidated accounts of Bactiguard Holding AB (publ) for the financial year 2016-01-01 - 2016-12-31 except for the corporate governance statement on pages 28 - 31. The annual accounts and consolidated accounts of the company are included on pages 23 - 56 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company as of 31 December 2016 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2016 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 28 – 31. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the statement of comprehensive income for the parent company and the group, the balance sheet for the parent company and the statement of financial position for the group.

#### Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

#### Revenue recognition

Total revenue for Bactiguard amounts to 128 MSEK for the financial year 2016 and consists to 80 % of license revenues and to 12 % of revenues from products sales.

License revenues are received and recognised based on the volume that the company's client has sold to the end-customer and is recognised in the period of the sale. The license contracts can contain various components and revenue streams that must be evaluated under the recognition criteria of IAS18.

Revenues from product sales are recognised when the products are delivered and risks and rewards associated with the ownership of the products have been transferred to the buyer. In the instances where deliveries are made close to a period-end an estimate needs to be made to determine when risk and rewards for the products have been transferred to the buyer and in what period to recognise the revenue.

Estimates related to various components in the license contracts and the cut off related to revenues from the sale of products make revenue recognition a key audit matter in the audit.

For further information refer to accounting principles on page 41, Note 3 and Note 5 in the annual report.

#### Our audit procedures

Our work included the following procedures, but were not limited to these:

- We have gained an understanding of the company's processes for recognising revenue in accordance with the criteria in IAS18. We have also tested key controls in these processes.
- We have audited a sample of material product deliveries to determine whether the revenue recognition criteria have been fulfilled.
- We have reviewed all material new agreements and assessed how the company have treated them in the financial reports.
- We have reviewed that appropriate disclosures have been presented in the relevant notes to the financial statements.

#### Valuation of Goodwill and other intangible assets

The Group has goodwill amounting to 226 MSEK and other intangible assets, foremost technology, amounting to 292 MSEK accounted for in the balance sheet. These assets are tested annually, or as soon there are events indicating that there is a need, for impairment. Since the total value of these assets represent a significant part of the total assets and is sensitive to changes in assumptions such as growth rate and discount factor we consider it to be a key audit matter in our audit.

For further information refer to accounting principles on page 43, Note 3 and Notes 13 to 16 in the annual report.



### **Our audit procedures**

Our work included the following procedures, but were not limited to these:

- We have reviewed and evaluated Bactiguard's process for impairment-testing of goodwill and other intangible assets in order to assure that assumptions are reasonable, that the processes are consequently applied and that there are integrity in the calculations performed.
- We have reviewed the integrity in calculations performed and the arithmetic correctness in the model used for impairment testing of goodwill by involving a valuation expert.
- We have compared the value of the company's assets with current market value in the form of the company's market cap.
- We have reviewed that appropriate disclosures have been presented in the relevant notes to the financial statements.

### **Refinancing of bond**

During 2016 Bactiguard has completed a refinancing by fully repaying the bond at a nominal value of 138 MSEK. As part of the refinancing the company has received a bank loan amounting to 100 MSEK with due date on December 31 2017 and a loan from the company's main shareholders amounting to 50 MSEK with due date on June 30 2018.

The accounting for the bond, at fair value, the accounting and disclosures related to the new financing has been a key audit matter in the audit since an incorrect presentation of these transactions can have a significant impact on the company's financial statements.

For further information refer to pages 23 – 25 in the management administration report and the accounting principles on page 43 and Notes 3 to 4 in the annual report.

### **Our audit procedures**

Our work included the following procedures, but were not limited to these:

- We have reviewed and evaluated the company's accounting principles for the bond loan and new financing together with the impact on the income statement during the year.
- We have reviewed the disclosure of these effects in the annual report to ensure that the financial reporting demonstrates a true and fair view.
- We have reviewed that appropriate disclosures have been presented in the relevant notes to the financial statements.

### **Accounting for accounts receivable**

Bactiguard has accounts receivable amounting to 43,8 MSEK. The receivables have in some instances long payment terms and are to a great extent related to foreign clients. For a portion of the receivables there is a risk for customers not paying due to that regulatory approvals are delayed or due to country and client specific risks.

Accounts receivable represent a significant asset in the company's balance sheet, is associated with difficult judgments related to the customer's ability to pay and as a consequence it is key audit matter in our audit.

For further information refer to accounting principles on page 43 and Note 3 in the annual report.

### **Our audit procedures**

Our work included the following procedures, but were not limited to these:

- We have reviewed the company's estimate of each individual significant receivable and performed client confirmation procedures for a sample of the most significant receivables.
- We have reviewed that receivables with payment conditions exceeding one year are accounted for in accordance with IAS 18.
- We have per discussion with management confirmed status on significant outstanding receivables up until the release of the annual report.
- We have reviewed that appropriate disclosures have been presented in the relevant notes to the financial statements.

### **Other information than the annual accounts and consolidated accounts**

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1 - 22 and 61. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated. If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

### **Responsibilities of the Board of Directors and the Managing Director**

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern

basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

### **Auditor's responsibility**

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts. As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to

the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

- evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

### **Report on other legal and regulatory requirements**

#### **Opinions**

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Bactiguard Holding AB (publ) for the financial year 2016-01-01 - 2016-12-31 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit to be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

### **Basis for Opinions**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### **Responsibilities of the Board of Directors and the Managing Director**

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

### **Auditor's responsibility**

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

### **The auditor's examination of the corporate governance statement**

The Board of Directors is responsible for that the corporate governance statement on pages 28 - 31 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's auditing standard RevU 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

Stockholm April 18, 2017  
Deloitte AB

Kent Åkerlund  
Authorised Public Accountant



## Glossary and references

### Antibiotic resistance

Microorganisms, such as bacteria, that have developed a resistance to antibiotics, which makes infections and diseases caused by these bacteria to no longer be able to be treated with antibiotics.

### BIP CVC

Bactiguard Infection Protection (BIP) central venous catheter.

### BIP ETT

Bactiguard Infection Protection (BIP) endotracheal tube.

### BIP Foley

Bactiguard Infection Protection (BIP) foley catheter.

### Clinical study

A study designed to determine the effects that medical technical devices have on human.

### Multi-resistant bacteria

Bacteria that are resistant towards several antibiotic treatments, so that established antibiotic alternatives no longer can be used for treatment or preventive purposes.

### Healthcare associated infections (HAI)

Infections that occur while Healthcare associated infections (HAI) affect patients while treated at hospital, healthcare unit or at home.

### Note

1.

### References

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