

BioGaia®

ANNUAL REPORT 2015

Preparing for the future **6**

22 new clinical studies **18**

Core issues in sustainability **22**

Sales up by
25%



The fight against
**antibiotic
resistance**

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Key events during the year

Quarter 1

STUDIES

- Publication of Spanish study showing that BioGaia's oral health tablets lozenges are effective in patients with dental implants

LAUNCHES

- Oral health tablets lozenges in Israel
- Oral health tablets lozenges and oral health drops in Italy
- Relaunch of drops in Malaysia
- Infant formula with *Lactobacillus reuteri* Protectis in Pakistan and the Middle East

AGREEMENTS

- Agreement for the sale of drops in Vietnam
- Agreement for the sale of oral health tablets lozenges in Mexico

OTHER

- BioGaia's subsidiary IBT given Orphan Drug designation in Europe for the drug being developed by the company to prevent the disease NEC

Quarter 2

STUDIES

- Publication of Chinese study showing that BioGaia's drops are effective in treating infants with colic

LAUNCHES

- Drops and digestive health tablets in Panama
- Relaunch of digestive health tablets in Indonesia

Quarter 3

STUDIES

- Publication of Swedish study showing that BioGaia's oral health tablets lozenges reduce oral *Candida* in the elderly

LAUNCHES

- Drops in Vietnam
- Oral health tablets lozenges in Austria and Switzerland
- Oral rehydration solution in Hungary
- Relaunch of drops in Israel

OTHER

- BioGaia invests further in IBT, bringing BioGaia's total investment in the company to around SEK 82 million
- TwoPac's production facility approved for pharmaceutical manufacturing

Quarter 4

STUDIES

- Presentation of study from Botswana showing that BioGaia's drops promote growth and prevent recurrent diarrhoea in children
- Meta-analysis confirms effectiveness of BioGaia's drops in treating infant colic

LAUNCHES

- Digestive health tablets (Gastrus) in the USA and Italy
- Oral rehydration solution in Russia

OTHER

- BioGaia appoints new Managing Director
- BioGaia invests further in MetaboGen

KEY EVENTS AFTER THE END OF 2015

- The subsidiary IBT receives approval for clinical studies in the USA and Sweden
- BioGaia's Board of Directors proposes that an Extraordinary General Meeting on 18 March 2016 approve the distribution of the shares in the subsidiary IBT to the shareholders in BioGaia



Sales
483
SEK million

Growth
25%

Number of employees
105

Operating profit
152
SEK million

Operating margin
31%

Now also on the Internet

Starting this year, BioGaia will also publish the annual report at biogaiaannualreport.com. Since many of you have chosen to read our annual report online rather than in printed form, we have been able to reduce paper consumption and transports by printing fewer paper copies and sending them by mail this year. This is well in line with BioGaia's environmental commitment.

At the same time, we want to ensure that everyone who is interested has access to the information, and BioGaia will therefore continue to make its annual report available in print for those who prefer to read it in this format. The annual report is wrapped in plastic for handling by the postal services, since there is otherwise a risk that other mail will slide in and get stuck between the pages. The plastic is made of a thin recyclable material that results in very little waste. Be sure to recycle both the plastic wrapper and the annual report itself when you are finished reading it.

At biogaiaannualreport.com you will find all of the information that is provided in the printed annual report. In addition, the website offers content such as video interviews with BioGaia's President Peter Rothschild and the President of our distributor in Brazil, Paulo Nigro.

Eva Nelson,
Project
Manager



2016

Annual General Meeting

Tuesday, 10 May 2016, 4:00 p.m.
at Lundqvist & Lindquist Klara Strand, Klarabergsviadukten 90 in Stockholm.

The annual report will be distributed only to those who have ordered it. Printed copies can be ordered by calling BioGaia's head office, +46 8-555 293 00, or via info@biogaia.se. The annual report is also published on biogaiaannualreport.com.

The year-end report, annual report and interim reports are published in both Swedish and English.



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The financial statements and notes are attached as an appendix





“With sales growth of 25 per cent, we cannot but feel happy and satisfied with our performance in 2015.”

A year summed up by strong growth and exciting ventures

We cannot but feel happy and satisfied with our performance in 2015, even if the three first quarters promised higher growth than we ultimately achieved for the full year. Thanks to sales growth of 16 per cent after exchange rate adjustments, we are now approaching sales of SEK 0.5 billion. According to our data, the total market for probiotic dietary supplements is expanding by around eight per cent annually, which means that we are gaining market shares.

OPERATING PROFIT OF OVER SEK 150 MILLION

Our operating profit reached SEK 152 million, resulting in an operating margin of over 31 per cent despite expenses of SEK 20.6 million for our subsidiary IBT. Without these expenses our operating margin would have been a full 36 per cent.

Brazil has emerged as an important market for us, and is now one of our largest. Development over the year was uneven, which gave us additional sales at the beginning of the year but markedly lower sales in the fourth quarter. After a highly successful launch and sales in the second quarter of 2015, our distributor Aché anticipated a need to increase its buffer stock. But its optimistic forecasts failed to materialize and Aché ended up with excess inventory, which meant that our sales to Aché in the fourth quarter were very limited compared to the same period of 2014. This will also impact our sales in 2016 until inventory levels have normalized. Sales from pharmacies remain high and are expected to show double-digit growth in 2016.

STRONG DEVELOPMENT IN THE LARGEST MARKET

The other markets in South America are showing excellent development and the region has grown in importance to us. Europe, our key market, is also showing good development despite the fact that we already have large market shares in certain countries.

Nestlé purchased significantly lower volumes of cultures for infant formula, since they are increasingly manufacturing the cultures in-house. This is affecting sales but not profit, since the margin on this product is low following the license agreement that was signed with Nestlé in 2012. However, our royalty agreement with Nestlé regarding Growing Up Milk for children older than one year is starting to generate sizeable revenue. The revenue stream from this agreement will increase year by year.

MODERATE COST INCREASE IN COMING YEAR

Operating expenses were up by 15 per cent compared to the previous year and reached SEK 186.1 million, which was lower than anticipated and a result of delays in a few clinical trials. Operating expenses include expenses of SEK 20.6 million (6.6) in the subsidiary IBT. Without these, the increase in operating expenses would have been seven per cent. Because IBT will be listed separately and is no longer consolidated in the BioGaia Group, BioGaia's operating expenses are expected to increase very moderately in 2016.

In 2015 several studies were published on oral health (inflammation related to dental implants, oral Candida) and colic that further consolidate our very strong position in these indication areas. At the beginning of 2016, a meta-analysis of 17 studies regarding different treatments for infant colic was published. The review showed that BioGaia's drops are the only probiotic that is effective against colic. According to the review and many doctors we have spoken to, the main competitor, an active ingredient called

simethicone, is not effective. These are naturally positive findings that will be used by our distribution partners.

THE FUTURE LIES IN THE MICROBIOME

We are seeing tremendous advances on the research front within our field, and today there is widespread consensus that the microbiome, i.e. the collective genetic material contained in the human intestinal tract, has a powerful impact on many of the body's functions through for example the nervous system, the endocrine system and the immune system. This means that BioGaia has a wide range of indication areas to choose from, which is increasing the importance of preclinical research. Our fantastic network of researchers helps us with this and we collaborate with the top people in each area.

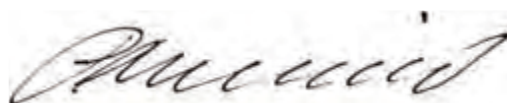
But the decisive factor is the clinical effect on humans, and here we are working with universities and hospitals in a large number of countries. The requirements for clinical studies are increasingly rigorous, and in response to this we have strengthened our own organization with additional highly skilled employees who have previously worked in the pharmaceutical industry.

The major potential that is seen in microbiome research is the background for BioGaia's investment in the research company MetaboGen in Gothenburg, Sweden, where we are collaborating with some of the leading researchers in this field. In its first year the company worked on prioritizing the various projects and is now up and running with those that have been deemed most important.

IBT LISTED ON FIRST NORTH

Our subsidiary IBT is making considerable progress in its development of a drug to prevent NEC, a disease that affects premature infants. The FDA has authorized a so-called IND (Investigational New Drug) for our first clinical study in the USA and we have also received approval from the Swedish Medical Products Agency to start a study in Sweden. BioGaia's Board of Directors has passed a decision to distribute its shares in IBT to BioGaia's shareholders and to list IBT on the First North stock exchange. The plan is then for the company to carry out a new share issue to raise approximately SEK 100 million for the first clinical study. The advantages of the separate listing are that BioGaia will not be burdened with IBT's heavy development expenses at the same time that IBT will have direct access to the capital market. Parallel to this, IBT is in discussions with possible license partners who, if an agreement is signed, will contribute capital to the project. It is impressive to see how much IBT has achieved in a short span of time, thanks to its focused working methods and its highly qualified and experienced employees.

In 2015 BioGaia's Board of Directors appointed *Axel Sjöblad* as the new Managing Director with effect from 1 March 2016, after which I will devote myself to BioGaia's long-term strategic development issues and its subsidiaries, which have demanded more and more of my time in the past few years. I am convinced that this is a change that will greatly benefit BioGaia's shareholders.



PETER ROTHSCHILD,
FOUNDER AND PRESIDENT BIOGAIA

BioGaia®

The name BioGaia is made up of two words, Bio and Gaia.

Bio stands for life and living organisms, natural, biological research and ecological systems.

Gaia, according to Greek mythology, is a goddess, the creator of all life, the sister of Eros and a personification of the Earth.

Preparing for the future

“It is therefore vital to ensure that the company has a strong management and organization that can capture and utilize all of BioGaia’s growth opportunities.”

DAVID DANGOOR,
CHAIRMAN OF BIOGAIA



In 2015 BioGaia continued its successful geographic expansion through both launches in new markets and widening of the product range in many of our established markets. Alongside this steady growth, BioGaia is continuing to develop new products and conduct research in promising and ground-breaking areas. The future looks very exciting, and it is therefore vital to ensure that the company has a strong management and organization that is able to capture and utilize all of BioGaia’s growth opportunities. Our brand provides a strong and dynamic platform for optimization of new product areas and launches.

As of year-end 2015, our President *Peter Rothschild* has led the company with enormous success from its founding in 1990 and for more than 25 years, of which 18 on the stock exchange. BioGaia has a very solid equity/assets ratio and is free from debt. During my time on the Board I have been consistently impressed by *Peter’s* leadership qualities, vision and commitment to social responsibility.

In the past year, however, the time was ripe for the company to secure a strong management succession and build an effective organization with the capacity to optimally realize all of BioGaia’s development potential.

MANAGEMENT SUCCESSION SECURED

It was therefore with great satisfaction that BioGaia’s Board of Directors announced that *Axel Sjöblad*, former Managing Director of *Getinge Sverige AB*, will assume duties as Managing Director of BioGaia on 1 March 2016, and will report directly to the Board. He comes to BioGaia with valuable experience and an impressive track record in the healthcare and life sciences areas from his earlier positions in the international *Getinge* and *Gambro* groups.

At the same time, the Board of BioGaia was delighted to announce that *Peter Rothschild* has been appointed as Group President, and will report directly to the company’s Board. It is a major advantage for the company that its successful founder and leader will continue in such a key position.

GREATER FOCUS THROUGH CLEAR SEPARATION OF DUTIES

Axel Sjöblad, with his extensive experience in marketing and sales, will lead the company’s current commercial operations, and, after a transitional period, will take over external communications. *Peter Rothschild*, in turn, will retain overall responsibility for the BioGaia Group’s R&D activities. He will also serve as Working Chairman of the group companies *TwoPac* (BioGaia’s production company), *IBT* (BioGaia’s venture to develop a drug for premature infants), and *CapAble* (BioGaia’s venture in innovative delivery systems), and actively support the development of BioGaia Japan. Furthermore, *Peter Rothschild* will continue as Chairman of *MetaboGen* (BioGaia’s investment in development of microbiome-based products and concepts).

Through these appointments and organizational changes, BioGaia will be able to further reinforce its sales capabilities and the geographic expansion of its existing business. At the same time, they will enable the company to strengthen the focus on its subsidiaries and associated companies, as well as realize the major development potential that the Board sees for the Group.

Together with the other members of the Board, I wish to thank and congratulate *Peter* for his highly successful management of BioGaia for so many years. We look forward to his continued strong and important involvement in the company. ■



BioGaia's value drivers



Dedicated and skilled employees who challenge existing solutions

To attract and retain skilled and motivated employees, BioGaia strives to create a culture where the employees are given the opportunity to develop, influence their own working situation and maintain a good balance between work and leisure in order to avoid stress. ■



Results of high quality clinical studies

BioGaia focuses strongly on research, both preclinical and clinical studies, with the aim of developing scientifically proven health-promoting products. BioGaia's research department collaborates with a network of researchers at hospitals and universities around the world.

In 2015 the results of 22 clinical and 11 preclinical studies were published in scientific journals. Most of the studies that are performed are carried out by external independent researchers. Such studies are regarded as more objective and also contribute to keeping research expenses down. ■



Powerful support to partners

BioGaia supports its partners, for example through training courses and information about new results from studies. The company also works internationally with PR and online marketing and produces marketing materials.

Participation in international medical congresses is a central component of BioGaia's partner support, but is also an important forum for meeting and getting a direct response from doctors and other healthcare professionals. During the year BioGaia took part in three major international congresses, ESPGHAN in Amsterdam (paediatric health), EuroPerio in London (oral health) and APDW in Taipei (adult health), where the respective products were marketed through exhibits in stands. In addition, BioGaia conducted a scientific programme in connection with the congresses. ■



Products and packaging solutions that meet customer needs

Another key area is to continuously develop new products and packaging solutions that meet customer needs. One vital condition for these activities is that the innovations can be protected. BioGaia therefore has a large portfolio of intellectual property rights such as patents, trademarks, names of strains and Internet domains. BioGaia works continuously to monitor the market and strengthen its intellectual property rights by protecting use of the company's products. ■



These are the main factors that drive BioGaia forward.

The company's success is also partly dependent on the ability to manage the risks that are associated with them.

Read more on page 6 in the appendix.





Today's modern lifestyle is challenging our health by depleting our gut flora. The connection between the gut flora – our bacteria – and illness is being increasingly studied. The question is

Bacteria control our

It is not only in the world around us that biological diversity is being depleted. A similar depletion is taking place in our own intestinal tract. **Research shows that people living in the industrialized world today have a less diverse gut flora** than those in traditional hunter-gatherer and rural agrarian populations. What difference does that make, you might ask, when we have around 100,000 billion microorganisms living on and inside us? A few less can't be so bad. But research shows the opposite.

In recent years, research on bacteria and their importance to us has literally exploded, and new insights and hypotheses are being published at a furious rate. There can be no doubt that bacteria have played a critical role in the history of mankind. Bacteria were the first form of life to "populate" the Earth some two billion years ago, and they still dictate the conditions for our existence today.

WE ARE BORN 100 PER CENT HUMAN AND DIE 50 PER CENT MICRO-ORGANISM! We are born virtually sterile and remain so until saliva from kisses, skin contact and other interactions introduce



“Today many babies are born at hospitals and delivered via caesarean section, which means that the first bacteria the body comes in contact with are different from before.”

that this imbalance persists for a long time.

Although the gut flora is relatively stable during our lives – just as when it is built up, it can be disrupted by external factors. Our modern lifestyle with a high intake of antibiotics and other drugs, low nutrition food, stress, sleep deficiency and environmental toxins leads to an imbalance in the system.

DO WE INHERIT OUR GUT FLORA? A recently published study followed mice for several generations. A group that had been fed a diet rich in fiber was compared to a group that had been fed a diet almost devoid of fiber. In the mice with the low-fiber diet, the diversity of the gut flora quickly declined. However, it could be partly restored if the mice were then switched to a high-fiber diet. But already by the second generation, the ability to repair the gut flora worsened and after three generations it was even

“The gut flora can be disrupted by external factors such as a high intake of antibiotics and other drugs, low nutrition food, stress, sleep deficiency and environmental toxins.”

more impaired. By the fourth generation, the loss of diversity in the mice’s gut flora was irreversible.² “If these findings can be transferred to humans, it could be one explanation why microbial diversity in the gut flora of people in the industrialized world today is lower than that of earlier generations,” says *Lars Engstrand*, Professor and Senior Physician at the Karolinska Institute and the Science for Life Laboratory.

The researchers then took the study a step further and tried introducing feces from the mice with greater diversity into the mice with a depleted gut flora. It worked, and the bacterial profiles of the mice’s gut flora were restored. “Transplanting” feces from healthy to sick humans is a treatment method that has long been used on a small scale in patients with severe and persistent diarrhoea caused by the bacterium *Clostridium difficile* following antibiotic treatment. And perhaps the areas of use will soon increase. “There are studies underway in which this

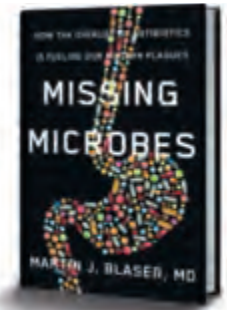
“If these findings can be transferred to humans, it could be one explanation why microbial diversity in the gut flora of people in the industrialized world today is lower than that of earlier generations.”

LARS ENGSTRAND, PROFESSOR AND SENIOR PHYSICIAN AT THE KAROLINSKA INSTITUTE AND THE SCIENCE FOR LIFE LABORATORY

method is being tested for treatment of patients with inflammatory intestinal diseases. And who knows, if an imbalanced gut flora is shown to lie behind other chronic diseases, the method is certain to be tested on these conditions,” says *Lars Engstrand*. Furthermore, a study in this “hot” field of research shows that frozen feces seem to be as effective as fresh, which would make the method more attractive to both doctors and patients.

A DISRUPTED GUT FLORA CAN MAKE YOU SICK New research indicates that there is a connection between a disrupted gut flora and many common conditions such as diabetes, obesity, cardiovascular disease and asthma. Current research is studying whether these illnesses could in fact be prevented by influencing and thereby improving the gut flora. It appears that that bacteria are once again showing us who controls our lives. ■

Sources are found at biogaiaannualreport.com



“Microbes play a critical role in your immunity as well as your ability to combat disease. In short, it is your microbiome that keeps you healthy. And parts of it are disappearing.”

Martin J. Blaser, Missing Microbes

The critical task of bacteria

The gut flora is now recognised as a one of the body’s organs. It weighs around two kilos and both the number of bacteria and their diversity are vital in maintaining the balance in the body and for the bacteria to remain friendly. Among other things, the bacteria in the digestive tract train our immune system, help to break down the food we eat and are our first line of defence from foreign and pathogenic microbes.

whether we can prevent illness by influencing the gut flora.

lives

the first bacteria to our bodies. Today many babies are born at hospitals and delivered via caesarean section, which means that the first bacteria the body comes in contact with are different from before. This fact and what happens during the first two years of life are decisive, because it is during this time that each individual’s unique gut flora is developed. The gut flora then remains more or less intact for the rest of our lives.

Aside from the way we are born, development of the gut flora is affected by factors like breast-feeding and diet, hygiene and the use of antibiotics and other drugs. For example, we know today that antibiotics disrupt the equilibrium in the gut flora and



“Many of the things we take for granted in modern medicine require antibiotics.”

In 30 years antibiotic resistance will kill more people than cancer

We are heading toward a “post-antibiotic era”.

A recent review of the situation shows that if the world doesn't take action, up to 20 million people annually will die as a result of resistant bacteria.¹

A few months ago, researchers in China identified a bacterium on pig farms that is resistant to that which is known as the last-ditch antibiotic, colistin.² After a short time, the same superbug was also detected in Denmark, England, Portugal, Malaysia and several other countries.

The bacterium carries a gene called MCR-1 that has developed resistance. The gene can be transferred between bacteria, and in this way the resistance is spreading quickly. Aside from finding MCR in livestock, the researchers have also detected it in meat products and in humans, both patients admitted to hospital and healthy individuals.

Although no human is currently known to have died as a result of resistance to colistin, it is clear that the problem has taken on a whole new dimension. The fact that the gene has also been transmitted to healthy humans indicates a rapid pattern of spread.

OLD ANTIBIOTIC BACK IN USE The antibiotic colistin, which can be used to treat everything from urinary tract infections to sepsis, was regarded as outdated for decades. But in recent years it has been increasingly prescribed as antimicrobial resistance renders newer antibiotics powerless. In 2012 the WHO declared that colistin, despite being rarely used, is of critical importance for human medicine.

A SERIOUS THREAT TO HEALTH The European Food Safety Authority (EFSA) warns that rising resistance to several of the antibiotics that are used to treat diarrhoea caused by *Campylobacter* is starting to pose a serious threat. Furthermore, scientists have found multi-resistant *Salmonella* bacteria in humans, poultry and meat – bacteria that are resistant to even colistin.

“Colistin, the last-resort drug, may soon no longer be effective for treating severe human infections with *Salmonella*,” says *Mike Catchpole*, Chief Scientist at the European Centre for Disease Prevention and Control (ECDC).³

In other parts of the world the problems are more acute. Researchers in China recently discovered multi-resistance to carbapenems, a group of wide-spectrum antibiotics that are often used to treat serious infections, for example in the lungs, the urinary tract and in connection with childbirth. This resistance is a result of the spread of the MCR-1 gene.

India is one of the countries that uses most antibiotics, and antibiotic resistance is an enormous problem there. For example, it is estimated that close to 60,000 infants die annually as a result of resistant infections.⁴

NO ONE CAN ESCAPE FROM THE POST-ANTIBIOTIC ERA If we no longer had any effective antibiotics, medicine as we know it would be cast back to the time before antibiotics. It would affect everything from hip replacement surgery to cancer care.

“Last line of defence” now breached?

Colistin was developed in the 1950s and belongs to a class called polymyxins. The reason doctors avoid using this antibiotic on humans is that it can be toxic to the kidneys. As a result, resistance to colistin has developed more slowly than to other antibiotics.

However, colistin is used extensively in agriculture to promote growth and to prevent disease among the animals. In China alone, 12,000 tonnes of colistin are used annually in agriculture.

Antibiotics

In 1928 the Scottish scientist Alexander Fleming discovered that a fungus growing in his laboratory had destroyed some of the bacteria he was studying. He named the substance it released penicillin, but didn't fully understand its effect. In 1945, other scientists found a cost-effective method for producing large quantities of penicillin and industrialized production was started. Several other effective antibiotics were soon discovered.

How resistance is developed

Antibiotics are drugs that are used to kill bacteria that cause infections. But every time an antibiotic is used, some of the bacteria will survive. Over time, these “survivors” multiply and form a new strain that is resistant to the antibiotic.

The problem is the same for every type of antibiotic that has been developed – the more it is used, the faster the emergence of new bacteria that are resistant to it.

To make matters worse, the number of new antibiotics in the development pipeline has fallen sharply. And all the while, several so-called superbugs are thriving and spreading around the world.

What is antibiotic resistance?

Antibiotic resistance is the ability of pathogenic bacteria to resist the effects of antibiotics. The pathogenic bacteria have then become resistant to the drug that is intended to kill them.

A human cannot be antibiotic-resistant but a human can carry antibiotic-resistant bacteria. Resistant bacteria can be spread between humans, animals and in the environment.

Common causes of antibiotic resistance

- Overuse of antibiotics
- Failure by patients to complete a course of antibiotics
- Overuse of antibiotics in animal agriculture
- Poor infection control in hospitals and clinics
- Inadequate sanitary conditions



“If we fail to act, we are looking at an almost unthinkable scenario where antibiotics no longer work and we are cast back into the dark ages of medicine.”

DAVID CAMERON,
PRIME MINISTER OF
THE UNITED KINGDOM



► Many of the things that we take for granted in modern medicine require antibiotics. If you get hit by a car and need surgery, doctors can perform the operation but the bacteria that unavoidably get into the wound will cause an infection, and if that infection can't be treated with antibiotics, there is a risk that you will die.

“We have seen Swedish tourists who have brought absolutely lethal bacteria with them home, and have been forced to amputate parts of the body where the bacterium has gained a foothold in order to save the patient's life.”

JOHAN THAM, SPECIALIST PHYSICIAN INFECTIOUS DISEASES

Johan Tham, a physician specialized in infectious diseases at Skåne University Hospital in Malmö, give an example of a reality that is already here.

– We have seen Swedish tourists who have gone on holiday to places like Greece, ended up in the hospital there and then brought absolutely lethal bacteria with them home. The most dangerous of these is ESBL-Carba – a type that is resistant to every known antibiotic. We have had to resort to extremely drastic methods, the same that were used at the beginning of the 1900s, to stop infections with this bacterium. We have been forced to amputate parts of the body where the bacterium has gained a foothold in order to save the patient's life.

AGRICULTURE A MAJOR CULPRIT Although gross overuse of antibiotics among people around the world is directly linked to today's alarming resistance situation, an ever greater problem is antibiotic resistance among humans caused by overuse in agriculture.

In December 2015 the US Food and Drug Administration (FDA) reported that US sales of antibiotics for use on livestock rose by 23 per cent between 2009 and 2014.⁵ Experts say that this widespread use must be curtailed immediately. The FDA hopes to begin a phase-out in 2016 and both China and Europe plan to soon introduce restrictions on the use of colistin, in particular, in animal agriculture.

GLOBAL STRATEGIES VITAL In 2015 the WHO presented a global action plan to get more countries to act and develop local plans for reducing the use of antibiotics. The plan is seen as a milestone in the global effort.

At the World Economic Forum in Davos, Switzerland, in February 2016, 85 pharmaceutical, biotechnology and diagnostics companies, together with nine industry associations, signed a declaration to combat antibiotic resistance around the world.⁶ Together with governments and politicians, the aims are to develop principles for better use of antibiotics and to support the development of new drugs, vaccines and diagnostics.

The greatest stumbling block for earlier initiatives has been financing. Antibiotic R&D, like that for other drugs, is enormously expensive. But unlike many other types of pharmaceuticals where the investments can be recouped through high prices for the finished drug, antibiotics offer poor profitability. The declara-

Perspectives on antibiotic resistance around the world



David Y. Graham
Professor of Medicine, Molecular Virology and Microbiology Baylor College of Medicine, Huston, USA



Ernesto Bachelet
Gastroenterologist, Hospital Gustavo Fricke, Viña del Mar, Chile



Lam Soe Tjhoen
Dr. of Family Medicine, Hong Kong Sanatorium & Hospital and Assistant Professor of Family Medicine and Primary Care, Hong Kong University



Ruggiero Francavilla
Paediatrician, Paediatric Gastroenterology and Hepatology, University of Bari, Italy

1 Briefly describe the situation in your country concerning antibiotic resistance.

Antibiotic resistance continues to increase. *C. difficile*, which causes life-threatening diarrhoea, is today considered an immediate threat to public health. In a single year *C. difficile* causes almost half a million infections, leading to an estimated 15,000 deaths.

In Chile we are unfortunately seeing the same pattern as in the rest of the world, a steady increase in antibiotic resistance.

Through inappropriate prescription and suboptimal dosage, we have now reached alarming levels of antibiotic resistance in Hong Kong.

Unfortunately, Italy still has one of the highest levels of antibiotic resistance in Europe. In particular, there is a rising trend of resistance to fluoroquinolones, third-generation cephalosporins and aminoglycosides.

2 What is being done in the your country to reduce the risk for antibiotic resistance?

Attempts to reduce antibiotic use in animals and to use antibiotics more wisely in humans are underway. The attempts to change overuse of antibiotics in humans has so far made little progress.

There is no national policy, but reviews of prescriptions have increased and also the control of intrahospitalarian infections.

In 1999 doctors and microbiologists from public and private hospitals formulated an action plan to curb antibiotic resistance (Interhospital Multi-disciplinary Programme on Antimicrobial ChemoTherapy, IMPACT). The fourth edition of the IMPACT guidelines was published in 2012.

Despite extensive information, there is a need for better communication between doctors and patients. Studies show that a patient's degree of satisfaction in primary care is more dependent on effective communication than whether or not the patient is given a prescription for antibiotics.

3 Have you changed your prescription pattern for antibiotics in the last 10 years?

No, mine has always been conservative. Most clinicians use antibiotics for elevated white counts and fever.

I am more restrictive with antibiotics today. For antibiotics like cephalosporins and fluoroquinolones, which were frequently used before, resistance is growing by the day.

I follow the IMPACT guidelines, among other things by focusing the treatment on the specific bacteria and using a suitable antibiotic, dose and duration of therapy. I also educate patients about the importance of completing their course of antibiotics.

I am more restrictive and also use more preventative measures. More and more studies are showing that prophylactic use of probiotics, at least among children, significantly reduces the number of infections and therefore also the need for antibiotics.

4 What are your thoughts on the future of antibiotics?

We, as humans, rarely respond before the catastrophe. Data showing a better way would be welcome.

Without a plan to regulate their use, antibiotics will soon disappear as drugs. This would be a catastrophe.

I prescribe probiotics to reduce the side effects of antibiotics, and this helps patients to complete the course. Probiotics can contribute to reducing the risk for side effects.

To avoid a catastrophe, we need to prevent infections by using documented probiotics and increased vaccination, reducing the use of antibiotics in animal agriculture and increasing R&D resources.

tion takes up the need to find new incentive models to realize R&D plans and accelerate the research currently in progress. It's a matter of breaking the link between sales and revenue, for example by giving the company an annual payment to guarantee a certain number of treatments, instead of receiving payment per treatment.

According to *Otto Cars*, Professor at Uppsala University in Sweden and one of the world's leading experts on antibiotic resistance, public agencies must contribute to financing new antibiotics in a whole different way than previously, either through milestone payments or, for example, by buying out patents.

At the beginning of 2015, the European Commission announced that a prize of EUR 1 million would be awarded to the person or team that develops a rapid diagnostic test to distinguish between patients with common infections that require antibiotics and those that can be managed without. Trials of several different methods are underway. One of these is a computer programme that can sequence the DNA of the bacteria in a patient's infection. In this way it is possible to predict which antibiotics will work and which the infection is resistant to. The computer programme is currently being tested at hospitals in the UK.

A NEED FOR MORE PREVENTATIVE MEASURES Alongside these gigantic global initiatives to find new antibiotics and bring about more restrictive use of the existing ones, there is surprisingly little talk about preventative measures. It is true that the WHO, the EU and the public health authorities around the world are conducting large-scale campaigns to tell us to wash our hands

more often and help vulnerable countries improve their vaccination programmes and similar, all of which are very important steps. But the question of how people should live in order to stay healthy – and thereby reduce the risk for antibiotic resistance – is not being emphasized with the same urgency on the part of public authorities.

“Public agencies must contribute to financing new antibiotics in a whole different way than previously, either through milestone payments or, for example, by buying out patents.”

OTTO CARS, PROFESSOR AT UPPSALA UNIVERSITY ONE OF THE WORLD'S LEADING EXPERTS ON ANTIBIOTIC RESISTANCE AND THE FOUNDER OF REACT (ACTION ON ANTIBIOTIC RESISTANCE)

THE TIME FOR DEBATE IS PAST Antibiotic resistance is a threat to all people on Earth. The number of difficult-to-treat and completely untreatable infections is increasing. The WHO and the leaders of regional, political and economic agencies, individual countries and scientific organizations have demanded action.

The question that ReAct, an independent global network for concerted action against antibiotic resistance, asks in its policy document is justified: So what are we waiting for? ■
Sources are found at biogaiaannualreport.com



Lactobacillus reuteri affects the immune system. This has been shown in several studies – children who were given supplements of *Lactobacillus reuteri* were healthier and used less antibiotics. When the need for antibiotics is decreased, the problem of antibiotic resistance is also reduced.

Stop the development of antibiotic resistance

Antibiotic resistance is a global threat to public health. And although scientists have discovered a whole new type of antibiotic for the first time in 30 years, a finished product is a long way into the future. The situation is alarming and new solutions and preventative treatments must be implemented already today.

Mankind is waging an uphill battle against bacteria that are developing resistance to antibiotics. What researchers need is time to find new principles for fighting this growing public health problem that is causing higher morbidity and mortality rates and leading to escalating healthcare costs for prolonged hospitalisation and more expensive drugs.

IN SPITE OF THE GLARING NEED, few new antibiotics are being developed today. Other types of drugs, such as cancer medicines, are far more profitable for the pharmaceutical companies and the incentives for research on new antibiotics are therefore few.¹ To combat this scenario, a number of national and international collaborative efforts between the industry and government agencies have been initiated.²⁻⁵ The agencies are also taking action by issuing new guidelines to curb overuse of antibiotics. But these measures are not sufficient. According to a recent report from the WHO, antibiotic resistance is a growing public health scourge of such magnitude that it threatens everything our modern medicines have succeeded in achieving.⁶

Alongside these enormous investments, we therefore need to take additional measures. "Furthermore, I believe that these other alternatives can be at least as effective as the billions that are spent on developing new drugs," says *Peter Rothschild*, BioGaiia's President and founder.

IN THE RESEARCH WORLD THERE ARE MANY who support the same reform agenda as Peter Rothschild and feel that we need to completely revise our approach to how antibiotics are used. The American professor *David Y. Graham* from the Department of Medicine-Gastroenterology at Baylor College of Medicine is one example. Graham stresses that we must explore the alternatives – while waiting for new ways to use antibiotics. Among other things, he believes that clinically tested probiotics can contribute to reducing the risk for antibiotic resistance and perhaps also the need for antibiotics at all. Another researcher whose voice is being heard in this debate is the American professor *Martin J. Blaser*. He claims that today's large-scale misuse of antibiotics is quite simply depleting and destroying the good bacteria inside us, and that this is a strongly contributing factor to the galloping increase in modern plagues such as asthma, allergies, diabetes, obesity and inflammatory intestinal disorders.⁷

FROM HEALTHCARE TO PREVENTATIVE CARE According to the Swedish National Board of Health and Welfare's guidelines for 2011, preventative care accounted for only 1 per cent of total healthcare and medical spending in Sweden.⁸ The remaining 99

per cent was devoted to alleviating symptoms or, in the best case, curing infections that had already occurred. Peter Rothschild's opinion is that this distribution should be completely different, since it is better from both a human and an economic perspective to prevent diseases than to treat them. Healthy people are less susceptible to infections, need fewer antibiotics and therefore cause less antibiotic resistance. In addition to a reallocation of economic resources, we must above all realign our focus from relieving symptoms to promoting preventative healthcare. To achieve this, we need incentives to change our habits, what we eat, how much we exercise – basically, our entire lifestyle, according to Peter.

So what can *Lactobacillus reuteri* do to fight the problem of antibiotic resistance? A great deal, believes *Peter Rothschild*. *Lactobacillus reuteri* affects the immune system and if it is possible to prevent infections, one logical consequence should be a decreased need for antibiotics. This is something we have shown in several studies – children who were given supplements of *Lactobacillus reuteri* were healthier and used less antibiotics.⁹⁻¹¹

Another area of use for *Lactobacillus reuteri* is in reducing the side effects of antibiotic treatment.⁹⁻¹¹

In this way, *Lactobacillus reuteri* can make it easier for patients to complete treatment, which can contribute to lowering the risk for antibiotic resistance.

Lactobacillus reuteri can thus create benefits in several ways – by preventing infection, by reducing the side effects of antibiotics and by thereby affecting antibiotic resistance.

– The threat of antibiotic resistance is like a ticking bomb and it is high time to better exploit the potential offered by well documented probiotic bacteria, concludes *Peter Rothschild*. ■

Sources are found at biogaiaannualreport.com

"Lactobacillus reuteri can do a great deal to fight the problem of antibiotic resistance.

PETER ROTHSCHILD
BIOGAIIA'S PRESIDENT
AND FOUNDER



About BioGaia



► **BUSINESS MISSION** BioGaia conducts research and development to provide consumers with clinically proven, health-promoting, patented and user-friendly probiotic products. e, hälsosamma, patenterade och användarvänliga probiotiska produkter.

► **POSITIONING** "Clinically Proven Probiotics". Dietary supplements containing scientifically tested probiotics of a high quality that are sold in pharmacies and similar sales outlets. In most markets, the products are recommended by doctors or other healthcare professionals.

► **VISION** BioGaias vision är att vara en banbrytande ledare inom probiotika genom:

- Innovative research
- Unique formulations and packaging solutions
- Strong brand recognition
- Social responsibility
- Excellence in intellectual property (IP)
- Global outreach
- Being an attractive workplace

► **BIOGAIAS CLASS B SHARE** is quoted on the Mid Cap list of Nasdaq OMX Nordic Exchange Stockholm.

► **FOUNDED** in 1990 by *Peter Rothschild* and *Jan Annwall*.

BIOGAIAS INTELLECTUAL PROPERTY RIGHTS

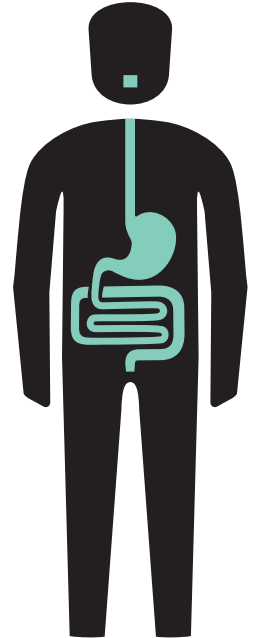
National trademarks in some 50 countries, in addition to a number of approved trademarks in Europe. Around 430 patents in 31 patent families.



A world-leader with unique products

Today BioGaia's products are sold in around 90 countries. Paediatrics accounts for over 80 per cent of total sales and Adult Health for 15 per cent. Other products account for 5 per cent.

BioGaia's focus is on finished consumer products that are sold under its own brand. In 2015 these sales, including co-branding, accounted for 62 per cent of sales of finished consumer products. The strategy is to continuously increase the share of products sold under the BioGaia brand. ■



Products for paediatric health

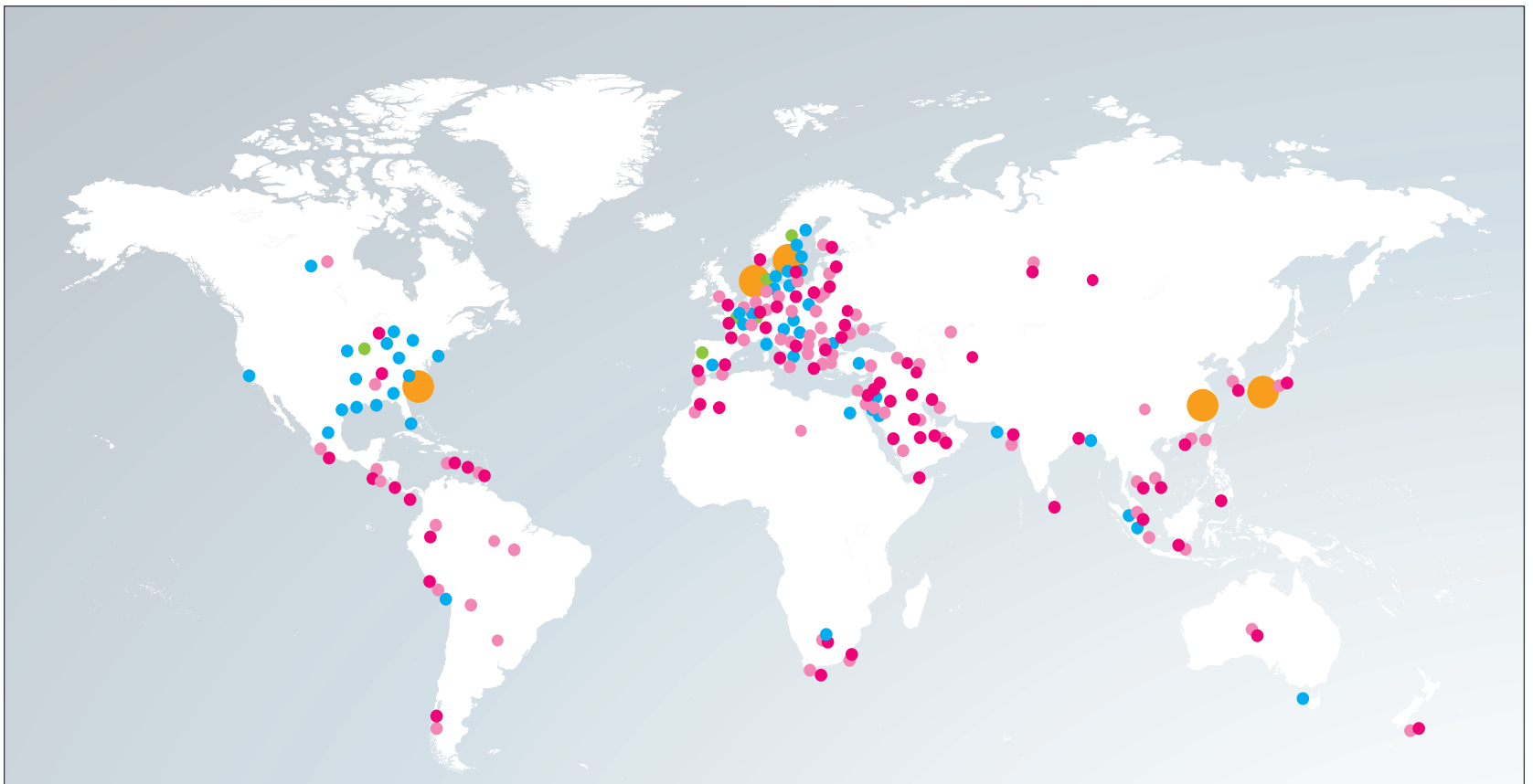
Probiotic dietary supplements that are used for prevention and treatment of colic, regurgitation, constipation and diarrhoea in children. The product range consists of drops (BioGaia's best-selling product), tablets and oral rehydration solution. Bacteria cultures of *Lactobacillus reuteri* Protectis are also used as an ingredient in infant formula and infant cereal. ■



Products for adult health

Probiotic dietary supplements in the form of tablets and oral rehydration solutions that are used preventatively for general digestive health, for treatment of constipation and diarrhoea and for adjunct treatment of *Helicobacter pylori* infection. For oral health there are lozenges and drops for prevention and treatment of periodontal disease and gingivitis. ■





- = BioGaia's offices: Stockholm (headquarters), Lund, Eslöv, Raleigh/USA, Hiroshima/Japan and Shanghai/China.
- = Universities and hospitals where research is conducted.
- = Manufacturing and packaging units.
- = Partners with sales of component products.
- = Partners with sales of finished products.

Business model with three external networks

Despite growing sales around the world and in different indication areas, the ambition is to preserve the advantages of a small company in the form of short decision-making paths. This is facilitated by BioGaia's business model based on external networks for research, production and distribution. ■



RESEARCH NETWORK

Collaboration with 50 research institutions and clinics

To maintain a position at the leading edge, it is of the utmost importance to collaborate with and inspire the top researchers in the various indication areas. ■



DISTRIBUTION NETWORK

Partners with sales in 90 countries

Most of the partner companies have representatives who visit doctors and other healthcare professionals. By informing them about the published results of clinical studies, they create interest and confidence among doctors who then recommend the products to their patients, who in turn buy the products in pharmacies and similar sales outlets. ■



PRODUCTION NETWORK

Manufacturing and packaging in six different facilities

The suppliers are found in Europe and the USA. Through close and long-term collaboration it is possible to continuously optimize production and logistics. The suppliers – above all the subsidiary TwoPac – are also important partners in product development. ■

Organization

BioGaia is divided into three business units, Paediatrics, Adult Health and New Business, that are responsible for product development and sales to their respective target groups. There are also central support functions such as sales, order and logistics, regulatory affairs, quality assurance and finance.

► **FOUR SUBSIDIARIES** TwoPac (manufacturing), BioGaia Japan (local sales company), CapAble (sales company for caps and straws) and Infant Bacterial Therapeutics (developing a drug for premature infants).

► **NUMBER OF EMPLOYEES** 105 employees, of whom 37 are based in Stockholm, 28 in Lund, 29 in Eslöv, three in Raleigh, USA, six in Hiroshima, Japan, and two in Shanghai, China.

► **NEW HIRES IN 2015** 20 people, while 10 left the company.

► **AVERAGE TERM OF SERVICE** 5 years.

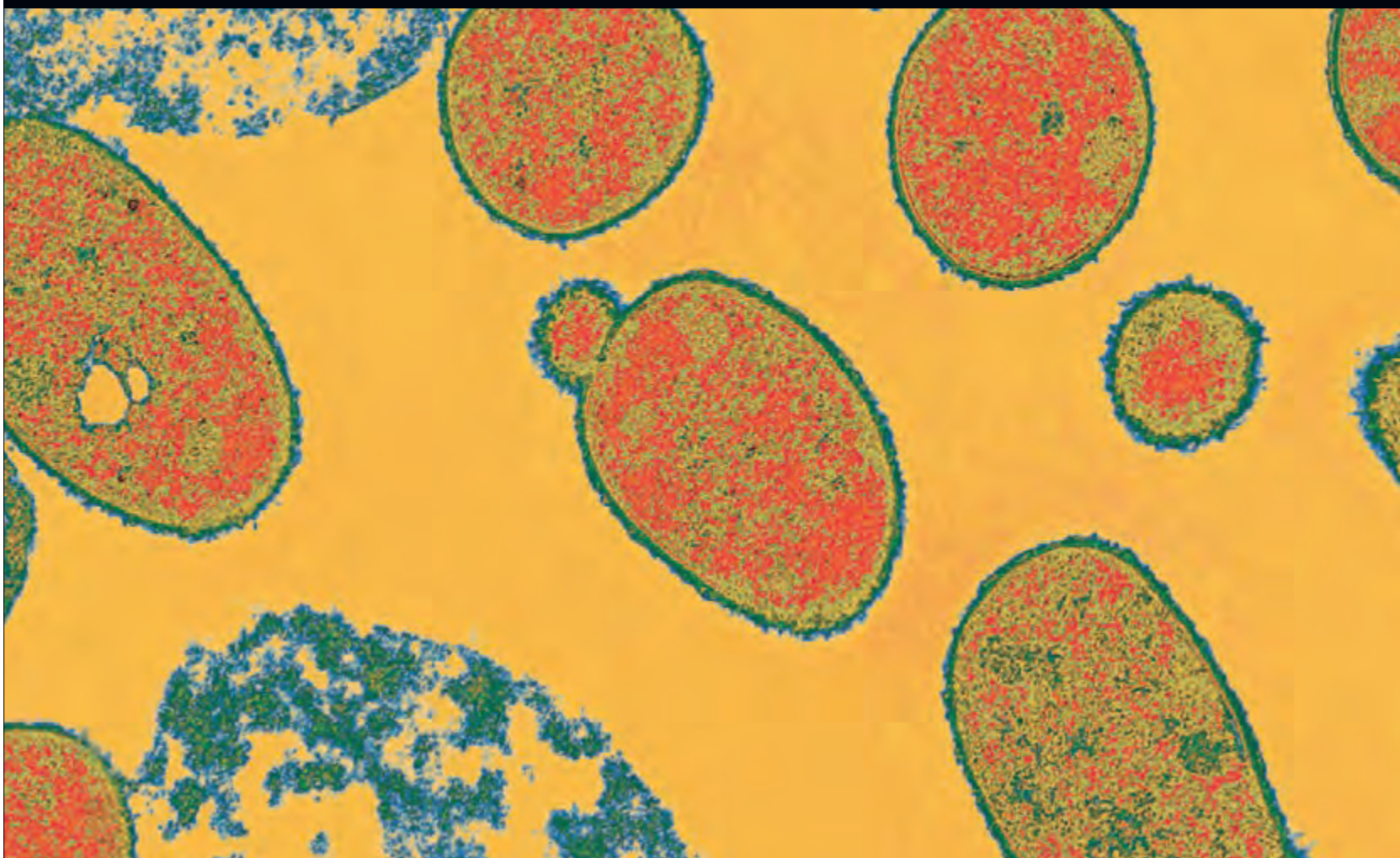
► **AVERAGE AGE** 44 years.

► **HIGH LEVEL OF EXPERTISE** 71 employees have a university education or the equivalent and seven hold a Ph.D.

► **LOW SICKNESS ABSENCE** In 2015 the employees had an average of 3.6 sick days. ■



Research



Strong network of independent researchers from around the world

BioGaia collaborates with specialists at over 50 research institutions and clinics. Many of these researchers are among the foremost in their areas.

In the adult health area, over half of the studies currently in progress were initiated by BioGaia and are being monitored by BioGaia's research supervisor. Around 25 per cent of the studies are initiated and performed by independent researchers. Aside from requesting the researcher's resume and study protocol, and requiring ethical approval of the studies, BioGaia has no influence over these studies. The remaining studies on adults have been initiated and conducted by one of BioGaia's partners.

In the paediatrics area, most of the clinical trials are either initiated by BioGaia or initiated and conducted by independent researchers. Around 20 per cent of the paediatric studies are initiated and conducted by BioGaia's partners. ■



Royal Children's Hospital & Murdoch Childrens Research Institute in Australia is one of the over 50 research institutions and clinics that BioGaia collaborates with.

Published studies of a high quality

Most of the clinical studies are fully comparable to pharmaceutical studies in terms of research quality. Furthermore, all studies must be approved by a local ethics review board before starting. Research on BioGaia's products should generate publication of well controlled and scientifically based articles. As a result, BioGaia actively supports publication of the results in well-reputed scientific journals. ■



13,000

To date, 155 clinical studies using BioGaia's human strains of *Lactobacillus reuteri* have been performed on 13,000 individuals of all ages.

136

The results have been published in 136 articles in scientific journals and nine doctoral theses (February 2016).

22

During the year, 22 studies were published in different indication areas.

CLINICAL STUDY PUBLISHED IN 2015

Swedish study shows reduction in oral *Candida* in the elderly

Svante Twetman, Professor in the Department of Odontology at The University of Copenhagen

Tell us briefly about the background for the study.

The fungus *Candida albicans* is found in the mouths of around half of the adult population, without any subjective symptoms. But when the environment in the oral cavity changes due to illness, medication or reduced saliva production, this can give rise to infections resulting in pain and discomfort. Earlier research has shown that probiotics have a beneficial effect on other diseases of the oral cavity that are caused by an imbalance in the bacterial flora, such as caries, gingivitis and periodontal disease. We therefore wanted to test whether lozenges with *Lactobacillus reuteri* Prodentis could also affect the prevalence of *Candida*. The study was performed on 215 elderly individuals at 20 different nursing homes in southern Sweden.

What did the results show?

After 12 weeks of intervention, there was a significant reduction in oral *Candida* among the patients who had been given Prodentis, while no improvement was seen in the placebo group. The results were statistically significant and showed that the probiotic was particularly effective in the patients with high *Candida* counts.

What conclusions can you draw from the results?

– The results show that *L. reuteri* Prodentis can reduce the prevalence of oral *Candida* in frail, elderly people. It's important to emphasize that oral *Candida* infections can be prevented through biologically gentle and simple means, and this is an area where family caregivers and healthcare personnel can play a central role. ■



Research is marketing

Lactobacillus reuteri is one of the world's most well researched probiotics and the number of scientific publications is growing continuously. At BioGaia, research is critical since scientifically based claims about the products are the company's most important marketing tool.



META-ANALYSIS PUBLISHED IN 2015

New meta-analysis confirms the effect of BioGaia's drops on colic

Tracy Harb, MPH at the Children's Nutrition Centre at the University of Queensland in Australia

There are already a number of studies and several systematic reviews of infant colic. What's new in your analysis?

Unlike previous analyses, our systematic review was focused around narrow inclusion criteria, which strengthens the results. It's a rigorous examination of commonly used interventions that are easily accessed by parents of colicky children. It provides healthcare professionals with updated evidence on the efficacy of the treatments they recommend. The analysis included both studies done in exclusively breastfed infants and studies in mixed fed infants.

What did the results show, and what conclusions can you draw from the analysis?

– 17 studies on different interventions for colic were evaluated. Six of the studies evaluated the effectiveness of *L. reuteri* Protectis, which was the only probiotic in the meta-analysis. The review showed that only *L. reuteri* Protectis and products containing fennel oil were effective for reducing colic, however, there were some limitations to these findings. For other substances, such as the frequently prescribed drug simethicone, the evidence was weak. The conclusion of our meta-analysis is that in the current situation, *L. reuteri* has the strongest scientific evidence for reducing colic in breast-fed infants. ■



Market



An expanding global market

In 2015 the global market for probiotic dietary supplements was worth around SEK 32 billion. At the global level probiotics are fastest-growing category of dietary supplements, but the differences between countries are vast. The USA, Canada and South Africa are the markets that have shown the highest growth in the past ten years. In Europe growth has been seen mainly in Italy and the UK, while growth in many other European countries has been flat.¹

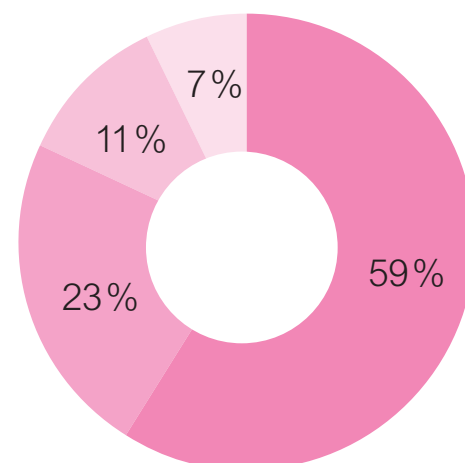
In Europe there is a relatively high acceptance and understanding of probiotics among both consumers and healthcare professionals, although there are major differences between countries. Probiotics are most firmly established in Finland, Italy and a number of Eastern European countries. These are regarded as mature probiotics markets, where probiotics are regularly prescribed and used. ■

¹ International Probiotics Association, Anvisa Probiotic Workshop, november 2015.



Sales by geographical market

Thanks to a sharp increase in sales in Brazil, together with good growth in Chile, Peru and Mexico, Rest of World grew by a full 87 per cent in 2015. The region is now BioGaia's second largest market with sales of SEK 111.2 million ■

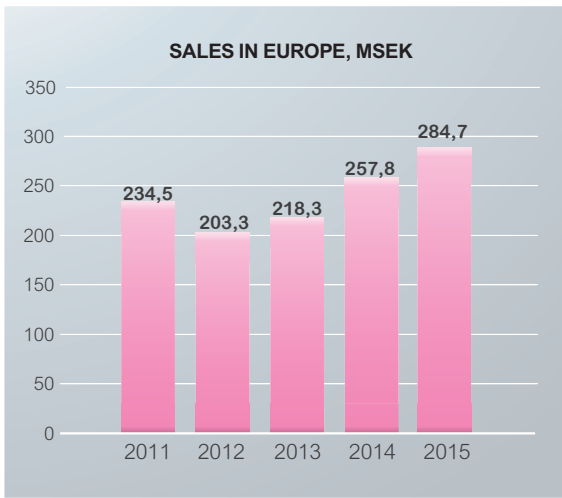


- = Europe 59% (67%)
- = Rest of the world 23% (15%)
- = Asia 11% (10%)
- = USA and Canada 7% (8%)

The BioGaia brand

Of the finished consumer products (drops, digestive health tablets, oral health tablets, oral rehydration solution, etc.), 62 per cent were sold under the BioGaia brand, including co-branding, in 2015 (52 per cent in 2014). ■



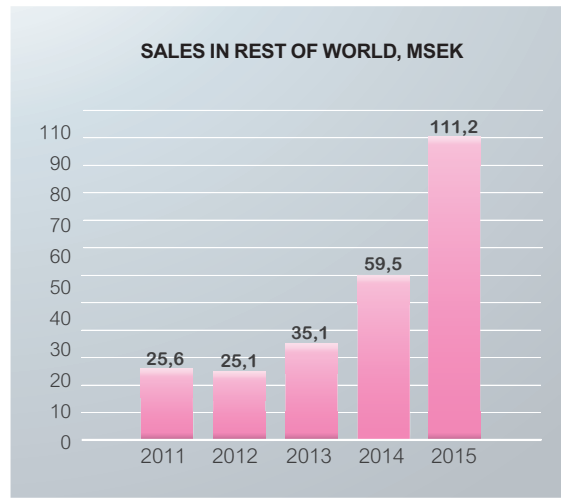


Europe

SALES DURING THE YEAR: Europe is BioGaia's largest market, accounting for 67 per cent of sales. In 2015 sales in this region rose by 10 per cent to SEK 284,7 million. The increase is mainly attributable to higher sales of drops, above all in Italy, Turkey, Germany, Spain and Sweden. Sales digestive health tablets for children were also up in several countries, particularly Bulgaria and Spain.

WORTH NOTING: Due to the continued instability in Ukraine, the partner Delta's sales of both drops and digestive health tablets have decreased. Sales of drops for children were also down in Finland as a result of aggressive price competition in this market, which is dominated by direct-to-consumer marketing. In contrast, the partner Verman saw an increase of around 7 per cent for digestive health tablets.

At the beginning of 2015 the partner Nóos in Italy launched oral health tablets and oral health drops. The products are sold both under Nóos' own brand Reuterin OS and under the BioGaia ProDentis brand. At the end of the year they also launched BioGaia Gastrus (under BioGaia's brand). ■



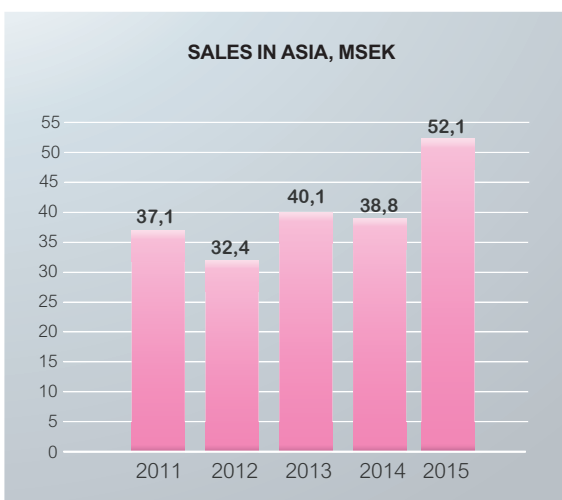
Rest of the world

SALES DURING THE YEAR: Rest of the world growing fastest thanks to a dramatic increase in sales in Brazil, together with solid growth in Chile, Peru and Mexico, Rest of World is now the second largest market with total sales of SEK 111.2 million. Sales in the region were up by 87 per cent during the year.

WORTH NOTING: At the end of 2015 BioGaia made the first sale of oral health products in Rest of World, to the new partner Silanes, ahead of the launch in Mexico. The launch will take place in the first quarter of 2016. ■

87%

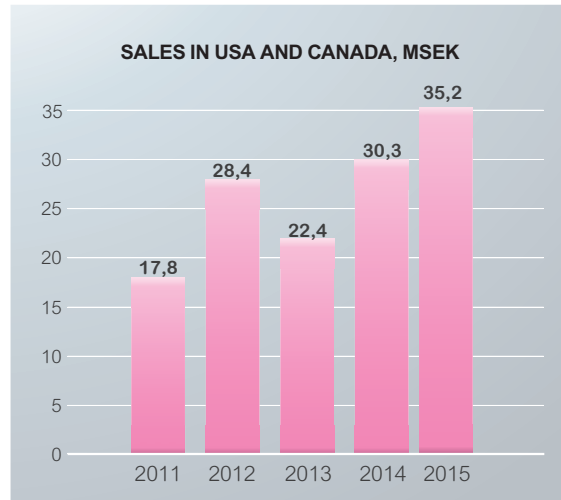
Sales growth in Rest of World during 2015



Asia

SALES DURING THE YEAR: Sales in Asia rose by 34 per cent to SEK 52.1 million. The drops increased in several countries, primarily Indonesia and South Korea. Growth was also noted for digestive health tablets for children, in Taiwan and Singapore, and for adults, in Hong Kong and Japan. Continued growth for oral health products was seen in Japan.

WORTH NOTING: The subsidiary BioGaia Japan has continued to focus on sales of the oral health products to dental clinics, which in turn recommend the products to their patients. Through its two channels, the distributor ADLIG and its own sales force, BioGaia Japan currently reaches 6,000 dental clinics and sells around 9,000 packages of BioGaia ProDentis per month. ■

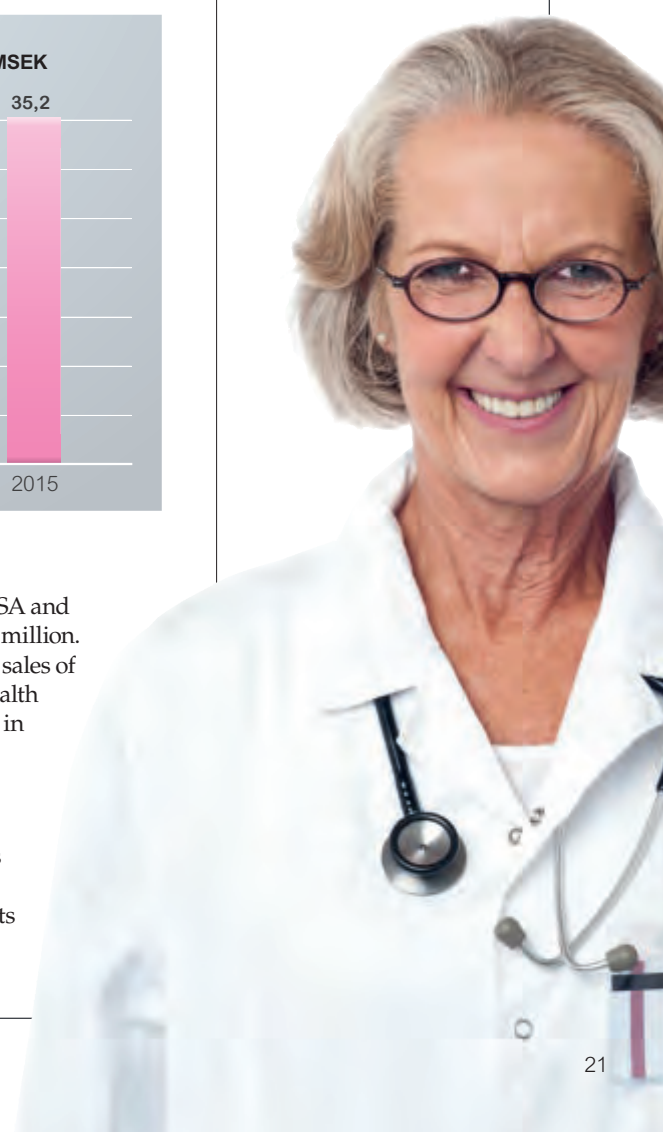


North America

SALES DURING THE YEAR: Sales in the USA and Canada grew by 16 per cent to SEK 35.2 million. Both the USA and Canada noted higher sales of drops but declining sales of digestive health tablets for children. Overall, all partners in North America increased their sales.

WORTH NOTING: At the end of 2015 the partner Everidis in the USA launched BioGaia Gastrus, digestive health tablets that are clinically documented as an adjunct to standard treatment for patients with *Helicobacter pylori* infection. ■

"The marketing is targeted towards doctors and other healthcare professionals and the most important benefits that are highlighted is the scientific evidence of the efficacy of the products."



Sustainability

BioGaia works with sustainability on the basis of three core issues


people


ethics


the environment

People

- BioGaia's employees are well aware of and work according to the company's values
- BioGaia strives for its employees:
 - to maintain a good balance between work and leisure time
 - to take responsibility for their health
- BioGaia makes charitable donations
- BioGaia strives for equality and diversity
- BioGaia encourages and supports employee initiatives for volunteer work

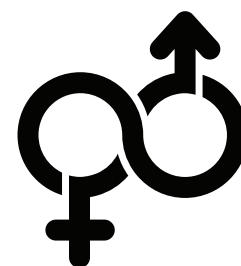
Promotes health and supports children's mission

Since 2007 BioGaia supports the Scandinavian Children's Mission in the Philippines, which helps children and their parents by taking care of malnourished children, running a preschool and offering vocational training to the parents. In 2015 BioGaia donated SEK 600,000 to the Scandinavian Children's Mission. In connection with the refugee crisis, BioGaia also donated SEK 50,000 to the UNHCR ■



Sweden's fifth most gender-equal company

In the AllBright report, an annual survey of gender equality among the management teams and boards of Swedish stock market companies, BioGaia is one of the companies that has improved most. In two years BioGaia has moved up from number 51 on the list to number five. A total of 264 listed companies take part in the report. BioGaia's Board of Directors consists of four women and four men and the executive management consists of seven women and five men. ■



Environment

- BioGaia reduces the use of antibiotics
- BioGaia measures the climate impact of the company and its products, take part in Carbon Disclosure Project reporting and compensates for its carbon dioxide emissions
- BioGaia strives for eco-friendly packaging (seen over the entire life cycle).
- BioGaia encourages its suppliers and distributors to take environmental aspects into account in their decisions



Striving for ecology and biology in balance


The microorganisms used by the company are completely natural and normally occurring in human beings. The modes of action of these microorganisms are based on biological principles. To stay healthy, the human body must maintain equilibrium between its various systems. An imbalance quickly results in diminished ability of the immune defence to prevent and fight disease. This ecological-biological approach is at the very core of BioGaia's operations. ■



Life cycle analysis of the packages

In 2013 BioGaia carried out a second, in-depth analysis of the packages' climate impact. The measurement, which was performed in collaboration with the Swedish Environmental Research Institute (IVL), showed for example that the tablet bottles with volumes of less than 60 tablets have the greatest impact per dose. BioGaia therefore recommends that the distributors choose blister packaging for smaller packages. Parallel to this, BioGaia is working to develop the existing packaging towards recyclable materials. ■

BioGaia contributes to a better environment by:

- 1 Selecting packages that have the smallest possible environmental impact during their life cycles.
- 2 Ensuring that the packages are not unnecessarily large and bulky.
- 3 Choosing modes of transport, for goods and employees, with the smallest possible environmental impact.
- 4 Urging suppliers to always take environmental aspects into account in their decisions.
- 5 Weighing in environmental aspects every time a significant decision is made. 

BioGaia's climate impact

BioGaia has measured the company's climate impact for the years 2012-2014. The greatest climate impact comes from the company's air travel, followed by the product packages.

In 2013 BioGaia took part for the first time in the CDP Nordic Climate Change report and won an award for its reporting as the best newcomer. BioGaia also participated in the CDP report in 2014 and will do so for 2015.

Since 2013 BioGaia climate compensates by purchasing certificates from Vi Agroforestry. In 2015 the company compensated for emissions in 2014 with an amount of SEK 150,000. ■



Ethics

- BioGaia's values form a basis for the company's ethical stance
- BioGaia's ethical policy states that the company shall:
 - respect the applicable laws and regulations
 - condemn bribery and corruption (also applies to suppliers and distributors)
 - only use animal models when necessary, and only in collaboration with well established research institutions

Setting a good example

BioGaia emphasizes the importance of always setting a good example by acting ethically in all contexts. Ethical issues can include which ingredients BioGaia's products contain or whether the company should allow the use of *Lactobacillus reuteri* in products that do not have a clear health profile.

BioGaia's management team regularly discusses ethical issues and the Managing Director makes the final decision in situations where setting of boundaries is difficult. Social responsibility is important to BioGaia, which works actively in this area. ■

Products

BioGaia's health-enhancing products are clinically tested, meaning that they are tested on humans. Research is conducted in an ethical manner with consumer safety as the top priority. By improving health through the use of probiotics, which are natural organisms without negative side effects, it is possible to reduce the use of antibiotics and other medications. In the long term, this will also have positive effects on the environment.

One central aspect of BioGaia's sustainability commitment is to conduct research and development aimed at offering products that reduce the use of antibiotics and the risk of antibiotic resistance. ■



B

SVERIGE
PORTO BETALT
PORT PAYÉ



Project management: Eva Nilsson, Corporate Communication Manager; BioGaia, Chaherin-Andersson, Marketing Assistant; BioGaia (financial sector), Anna Jonsson, AD/Communication Strategist; K&A, Illustration; K&A Edsten, Photos; Heiki Karlsson, and Johnér Bildbyrå, Translation; GH Language Solutions, Printing; Heiko 2016.

Experts at bacteria

BioGaia is an innovative Swedish health care company and has been a world-leader in dietary supplements with probiotics for more than 25 years. The products are based mainly on different strains of *Lactobacillus reuteri* and are sold by local distribution partners in around 90 countries.



2015

Financial information and Notes



BioGaia®

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Administration report

Figures in brackets refer to the previous year.

The Board of Directors and the President of BioGaia AB (publ.), corporate identification number 556380-8723, hereby submit their annual report and consolidated accounts for the financial year 2015.

The financial statements were approved for publication by the Board of the Parent Company on 24 February 2016.

BioGaia

The company BioGaia is a health company that develops, markets and sells probiotic products with documented health benefits. The products are primarily based on different strains of the lactic acid bacterium *Lactobacillus reuteri* in combination with unique packaging solutions that make it possible to create probiotic products with a long shelf life.

The class B share of the Parent Company BioGaia AB is quoted on the Mid Cap list of Nasdaq OMX Nordic Exchange Stockholm.

BioGaia has 105 employees, of whom 37 are based in Stockholm, 28 in Lund, 29 in Eslöv, three in Raleigh, USA, six in Hiroshima, Japan, and two in Shanghai, China.

Business model BioGaia's revenue comes mainly from the sale of drops, digestive health tablets, oral rehydration solution (ORS) and oral health products to distributors, but also of revenue from the sale of bacteria cultures to be used in a licensee's products (for example infant formula and dairy products), royalty income for the use of *Lactobacillus reuteri* in a licensee's product and sales of packaging solutions such as straws and caps.

The products are sold through distributors, of which several are pharmaceutical companies, in 90 countries. BioGaia holds patents for the use of *Lactobacillus reuteri* and certain packaging solutions in all major markets.

The BioGaia brand At the beginning of 2006 BioGaia launched its own consumer brand and today there are a number of distribution partners that sell finished products under the BioGaia brand in a large number of markets. One central part of BioGaia's strategy is to increase the share of sales consisting of BioGaia-branded products.

Some of BioGaia's distributors sell finished consumer products under their own brand names. For these products, the BioGaia brand is shown on the consumer package since BioGaia is both the manufacturer and licensor.

BioGaia's licensees add reuteri culture to their products and sell these under their own brand names. On these products, the BioGaia brand is most often shown on the consumer package as the licensor/patent holder.

Key events in 2015

New agreements

- **Agreement for the sale of drops in Vietnam** In January 2015 BioGaia signed an exclusive agreement with VietPhap International Co Ltd/Biovagen for the right to sell BioGaia ProTectis drops in Vietnam.
- **Agreement for the sale of oral health products in Mexico** In March BioGaia signed an exclusive agreement with Silanes for the rights to sell BioGaia's oral health lozenges in Mexico. The launch is planned for the beginning of 2016.
- **Agreement for the sale of BioGaia's products in Sri Lanka** In October BioGaia signed an agreement with Axero Associated for the right to sell drops, digestive health tablets, oral health tablets and Gastrus digestive health tablets in Sri Lanka.

Clinical studies

- **Publication of study showing that *Lactobacillus reuteri* Prodentis is effective in patients with dental implants** Inflammation and other complications from dental implants are common. The results from a double-blind, randomized controlled study on 34 patients with implants show that 30 days of supplementation with *Lactobacillus reuteri* Prodentis significantly reduced inflammation related to implants. The study was published in Journal of Periodontal Research on 25 February 2015.
- **Publication of Chinese study showing the effect of BioGaia's drops in infants with colic** A Chinese study on infants with colic showed that babies given *Lactobacillus reuteri* Protectis cried significantly less compared to babies given placebo. The study is the fifth positive colic study with *Lactobacillus reuteri* Protectis and the results confirm the positive findings from earlier studies. The study was published in the medical journal Antonie van Leeuwenhoek on 16 April 2015.
- **Publication of study showing that Prodentis reduces candida in the elderly** A double-blind, randomized, placebo-controlled study on 215 elderly nursing home residents showed that *Lactobacillus reuteri* Prodentis reduced the prevalence of oral Candida by 53% compared to placebo. The study was published in Journal of Dental Research on 22 July 2015.
- **BioGaia's probiotic promotes growth of children and prevents recurrent diarrhoea** The results of a randomized, controlled pilot study of 76 children with acute diarrhoea showed that rapid diagnostic testing in combination with *Lactobacillus reuteri* Protectis

supplementation for 60 days was associated with a significant increase in height and significantly less recurrent diarrhoea compared to standard care and placebo treatment. The study was conducted in Botswana and the preliminary results were presented at Infectious Disease Week in San Diego, USA, on 10 October 2015.

- **New meta-analysis confirms effectiveness of Protectis for colic** The analysis evaluated 17 studies on treatments for colic, of which *L. reuteri* Protectis was the only probiotic. Only one other product was found to be effective. Simethicone, a drug often prescribed for colic, was shown to have no effect. The systematic review and meta-analysis was published online by researchers Tracey Harb and colleagues at the University of Queensland, Australia, in Journal of Pediatric Gastroenterology and Nutrition on 14 December 2015.

Other key events during the year

- **BioGaia appoints new Managing Director AB** In October BioGaia's Board of Directors decided to appoint Axel Sjöblad as the new Managing Director of BioGaia AB. Peter Rothschild has been appointed as Group President.

Axel Sjöblad was previously Managing Director of Getinge Sverige AB and VP North and Central Europe, and prior to this Regional VP Northern European Markets at Gam-bro Lundia AB. He will take up duties as Managing Director of BioGaia AB on 1 March 2016. His extensive experience in marketing and sales makes him ideally suited to take over management of the company's operations.

In the capacity of Group President, Peter Rothschild will retain overall responsibility for the BioGaia Group's research and development activities and will serve as Working Chairman of the group companies TwoPac and CapAble. He will also support the development of BioGaia Japan. Peter Rothschild is also Chairman of the current subsidiary IBT, whose shares BioGaia's Board of Directors has decided to propose for distribution to BioGaia's shareholders, conditional on approval by the Extraordinary General Meeting on March 2016. See below under "Key events after the end of the financial year". Furthermore, Peter Rothschild will continue as Chairman of BioGaia's associated company MetaboGen.

- **Additional investment in MetaboGen** In December 2014 BioGaia reported its decision to invest SEK 12 million in MetaboGen AB in Gothenburg, Sweden. The investment was to be made over a two-year period. The first investment of SEK 4 million took place in December 2014 and, as MetaboGen had reached the agreed milestones, the second investment of SEK 4 million was made in December 2015. BioGaia's holding in MetaboGen thereafter amounts to 27%, and if further milestones are reached, the final investment of SEK 4 million will be made at the end of 2016. The holding will then amount to 35%.

MetaboGen is a research company that was founded in 2011 in Gothenburg by Professor Fredrik Bäckhed at the University of Gothenburg and Professor Jens B. Nielsen at Chalmers University of Technology, together with GU Holding, which commercializes research results and develops companies linked to the University of Gothenburg. MetaboGen conducts research on metagenomics. The aim is to develop new treatments and products for different metabolic and other microbial associated diseases by influencing large parts of the microbiota.

- **TwoPac approved for pharmaceutical production** In the third quarter of 2015, BioGaia's subsidiary TwoPac received approval from the Swedish Medical Products Agency for pharmaceutical production at its factory in Eslöv.

Key events after the end of the year

- **Proposal for distribution and separate listing of the subsidiary Infant Bacterial Therapeutics (IBT)** In February 2016 the Board of BioGaia AB resolved to propose that an Extraordinary General Meeting of BioGaia on 18 March 2016 approve the distribution of the shares in the subsidiary IBT to the shareholders in BioGaia. IBT will apply for listing of the company's shares on Nasdaq First North in connection with the distribution. As previously communicated, IBT has required additional capital of around SEK 100 million to finance the first clinical study, which is planned to be raised through a new share issue with preferential rights for IBT's shareholders in the second quarter of 2016.

The Board of BioGaia believes that a separate listing of IBT would be beneficial for BioGaia's shareholders, as it will highlight the value of the drug development project managed by IBT and result in streamlining of both BioGaia's and IBT's businesses. A separate listing would also enable BioGaia's shareholders to invest directly in IBT. The Board of BioGaia has therefore decided to propose that the Extraordinary General Meeting of BioGaia approve the distribution of all shares in IBT that are currently held by BioGaia to its shareholders. BioGaia's holding in IBT amounts to 94.5% and the remaining shares are held by management and one board member of IBT. The distribution is intended to be carried out according to the so-called Lex Asea rules, which means that the distribution is tax exempt in Sweden for both BioGaia and BioGaia's Swedish shareholders.

For more information see Note 5, Operations proposed for distribution.

Financial performance in 2015

Sales 2015 Net sales amounted to SEK 483.2 million (386.4)¹⁾, which is an increase of SEK 96.8 million (25%) compared to the previous year.

Most of the company's sales are denominated in foreign currency, primarily EUR but also USD, CHF and JPY. With unchanged exchange rates compared to the same period of last year, net sales would have been SEK 35.6 million lower. Excluding foreign exchange effects, net sales thus rose by 16%¹⁾ compared to the previous year.

- **License revenue from Nestlé in 2014** In the first quarter of 2014 BioGaia received license revenue from Nestlé in the amount of SEK 95.4 million attributable to the license agreement from 2012. In February 2012 BioGaia sold the rights for the use of *Lactobacillus reuteri* Protectis in infant formula to Nestlé for the remainder of the patent lifetime. The purchase price was EUR 50.8 million, of which EUR 40.0 million (SEK 356.0 million) was received and recognized in the first quarter of 2012. The additional payments of EUR 10.8 million (SEK 95.4 million) were received and recognized in the first quarter of 2014.

Since the license revenue in 2012 and 2014 is regarded as non-recurring and has a significant impact on the key ratios, it is stated on a separate line in the statement of comprehensive income, and the key ratios have been calculated both including and excluding license revenue from Nestlé. The license revenue is included in the Paediatrics business unit and the European market. In the comparative figures in the text below, license revenue is excluded. For comparative figures including license revenue, see Note 1 on page 6 and the key ratios on page 9.

- **Sales by segment 2015** A reallocation of revenue between the Paediatrics and New Business business units was made in 2015. The reallocation refers to BioGaia's royalty revenue arising from the collaboration agreement with Nestlé. The royalty revenue, amounting to a total of SEK 92.0 million for the period 2014-2017, was previously recognized in the Paediatrics business unit (SEK 22.9 million for the full year 2014), but as of 2015 has been reallocated between the Paediatrics and New Business business units. Under the agreement with Nestlé, BioGaia has undertaken to carry out clinical studies in the paediatric area and develop new products in new areas. The figures for 2014 have also been affected and have been adjusted in order to achieve comparability between years. As a result of the adjustment, SEK 12.5 million was reallocated from Paediatrics to New Business in 2014.
- **Paediatric business unit 2015** Sales in BioGaia's core area, Paediatrics, amounted to SEK 389.6 million (301.2)¹⁾²⁾, an increase of SEK 88.4 million (29%). Excluding foreign exchange effects, the increase was 19%.

The increase is primarily attributable to sales of drops, which showed growth in all regions.

In "Rest of world", sales of drops were up primarily in Brazil, where the launch took place in October 2014, as well as Chile, Peru and Mexico.

In Europe, sales of drops increased in several countries but above all in Italy, Turkey, Germany, Spain and Sweden, while they declined mainly in Finland but also in Poland, the Czech Republic and Ukraine. The downturn in Ukraine is due to the current instability in the country and in Finland to aggressive price competition in this market, which is dominated by direct-to-consumer marketing.

In North America, sales of the drops were up in both the USA and Canada.

In Asia, the sales growth was attributable to several countries but primarily Indonesia and South Korea.

Sales of digestive health tablets in the Paediatrics business unit rose in all regions but North America, where they declined in both the USA and Canada. The increase in "Rest of World" is mainly attributable to Brazil, where the tablets were launched in September 2014, as well as South Africa. In Europe, sales of the digestive health tablets were up in several countries, most notably Bulgaria and Spain, but fell in Ukraine. The increase in Asia was attributable to Taiwan and Singapore.

Sales of cultures for infant formula declined by SEK 5.7 million. This has affected sales but not profit, since the margin on this product is very low following the license agreement signed with Nestlé in 2012 in which Nestlé acquired the right to use *L. reuteri* Protectis in infant formula (for more information, see above).

Royalty revenue from Nestlé for the use of Protectis in Growing Up Milk for children older than one year were up compared to the previous year.

Royalty revenue from the collaboration agreement that was signed with Nestlé in March 2014 amounted to SEK 5.3 million (10.5)²⁾ in the Paediatrics business unit. Royalty revenue was previously recognized on a straight-line basis over the term of the agreement (2014-2017), but as of 2015 is recognized in pace with completion of the projects. For the current year, this resulted in lower revenue than in straight-line recognition.

During the year the Paediatrics business unit was focused on preparing for the start of a number of clinical studies in BioGaia's core areas and worked on technical and commercial development of new packaging solutions. The past year saw the publication of several interesting findings from the use of BioGaia ProTectis in independent clinical studies. These included a randomized, controlled pilot study on 76 children with acute diarrhoea from Bangladesh, where the results showed that rapid diagnostic testing in combination with *Lactobacillus reuteri* Protectis supplementation for 60 days led to a significant increase in standardized height and reduction in recurrent diarrhoea compared to standard care and placebo. The fifth clinical study with positive effects on infant colic and the first independent study from China were published in 2015. Furthermore, a new meta-analysis from a research team in Australia was published in December. This meta-analysis reviewed several different treatments for infant colic and the results showed that ProTectis was the only effective probiotic and that Simethicone, a drug often prescribed for colic, had no effect.

Launches in 2015



DISTRIBUTOR/LICENSEE	COUNTRY	PRODUCT	BRAND
Abbot/Recalcine	Panama	Drops and Protectis digestive health tablets	BioGaia
BG Distribution	Hungary	Oral rehydration solution	BioGaia
Biovagen	Vietnam	Drops and Protectis digestive health tablets	BioGaia
Delta Medical	Russia	Oral rehydration solution	BioGaia
Dexcel	Israel	Oral health tablets	BioGaia
Everidis	USA	Gastrus digestive health tablets	BioGaia
Nestlé	Pakistan and Middle East	Infant formula <i>Lactobacillus reuteri</i> Protectis	Partner brand
Noos	Italy	Oral health tablets, oral health drops and Gastrus digestive health tablets	Partner brand
Pharma Ace	Malaysia	Relaunch of drops	BioGaia
Pharmabest	Israel	Relaunch of drops	BioGaia
PT Interbat	Indonesia	Relaunch of Protectis digestive health tablets	BioGaia co-branding
Streuli Pharma	Switzerland	Oral health tablets	BioGaia
Sunstar	Austria	Oral health tablets	Partner brand

- **Adult Health business unit 2015** Net sales in the Adult Health business unit amounted to SEK 74.7 million (69.4), an increase of SEK 5.3 million (8%) (excluding foreign exchange effects, 2%) compared to the previous year.

The increase is due mainly to higher sales of oral health tablets, as well as digestive health tablets.

Sales of oral health products grew all regions but primarily in Asia (Japan) and Europe (Italy). The first sales in "Rest of World" to our partner Silanes ahead of the launch in Mexico were made in the third quarter of 2015. The launch will take place in the first quarter of 2016.

The increase in sales of digestive health tablets in the Adult Health business unit was mainly attributable to Europe (primarily Finland, Italy and Belgium), but sales were also up in Asia (Japan and Hong Kong). In "Rest of world", sales decreased (Australia and South Africa). In North America, no digestive health tablets are sold in the Adult Health business unit.

Sales of yoghurt in Japan decreased as the company discontinued sales in September 2014 because the margin did not meet expectations.

The Adult Health business unit is working in various ways to support expansion of the distribution network for its existing products. Parallel to this, the focus has been on starting clinical studies, both to enhance the existing products and to create new indication areas, especially in the key areas of gastroenterology and oral health. At the beginning of December the company exhibited at the APDW gastroenterology congress in Taipei. The well visited stand functioned as a platform and meeting place for discussion with regional gastroenterologists with a special focus on research relating to *Helicobacter pylori*.

- **New Business unit 2015** Other sales amounted to SEK 19.0 million (15.7)²⁾, an increase of SEK 3.3 million. The "New Business" business unit is included in "Other sales" in the segment reporting.

The New Business business unit includes royalty revenue of SEK 12.1 million (12.5)²⁾ arising from the collaboration agreement that was signed with Nestlé in March 2014. Royalty revenue amounting to a total of SEK 92.0 million for the period 2014-2017 has been previously reported in the Paediatrics business unit (SEK 22.9 million for the full year 2014) but will be allocated between the Paediatrics and New Business business units in the future. In order to achieve comparability between years, the previous year's amount has been adjusted. Under the agreement, BioGaia has undertaken to carry out clinical studies in the paediatric area and develop new products in new areas. BioGaia will recognize the royalty revenue in pace with completion of the projects.

- **Sales by geographic market 2015** Sales in Europe were up by SEK 26.9 million (10%)¹⁾ to SEK 284.7 million.

Sales in the USA and Canada rose by SEK 4.9 million (16%) to SEK 35.2 million.

Sales in Asia increased by SEK 13.3 million (34%) to SEK 52.1 million.

Sales in "Rest of world" grew by SEK 51.6 million (87%) to SEK 111.2 million.

- **The BioGaia brand** Of total finished consumer products, (drops, digestive health tablets, oral health tablets, oral rehydration solution, etc.) 60% (52%) were sold under the BioGaia brand, including co-branding, during 2015.

Gross profit 2015 Gross profit amounted to SEK 336.6 million (255.1)¹⁾, which is an increase of SEK 81.5 million (32%) compared to the previous year. The total gross margin rose from 66%¹⁾ to 70%.

Gross margin for the Adult Health business unit strengthened from 65% to 68%. This is mainly because the figures for the previous year included extra costs for the stability problems that arose for certain products.

Gross margin for the Adult Health business unit increased from 64% to 70%. This is mainly due to the discontinuation of yoghurt sales with very low margins, but also to increased sales of other products in Japan, where the margin is higher.

Operating expenses 2015 Total operating expenses rose by 15% compared to the previous year and amounted to SEK 186.1 million. Operating expenses include expenses for the subsidiary IBT totalling SEK 20.6 million (6.6). Without these, the increase in operating expenses would have been 7%.

Selling expenses increased by SEK 6.6 million compared to the previous year (7%) and amounted to SEK 96.3 million (89.8), which is equal to 20% (23)¹⁾ of net sales. It was primarily personnel and agency expenses that were up compared to the previous year. In contrast, expenses for marketing activities decreased, mainly with regard to product samples, which were a considerable expense in the previous year in connection with major launches. Selling expenses also include expenses of SEK 2.6 million for IBT. Excluding the expenses for IBT, selling expenses were up by 4%.

Administrative expenses amounted to SEK 18.5 million (17.7), which is equal to 4% (5)¹⁾ of net sales. The increase of SEK 0.8 million (5%) is mainly explained by higher personnel and consulting expenses.

R&D expenses are reported at SEK 71.3 million (53.9), which is equal to 15% (14)¹⁾ of net sales. The increase of SEK 17.4 million (32%) is due mainly to costs for the subsidiary IBT, which rose by SEK 11.4 million (see below). Furthermore, both patent expenses and costs for development projects increased, primarily as a result of the collaboration agreement with Nestlé. Excluding expenses for IBT, R&D expenses were up by 13%. In the fourth quarter a provision of SEK 3.9 million was reversed, which had a positive impact on profit. Without this reversal, the increase in R&D expenses would have been SEK 21.3 million.

Other operating income/expenses refer to foreign exchange gains/losses on operating receivables and liabilities.

Share in profit of associates In December BioGaia made a further investment in MetaboGen AB (see below). Following this investment, the holding amounts to 27% and MetaboGen is thus reported as an associate to BioGaia. The share in MetaboGen's profit is recognized according to the equity method over the consolidated income statement.

Operating profit 2015 Operating profit was SEK 152.2 million (101.5)¹⁾, an increase of SEK 50.7 million (50%) (excluding foreign exchange effects, 24%) and operating margin was 31% (26)¹⁾. Excluding the subsidiary IBT, operating profit was SEK 172.8 million (108.1) and operating margin was 36% (28%)¹⁾.

Financial items and profit before tax 2015 Profit before tax was SEK 157.4 million (97.1)¹⁾, an increase of SEK 60.3 million (62%) compared to the previous year. Net financial items include a foreign exchange gain of SEK 5.1 million on forward exchange contracts in EUR and USD. The figures for the previous year included a foreign exchange loss of SEK -6.6 million. At 31 December 2015 the company had outstanding forward exchange contracts for EUR 11.8 million at an average exchange rate of SEK 9.31 and USD 1.0 million at an average exchange rate of SEK 8.50. Forward exchange contracts amounting to EUR 8.3 million and USD 1.0 million will mature for payment in 2016 and EUR 3.5 million in 2017. The actual exchange gain/loss depends on the exchange rate on the maturity date of the contracts.

Profit after tax 2015 Profit after tax was SEK 121.3 million (73.6)¹⁾, an increase of SEK 47.7 million (65%).

The tax rate for the Group was 23% (23). The company pays tax in the Swedish companies, where the tax rate is 22%. BioGaia has had a tax matter related to a write-down of receivables from the Japanese subsidiary. At the end of 2015, the Administrative Courts announced that it had ruled against BioGaia AB. The Parent Company was not allowed a deduction for the write-down of receivables from the Japanese subsidiary. BioGaia therefore recognized the expense of SEK 3.0 million in the fourth quarter of 2015. In the first quarter of 2015, the Parent Company received SEK 1.5 million in refunded tax from previous fiscal years. This refers to a correction of previous years' tax returns regarding foreign exchange losses on loans to the subsidiary in Japan. Consequently, tax expenses amounting to a total of SEK 1.5 million attributable to previous years have been charged to profit for the year.

Tax loss carryforwards in the Japanese subsidiary amounted to SEK 31.3 million at 31 December 2015. The deferred tax asset for these has not been recognized, since a sustainable profit level has not yet been shown in the Japanese subsidiary.

Earnings per share 2015 Earnings per share were SEK 7.01 (4.23)¹⁾.

Cash flow 2015 Cash flow for the year amounted to SEK 15.1 million (-25.0). Cash flow included dividends of SEK -86.4 million (-120.9) and SEK 15.8 million arising from the issue of new shares through the warrant programme (0.0). Cash flow for the previous year included payment of SEK 95.4 million in license revenue from Nestlé.

The Group's cash and cash equivalents at 31 December 2015 amounted to SEK 226.9 million (210.7).

Equity at 31 December 2015 Consolidated equity at 31 December 2015 totalled SEK 395.8 million (344.6). The Group's equity/assets ratio was 84% (83).

The warrant programme for the employees that was resolved on by the Annual General Meeting on 8 May 2012 expired on 1 June 2015. A total of 65,500 warrants were redeemed and the share capital now amounts to SEK 17,336,462. The number of class B shares now amounts to 16,595,794 and the number of class A shares is unchanged at 740,668. The subscription price for the share was SEK 241.90 and the company was thus provided with proceeds of SEK 15.8 million in the second quarter. The reserve of SEK 1.1 million intended for a subsidy of SEK 10 per share to those who had subscribed for subscription warrants but had not exercised the right to buy shares was only partially utilized (SEK 0.2 million). The remaining reserve of SEK 0.9 million was dissolved in the second quarter and had a positive impact on operating expenses.

Investments in property, plant and equipment 2015 Investments in property, plant and equipment totalled SEK 17.8 million (18.4), of which SEK 17.6 million (17.3) refers to the subsidiary TwoPac AB, where expansion of the production plant was started in 2014 and has continued during 2015. The expansion is expected to be completed in 2016.

Investments in capitalized development expenditure amounted to SEK 10.1 million (6.1) and refer to development of a product for the NEC project in the subsidiary IBT AB.

Subsidiary in Japan 2015 Net sales in the wholly owned subsidiary in Japan reached SEK 21.1 million (17.1). Operating profit/loss in the Japanese subsidiary was SEK -2.8 million (-6.1). Efforts to launch the drops are continuing and the company has initiated a cost-cutting programme that will significantly contribute to improved earnings in the Japanese company.

Subsidiary TwoPac AB (incl. subsidiary) 2015 Net sales in the wholly owned subsidiary TwoPac, of which 100% consists of sales to the Parent Company, amounted to SEK 52.6 million (44.7). Operating profit was SEK 9.9 million (7.7). Profit after tax was SEK 7.2 million (5.5). Operating expenses in the company increased, which is due to higher personnel expenses resulting mainly from more stringent quality criteria. The higher quality criteria are internally driven but are also explained by the fact that TwoPac obtained approval of the facility for pharmaceutical production from the Swedish Medical Products Agency in the third quarter of 2015.

Subsidiary CapAble AB 2015 CapAble, which is owned 90.1% by BioGaia AB and 9.9% by the company's President, was started in November 2008 to manufacture and sell the patented LifeTop Cap.

Net sales in CapAble totalled SEK 1.6 million (0.5). Operating profit amounted to SEK -3.5 million (-2.9). In 2014 and the first quarter of 2015 the company experienced quality problems, which meant that sales have not gained momentum as anticipated. The company's assessment is that the problems have now been solved and that sales will pick up speed during 2016. CapAble has now also commenced marketing of the company's LifeTop Straw with probiotics. During the year CapAble signed two new agreements for LifeTop Straw, one with Ganeden, USA and one with Alimentary Health, Ireland.

Subsidiary IBT AB 2015 In November 2013, the Board of BioGaia made a decision to invest in a first phase of a long-term project aimed at developing a drug with rigorous hygiene, analysis and documentation requirements, to treat the highly fatal disease necrotizing enterocolitis (NEC), which affects premature infants. At that time BioGaia decided to invest up to SEK 42 million in the project. In 2015 the Board of BioGaia decided to invest a further SEK 40.0 million in IBT. IBT therefore carried out a new issue. BioGaia's total investment in IBT after the new share issue amounts to approximately SEK 82 million and its holding to 94.5%. The remaining 5.5% is owned by IBT's President, Staffan Strömberg (2.5%), and its Head of Research and Development, Eamonn Connolly (2.5%), as well as Board member Anders Eklom (0.5%), former Global Head of R&D Science & Technology Integration at AstraZeneca AB and CEO of AstraZeneca AB).

In February IBT was granted orphan drug designation for the prevention of NEC in Europe, following a similar decision by the FDA in August 2013.

At the beginning of 2016 IBT received approval for clinical studies in the USA and Sweden. The so-called IND (Investigation New Drug) for the prevention of NEC was authorized by the FDA. Furthermore, the Swedish Medical Products Agency gave IBT approval to conduct the study in Sweden.

To finance the first study, IBT will require estimated additional capital of approximately SEK 100 million. To enable BioGaia's shareholders to invest directly in this project, in 2015 the Board instructed the executive management to evaluate the possibilities for a separate listing of IBT. The Board of BioGaia has today passed a decision to distribute the shares in IBT to the company's shareholders in connection with IBT's application for a separate listing on the First North marketplace.

Operating profit in IBT amounted to SEK -20.6 million (-6.7) in 2015. The company made investments in capitalized development expenditure of SEK 10.1 million (6.1) during the year. The company does not yet have any revenue.

Parent Company 2015 Net sales in the Parent Company reached SEK 470.6 million (368.8)¹⁾ and profit before tax was SEK 165.6 million (97.2)¹⁾.

Cash flow in the Parent Company totalled SEK -30.0 million (-27.6).

Research and development activities

BioGaia has an extensive research network and collaborates with numerous universities and hospitals around the world, such as the Swedish University of Agricultural Sciences in Uppsala, Sweden, the Karolinska Institute in Stockholm, Sweden, Sahlgrenska University Hospital in Gothenburg, Sweden, Texas Children's Hospital in the USA, and the University Hospitals of Bari and Turin in Italy.

BioGaia's strains of *Lactobacillus reuteri* are some of the world's most well researched probiotics, especially in young children. To date, 152 clinical studies using BioGaia's human strains of *Lactobacillus reuteri* have been performed on around 13,000 individuals. The results have been published in 136 articles in scientific journals.

Studies have been performed on:

- Infantile colic and digestive health in children
- Antibiotic-associated diarrhoea (AAD)
- Acute diarrhoea
- Gingivitis (inflammation of the gums)
- Periodontal disease (tooth loss)
- General health
- *Helicobacter pylori* (the gastric ulcer bacterium)
- Necrotizing enterocolitis (NEC)

R&D expenses are reported at SEK 71.3 million (53.9), which is equal to 15% (14) of net sales. The increase of SEK 17.4 million (32%) is due mainly to costs of SEK 20.6 million for the subsidiary IBT (6.6) (see above). Furthermore, costs for development projects increased primarily as a result of the collaboration agreement with Nestlé (see above). Patent expenses were also higher during the year. Excluding expenses for IBT, R&D expenses were up by 13%.

IBT has invested in capitalized development expenditure for development work in an amount of SEK 10.1 million (6.1). The investment refers to external and internal expenses for development of a manufacturing process for the new formulation. The company's assessment is that the formulation can also be used for products other than the NEC product.

Reporting of clinical studies Publication of clinical trial results is a key success factor for BioGaia. The International Committee of Medical Journal Editors has initiated a policy requiring clinical investigators to deposit information about trial design into an accepted clinical trials registry before the onset of patient enrolment, and this has now become a prerequisite for publication of trial outcomes in major medical journals. ClinicalTrials.gov is a registry of clinical trials provided by the U.S. National Institutes of Health and BioGaia encourages all clinicians working with BioGaia products to register their trials on this site. Many of the trials are registered at an early stage, which means that some of the registered trials will not be performed as planned. Consequently, BioGaia takes no responsibility for ensuring that the registered trials reach completion or are successfully reported in the register or the scientific literature. When clinical trial results of significance for the company's operations do become available, BioGaia will report these through press releases.

Environmental information

BioGaia has a fundamentally ethical and environmentally friendly mission, namely to conduct research and development aimed at offering clinically proven, health-enhancing and user-friendly probiotic products. By offering alternatives that make it possible to improve health through the use of natural organisms, without side effects, the company's hope is to reduce the use of medications and antibiotics. In a longer perspective, this will also have positive effects on the environment.

BioGaia has measured the company's climate impact in 2012-2015. Starting in 2013, the subsidiary TwoPac AB is also included. The greatest climate impact is caused by the company's air travel, followed by product packages.

In 2013 BioGaia took part in CDP Nordic Climate Change report for the first time and won a prize for its report as the best newcomer. BioGaia also participated in the CDP report in 2014. The report provides investors and the market worldwide with information about the climate impacts of the largest corporations and how efforts to reduce negative impact are integrated in their business strategies.

BioGaia climate compensates by purchasing certificates from Vi Agroforestry. In 2013 and 2014 a total of 9,286 trees were planted through BioGaia's contribution of SEK 140,000 to Vi Agroforestry projects in the Kagera region of western Tanzania. In 2015 BioGaia climate compensated through contributions of SEK 150,000 to Vi Agroforestry projects.

Goals for environmental work in 2016

1. Report on BioGaia's climate impact in 2015
2. Communicate BioGaia's environmental responsibility to employees and distributors.
3. Climate compensate in selected projects for emissions during 2015.
4. Take part in CDP Nordic Climate Change Report.

BioGaia conducts no operations that are subject to permit or notification requirements.

Business risks and uncertainties

BioGaia's operations are associated with both risks and opportunities of various types. Certain risks are of a general nature, while others are more specific to the company. The following section is not a complete risk analysis, but an indication of the factors of significance for future development.

The Japanese subsidiary The Japanese subsidiary has operated at a loss since the start in 2006. On the balance sheet date, assets in the Japanese subsidiary were reported at SEK 15.6 million in the Group. BioGaia's assessment is that there is no indication of impairment of these assets. In the Parent Company, the loan to the Japanese subsidiary and participations in the company have been written down to zero.

Subsidiary CapAble AB CapAble, which is 90.1% owned by BioGaia AB, was started in November 2008 to manufacture and sell the patented LifeTop Cap. The shares in the subsidiary CapAble amount to a total of SEK 6.9 million in the Parent Company. CapAble has operated at a loss since the start in 2008. BioGaia made total conditional shareholder contributions of SEK 6.0 million to CapAble in 2009 and 2010. BioGaia AB made total group contributions of SEK 15.1 million during the period from 2010 to 2015. Profit before tax and group contributions for 2015 amounted to SEK -3.5 million (-2.9). On the balance sheet date, assets in CapAble were reported at SEK 3.1 million and in the Parent Company at SEK 6.9 million. BioGaia's assessment is that CapAble will show profitability in coming years, for which reason there was no indication of impairment on the balance sheet date.

Development of drug to treat NEC Infant Bacteria Therapeutics AB (IBT), which is 94.5% owned by BioGaia, was established in November 2013. For more information see above. BioGaia's total investment in IBT amounts to SEK 81.8 million. On the balance sheet date, assets in IBT were reported at SEK 62.1 million in the Group. BioGaia's assessment is that IBT and the research and development projects currently underway in the company

¹⁾ Excluding SEK 95.4 million in license revenue from Nestlé. Including license revenue from Nestlé, net sales for 2014 amounted to SEK 481.8 million, net sales in the Paediatrics business unit to SEK 396.6 million, net sales in Europe to SEK 353.2 million, gross profit to SEK 350.5 million, operating profit to SEK 196.9 million, profit before tax to SEK 192.5 million, profit after tax to SEK 147.9 million and earnings per share to SEK 8.53. Operating margin was 41%. Net sales for the Parent Company including license revenue amounted to SEK 464.2 million and profit before tax was SEK 192.6 million.

²⁾ A minor reallocation of last year's sales between segments has been made in order to achieve better comparability with the year's figures.

will show profitability in the future, for which reason there was no indication of impairment on the balance sheet date. In February 2016 the Board of BioGaia resolved to distribute the shares in IBT to the company's shareholders in connection with IBT's application for listing on the First North marketplace.

Associated company MetaboGen AB Since 1 December 2015, BioGaia owns 27% of MetaboGen AB. The remaining shares are held by the researchers who founded the company. So far, MetaboGen has shown a loss. On the balance sheet date, assets in MetaboGen were reported at SEK 7.9 million in the Group. BioGaia's assessment is that MetaboGen will show profitability in the future, for which reason there was no indication of impairment on the balance sheet date.

BioGaia's partners BioGaia does not sell directly to end-users but instead sells its products to companies (partners) which then sell the products to third parties (end-users). The agreements normally have a term of 3-7 years.

BioGaia is dependent on these partners to invest the resources necessary for marketing and sales. In order to influence this to a greater extent on its own, BioGaia launched its own brand in 2006. Today a number of BioGaia's partners sell products wholly or partly under the BioGaia brand and BioGaia-branded products are currently sold in more than 50 countries. BioGaia also provides its partners with strong support in the form of education, information about new clinical studies and speakers at symposia, as well as marketing and PR support. There is a risk that BioGaia's partners will not perform according to the company's wishes. However, BioGaia has formulated its agreements so that it is possible to terminate the agreement if a distributor does not meet certain minimum sales targets.

Research and development BioGaia invests considerable sums in research, clinical studies and product development with the aim of developing products with proven health benefits. Even after thorough pilot studies, there is always a risk that a project will be wholly or partly unsuccessful.

Intellectual property BioGaia's business activities are based on a large number of intellectual property rights, such as patents, trademarks, names of strains and Internet domains. The company works continuously to strengthen its intellectual property rights by protecting the use of the company's products. The various patents have different terms but those covering the most used strains in BioGaia's products apply until 2027.

There is always a risk for infringement of intellectual property. These rights are enforced on an ongoing basis, but there are no guarantees that future infringements will not cause the company damage. BioGaia continuously monitors the market.

Regulatory situation BioGaia's products are currently sold in some 95 countries around the world. Due to their differing regulatory systems, the length of time between contract and product launch varies between countries. In most countries the products are registered as dietary supplements but in certain markets, like Turkey, Hong Kong and Peru, they are registered as a category of pharmaceuticals.

There is always a risk that the rules will be changed in the different markets with a resulting negative impact on sales, at least for a limited period of time.

In the EU, the use of nutrition and health claims is regulated by the European Food Safety Authority (EFSA). The EFSA rules, which went into effect in December 2012, apply to food products that are marketed to consumers with various claims about preventative health effects, for example that a lower intake of cholesterol reduces the risk for cardiovascular disease or a food product's ability to improve the immune defence. In order to make a health claim for a product and in marketing, EFSA approval is required.

In the case of BioGaia's products, the distributors show the clinical studies to healthcare professionals (doctors, midwives, etc.) who then recommend the products to patients because the patient in question is in more or less urgent need of the product's probiotic effects. As a result, the EFSA rules are not applicable to the majority of BioGaia's products. Furthermore, because the products are primarily recommended by healthcare professionals, such as doctors and nurses, in most countries there is no need to make general health claims in the marketing materials as would be the case if the company was marketing a yoghurt or beverage directly to consumers.

If it becomes necessary to use another type of marketing for future products, BioGaia will apply for approval of its health claims from the EFSA. Together with partners BioGaia is assessing the opportunities to register its products under the existing regulations as Food for Special Medical Purposes, natural remedies or other registration categories depending on the type of product and the country involved.

Employees BioGaia's operations are wholly dependent on the employees' expertise, and they therefore make up the company's most valuable resource. In order to attract and retain skilled and motivated employees, BioGaia strives to create a culture in which all employees are given the opportunity to develop, influence their own work situation and maintain a good balance between work and leisure in order to avoid stress.

Product liability insurance BioGaia's partners require the company to have product liability insurance as protection against liability claims for third party damage. BioGaia has product liability insurance that provides coverage up to SEK 60 million per claim up to a maximum of SEK 120 million per year. The insurance is valid worldwide. BioGaia's assessment is that these insurance amounts are relevant and adequate for the company's operations.

Financial risk management

The overall objective of the Group's finance function is to secure cost-effective financing for the Group's operations and group companies and to provide secure cash management with a market-based return on investment. The overall objective of financial risk management is to minimize the risk for negative effects on the Group's earnings. Consequently, the Group's financial investments must have a low risk profile.

Below is a description of the Group's assessed risk exposure and the related risk management.

Currency risk BioGaia has revenue primarily in EUR, but also in USD, SEK, CHF and JPY, and expenses primarily in SEK, EUR, JPY and USD.

The breakdown of net sales in 2015 was approximately:

EUR 49%
USD 28%
SEK 15%
JPY 4%
Other currencies 4%

In 2015 the company had a cash flow surplus of approximately EUR 14.5 million (25.9) (including the payment of EUR 10.8 million from Nestlé), a cash flow deficit of JPY -62.0 million (-76.8) and a cash flow surplus of USD 12.8 million (3.5).

Growth in sales has also led to increased currency risks, for which reason the company has taken currency hedges in EUR. The company's Board of Directors has issued a policy to hedge approximately 50-60% of projected cash flow 12 months forward and approximately 10-40% of projected cash flow 13-24 months forward in order to spread the risk for exchange rate fluctuations. At 31 December 2015 the company had outstanding forward exchange contracts for EUR 11.8 million at an average exchange rate of SEK 9.31 and USD 1.0 million at an average exchange rate of SEK 8.50. Forward exchange contracts amounting to EUR 8.3 million and USD 1.0 million will mature for payment in 2016 and EUR 3.5 million in 2017. The actual exchange gain/loss depends on the exchange rate on the maturity date of the contracts. For more information see Notes 10, 11, 23 and 26.

The average exchange rate for EUR/SEK in 2015 was 9.35. If the EUR/SEK rate had been SEK 0.10 higher, BioGaia's net sales would have been approximately SEK 2.5 million higher and operating profit would have been around SEK 1.4 million higher.

The average exchange rate for USD/SEK in 2015 was 8.43. If the USD/SEK rate had been SEK 0.10 higher, BioGaia's net sales would have been approximately SEK 1.6 million higher and operating profit would have been around SEK 1.2 million higher.

A stronger SEK rate, primarily against the EUR and USD, will decrease the value of BioGaia's sales and profit, but through profitable forward exchange transactions and by trying to reallocate a portion of expenses to EUR, the company is trying to minimize the impact. BioGaia is also trying to reallocate a share of revenue from EUR to other currencies.

Interest rate and liquidity risk The Group has no external loans.

For cash and cash equivalents, the company has a liquidity policy in which the basic principles are that investment risks should always be minimized and investments should be made primarily in Swedish kronor. To minimize currency risk, other currencies may also be considered. The company's excess liquidity may be invested only in bank accounts, commercial paper or other fixed income securities with very limited risk. This means that no investments may be made in shares, equity funds, options, etc.

Credit risks BioGaia's credit risks are attached to trade receivables and, for the Parent Company, also loans to subsidiaries. When signing agreements with new customers, BioGaia always carries out an assessment of the customer's financial position. The company has routines for collection of past due accounts receivable and additional evaluation of the customers' financial position is carried out when needed in order to minimize risks.

The loan from the Parent Company to the subsidiary TwoPac AB has been used mainly for construction of the production facility in Eslöv. The first facility was completed and taken into operation in 2012. In 2014 and 2015, additional loans were paid for expansion of the production facility, which took place during the year. The expansion is expected to be completed 2016. The company's assessment is that the credit risk on the loan is low.

Cash flow risk Cash flow for the period amounted to SEK 15,1 million (-25,0). Cash flow included license revenue from Nestlé of SEK 0 million (95,4), dividends of SEK -86,4 million (-120,9) and tax payments of SEK -50,1 million (-66,8). Because cash and cash equivalents at 31 December 2015 amounted to SEK 226,9 million (210,7), no infusion of capital is necessary during the coming 12-month period.

Price risk BioGaia buys most of its goods on the international market and has several alternative suppliers, which reduces the company's price risk. BioGaia's price to distributors is largely the same for all, but can vary with respect to the order volume. Certain markets are subject to aggressive price competition towards consumers. However, BioGaia's strategy is not to compete in terms of price but to instead convince doctors of the effectiveness and safety of the products by showing the results of clinical studies.

Employees

The number of employees in the Group at 31 December 2015 was 105 (95), consisting of 59 women and 46 men. The management team includes five men and seven women. In 2015, 20 new employees were hired and ten left the company. See Note 4 for additional information about employees and personnel expenses.

BioGaia's incentive scheme for the employees The warrant programme for the employees that was resolved on by the Annual General Meeting on 8 May 2012 expired on 1 June 2015. A total of 65,500 warrants were redeemed and the share capital now amounts to SEK 17,336,462. The number of class B shares now amounts to 16,595,794 and the number of class A shares is unchanged at 740,668. The subscription price for the share was SEK 241.90 and the company was thus provided with proceeds of SEK 15.8 million in the second quarter. The reserve of SEK 1.1 million intended for a subsidy of SEK 10 per share to those who had subscribed for subscription warrants but had not exercised the right to buy shares was only partially utilized (SEK 0.2 million). The remaining reserve of SEK 0.9 million was dissolved in the second quarter and had a positive impact on operating expenses.

BioGaia has no incentive schemes currently in force for the employees and in 2015 has only paid basic salary to the employees

Future outlook

BioGaia's goal is to create strong value growth and a good return for the shareholders. This will be achieved through a greater emphasis on the BioGaia brand, increased sales to both existing and new customers and a controlled cost level.

In view of the Company's strong portfolio consisting of an increased number of innovative products that are sold under the BioGaia brand to a growing extent, successful clinical trials and an expanding distribution network that covers a large share of the key markets, BioGaia's future outlook is bright.

Financial target and dividend policy The financial target is a sustainable operating margin (operating profit in relation to sales) of at least 30% with continued strong growth and increased investments in research, product development and brand building.

BioGaia's dividend policy is to pay a shareholder dividend equal to 40% of profit after tax.

The Board of Directors' proposal to the AGM regarding remuneration and other terms of employment for senior executives

The Board of Directors proposes that the AGM approve the following guidelines for remuneration and other terms of employment for senior executives in the Group. These principles apply to employment contracts entered into after the decision of the AGM and in the event that changes are made in the existing terms after this date.

It is of fundamental importance for the Board that the principles for remuneration and other terms of employment for senior executives in the Group create long-term motivation and enable the company to retain competent employees who work to attain maximum shareholder and customer value. In order to achieve this, it is vital to uphold fair and internally balanced terms that are market-based and competitive with respect to the structure, scope and level of remuneration. The total remuneration package for the affected individuals should contain a well-balanced mix of basic salary, variable remuneration, long-term incentive schemes, pension benefits, other benefits and terms of notice/termination benefits.

- **Basic salary** Basic salary shall be differentiated on the basis of the individual's role and responsibilities, as well as the individual's competence and experience in the relevant position.
- **Variable remuneration** The amount of variable remuneration shall not exceed 25% of total remuneration.
- **Long-term incentive schemes** Every year, the Board of Directors shall evaluate whether a long-term share-based or share price-based incentive scheme should be proposed to the AGM. Other types of long-term incentive schemes can be decided on by the Board. Any remuneration in the form of long-term incentive schemes shall be consistent with generally accepted practices in the respective market.
- **Pensions** Senior executives who are entitled to pension benefits shall have pension agreements of the defined contribution type. The amount of benefit payable depends on the amount payable under the pension agreements in force.
- **Other benefits** Other benefits shall be of limited value in relation to other remuneration and shall be consistent with general norms in the respective geographical market.
- **Terms of notice and termination benefits** In the event that employment is terminated by the company, the term of notice for senior executives may not exceed 18 months. In the event that employment is terminated by the employee, the term of notice may not be shorter than three months.

The Board of Directors proposes that the Board be authorized to deviate from the above proposed guidelines in individual cases when there is special reason to do so.

For more information about remuneration to senior executives, see Note 4.

Most recently adopted guidelines regarding remuneration and other terms of employment of senior executives

The most recently adopted guidelines correspond to those that are proposed to the AGM (see above) with the exception of the sections about "Pensions" and "Terms of notice and termination benefits".

The following sentence was included in the previous year under "Pensions" - The mandatory age of retirement for senior executives who are Swedish citizens is 65 years, and for others according to the pension rules in their respective countries. The section "Terms of notice and termination benefits" has also been changed. The wording in the previous year was: The President and the company have a mutual notice period of 18 months. The company's Vice Presidents have a corresponding notice period of six months. For other senior executives, the notice period is three months.

Corporate governance

BioGaia has issued a separate corporate governance report. See page 27-29.

Proposed appropriation of profits

The following funds in the Parent Company are at the disposal of the Annual General Meeting (SEK):

Retained earnings	245,421,510
New issue of warrants	15,778,950
Profit for the year	130,779,429
Together amounting to:	391,979,889

The Board of Directors proposes that the profits be appropriated as follows

To be paid as a dividend to the shareholders	86,682,310*
Distribution of the shares in IBT	81,805,856
To be carried forward to new account	223,491,723
Total	391,979,889

**) The proposed dividend consists of an ordinary dividend of SEK 3.03 per share and, in view of the company's good liquidity and the strong balance sheet, an extraordinary dividend of SEK 1.97 per share, amounting to a total dividend of SEK 5.00 per share.*

Five-year summary

Key ratios	2015	2014	2014 ¹⁾	2013	2012	2012 ¹⁾	2011
Net sales, SEK M	483.2	481.8	386.4	315.9	645.2	289.2	315.0
Net sales, Paediatrics, SEK M	389.6	409.1	313.7	238.6	N/A	N/A	N/A
Net sales, Adult Health, SEK M	74.7	69.4	69.4	75.6	N/A	N/A	N/A
Net sales, other SEK M	19.0	15.7	15.7	1.7	N/A	N/A	N/A
Operating profit, SEK M	152.2	196.9	101.5	81.7	428.1	72.1	103.2
Profit before tax, SEK M	157.4	192.5	97.1	83.8	442.2	86.2	108.9
Profit after tax, SEK M	121.3	148.0	73.6	64.2	329.9	63.7	79.5
Profit after tax attributable to owners of the Parent Company, SEK M	121.4	147.4	73.0	61.7	327.0	60.8	76.4
Growth net sales %	25	53	22	9	105	-8	33
Operating margin, %	31	41	26	26	66	25	33
Profit margin, %	33	40	25	27	69	30	35
Current ratio, times	4.7	4.7	4.8	4.9	13.2	5.1	5.2
Equity/assets ratio, %	84	83	84	83	88	82	82
Capital employed, SEK M	396.2	344.8	270.4	316.9	481.5	195.7	230.5
Return on capital employed, %	43	60	35	22	124	40	52
Return on equity, %	33	45	25	16	96	29	37
Average number of employees	102	90	90	82	70	70	61
Data per share							
Number of shares at 31 Dec., thousands ²⁾	17,336	17,271	17,271	17,271	17,271	17,271	17,271
Average number of shares, thousands	17,309	17,271	17,271	17,271	17,271	17,271	17,271
Number of outstanding warrants, thousands	-	87	87	87	87	87	-
Number of outstanding warrants with a dilutive effect, thousands	-	-	-	87	-	-	-
Number of outstanding shares including outstanding warrants with a dilutive effect, thousands	17,336	17,271	17,271	17,358	17,271	17,271	17,271
Basic earnings per share, SEK	7.01	8.53	4.23	3.57	18.93	3.52	4.42
Diluted earnings per share, SEK	7.01	8.53	4.23	3.56	18.93	3.52	4.42
Equity per share, SEK	22.87	19.95	15.64	18.37	26.25	10.83	13.30
Equity per share after dilution, SEK	22.87	19.95	15.64	18.28	26.25	10.83	13.30
Cash flow from operating activities per share, SEK	6.78	7.20	E/T	4.54	19.43	E/T	4.21
Cash flow from operating activities per share after dilution, SEK	6.78	7.20	E/T	4.52	19.43	E/T	4.21
Share price on the balance sheet date, SEK	281.50	179.50	179.50	253.50	175.00	175.00	163.00
Dividend per share, SEK	5.00 ³⁾	5.00	5.00	7.00	10.00	10.00	6.00

¹⁾ Key ratio excluding license revenue from Nestlé of SEK 95.4 million in 2014 and SEK 356.0 million in 2012. For more information, see administration report.

²⁾ The share capital consists of 740,668 class A shares and 16,595,794 class B shares. The quota value is SEK 1 per share.

³⁾ Dividend proposed but not yet approved.

For definitions of key ratios, see page 34.

Group

Statement of comprehensive income

SEK 000s	Note	2015	2014
Net sales	2, 3	483,241	481,802
Cost of goods sold	2	-146,657	-131,338
Gross profit	2	336,584	350,464
Selling expenses	4, 5	-96,335	-89,759
Administrative expenses	4, 6	-18,475	-17,666
Research and development expenses	4, 5, 14	-71,257	-53,867
Share of profit of associates	7	-65	-
Other operating income	8	1,732	7,711
Operating profit	9	152,184	196,883
Financial income	10	5,438	2,382
Financial expenses	11	-269	-6,740
Net financial items		5,169	-4,358
Profit before tax		157,353	192,525
Tax	12	-36,062	-44,536
PROFIT FOR THE YEAR		121,291	147,989
<i>Other comprehensive income:</i>			
Gain/losses arising on translation of the financial statements of foreign operations:		462	642
Comprehensive income for the year		121,753	148,631
<i>Profit for the year attributable to:</i>			
Owners of the Parent Company		121,408	147,406
Non-controlling interests	13	-117	583
		121,291	147,989
<i>Comprehensive income for the period attributable to:</i>			
Owners of the Parent Company		121,870	148,048
Non-controlling interests	13	-117	583
		121,753	148,631
Earnings per share			
Basic earnings per share, SEK		7.01	8.53
Diluted earnings per share, SEK		7.01	8.53
Number of shares, thousands		17,336	17,271
Average number of shares, thousands		17,309	17,271
Number of outstanding warrants, thousands		-	87
Number of outstanding warrants with a dilutive effect, thousands		-	-
Average number of shares after dilution, thousands		17,309	17,271

Cash flow statement

SEK 000s	Note	2015	2014
Operating activities			
Operating profit		152,184	196,883
<i>Adjustments for non-cash items:</i>			
Depreciation/amortization		6,548	5,652
Capital gains/losses on the sale of shares		-	-4
Capital gains/losses on the sale of non-current assets		-	307
Share of profit of associates		65	-
Other non-cash items		-878	-1,156
		157,919	201,682
Realized forward exchange contracts		2,203	-1,186
Interest received		331	2,362
Interest paid		-268	-148
Taxes paid		-50,124	-66,829
Cash flow from operating activities before changes in working capital		110,061	135,881
<i>Cash flow from changes in working capital:</i>			
Inventories		-22,438	-6,412
Current receivables		17,855	-19,048
Trade payables		6,595	-1,000
Current interest-free operating liabilities		5,428	14,962
Cash flow from operating activities		117,501	124,383
<i>Investing activities:</i>			
Acquisition of intangible assets	14	-10,150	-6,075
Purchase of property, plant and equipment	15	-17,780	-18,406
Sale of property, plant and equipment		-	-
Purchase of financial assets	16	-4,000	-4,000
Cash flow from investing activities		-31,930	-28,481
<i>Financing activities:</i>			
Sale of financial assets		-	5
Dividend		-86,355	-120,897
New issue of warrants		15,844	-
Cash flow from financing activities		-70,511	-120,892
CASH FLOW FOR THE YEAR		15,060	-24,990
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR			
Exchange difference in cash and cash equivalents		1,156	1,385
CASH AND CASH EQUIVALENTS AT END OF YEAR		226,882	210,666

Statement of financial position

SEK 000s	Note	31 Dec 2015	31 Dec 2014
ASSETS			
<i>Non-current assets:</i>			
Intangible assets	14	16,225	6,075
Property, plant and equipment	15	83,934	72,752
Investments in associates	16	7,936	–
Financial assets	16	–	4,000
Deposits		22	20
Total non-current assets		108,117	82,847
<i>Current assets:</i>			
Inventories	18	43,546	21,148
Trade receivables	19, 23	65,937	75,911
Current tax assets	21	7,129	–
Other receivables	21	7,600	6,726
Deferred expenses and accrued income	22	13,954	18,297
Short-term investments	23	13	13
Cash and cash equivalents	23	226,882	210,666
Total current assets		365,061	332,761
TOTAL ASSETS		473,178	415,608

Statement of financial position

SEK 000s	Note	31 Dec 2015	31 Dec 2014
EQUITY AND LIABILITIES			
<i>Equity</i>			
Share capital	24	17,336	17,271
Other contributed capital		21,831	6,053
Reserves		270	–193
Retained earnings		235,006	173,955
Profit for the year attributable to owners of the Parent Company		121,408	147,406
Total equity attributable to owners of the Parent Company		395,851	344,492
Non-controlling interests	13, 16	–18	99
Total non-controlling interests		–18	99
Total equity		395,833	344,591
<i>Non-current liabilities:</i>			
Deferred tax liability	12	351	192
Total non-current liabilities		351	192
<i>Current liabilities:</i>			
Other provisions	25	–	3,900
Prepayments from customers	23	16,762	6,804
Trade payables	23	23,638	16,952
Current tax liability		–	5,827
Other liabilities	26	4,754	8,991
Accrued expenses and deferred income	27	31,840	28,351
Total current liabilities		76,994	70,825
Total liabilities		77,345	71,017
TOTAL EQUITY AND LIABILITIES		473,178	415,608
Pledged assets and contingent liabilities in the Group	28		

Statement of changes in equity

SEK 000s	Share capital	Other contributed capital	Foreign currency translation reserve	Retained earnings incl. profit for the year	Equity attributable to owners of the Parent Company	Non-controlling interests	Total equity
Opening balance, 1 January 2014	17,271	6,053	–835	294,852	317,341	–484	316,857
Dividend				–120,897	–120,897		–120,897
Disposal of 9% of IBT AB						0	0
Total transactions with owners				–120,897	–120,897	0	–120,897
Profit for 2014				147,406	147,406	583	147,989
<i>Other comprehensive income</i>							
Gain/losses arising on translation of the financial statements of foreign operations			642		642		642
Comprehensive income for the year			642	147,406	148,048	583	148,631
Closing balance, 31 December 2014	17,271	6,053	–193	321,361	344,492	99	344,591
Dividend				–86,355	–86,355		–86,355
New issue, warrant programme	65	15,778			15,844		15,844
Total transactions with owners	65	15,778		–86,355	–70,511		–70,511
Profit for 2015				121,408	121,408	–117	121,291
Gain/losses arising on translation of the financial statements of foreign operations			462		462		462
Comprehensive income for the year			462	121,408	121,870	–117	121,753
Closing balance, 31 December 2015	17,336	21,831	270	356,414	395,851	–18	395,833

Parent Company

Income statement

SEK 000s	Note	2015	2014
Net sales	2, 3	470,612	464,206
Cost of goods sold	2	-157,364	-139,971
Gross profit	2	313,248	324,235
Selling expenses	4, 5	-78,480	-68,720
Administrative expenses	4, 6	-16,360	-15,075
Research and development expenses	4, 5, 14	-54,072	-46,346
Other operating income	8	1,789	7,851
Operating profit	9	166,125	201,945
<i>Result from financial investments</i>			
Impairment loss on shares in group companies	16	-22,974	-2,874
Anticipated dividends from subsidiaries	5	20,600	-
Impairment loss on non-current receivables from group companies	17	-4,052	-2,835
Interest income and similar profit/loss items	10	6,121	3,096
Interest expense and similar profit/loss items	11	-193	-6,707
Net financial items		-498	-9,320
Profit before tax		165,627	192,625
Tax	12	-34,847	-43,035
PROFIT FOR THE YEAR		130,780	149,590

The Parent Company has no transactions in other comprehensive income, which means that comprehensive income for the year corresponds to profit for the year above. As a result, the Parent Company presents no separate statement of comprehensive income.

Cash flow statement

SEK 000s	Note	2015	2014
Operating activities			
Operating profit		166,125	201,945
<i>Adjustments for non-cash items:</i>			
Depreciation/amortization		560	867
Capital gains/losses on the sale of shares		-	-4
Capital gains/losses on the sale of noncurrent assets		-	-
Other non-cash items		-947	-1,156
		165,738	201,652
Realized forward exchange contracts		2,203	-1,186
Interest received		1,014	3,077
Interest paid		-193	-116
Taxes		-47,296	-64,828
Cash flow from operating activities before changes in working capital		121,466	138,599
<i>Cash flow from changes in working capital:</i>			
Inventories		-19,064	-5,368
Current receivables		15,956	-30,097
Trade payables		10,661	-4,015
Current interest-free operating liabilities		-1,633	22,653
Cash flow from operating activities		127,386	121,772
<i>Investing activities:</i>			
Purchase of property, plant and equipment	15	-60	-169
Purchase of financial assets	16	-67,800	-14,000
Sale of financial assets		-	5
Payment of loan to subsidiary	17	-18,873	-14,335
Cash flow from investing activities		-86,733	-28,499
<i>Financing activities:</i>			
Dividend		-86,355	-120,897
New issue of warrants		15,844	-
Cash flow from financing activities		-70,511	-120,897
CASH FLOW FOR THE YEAR		-29,858	-27,624
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR		201,988	228,456
Exchange difference in cash and cash equivalents		947	1,156
CASH AND CASH EQUIVALENTS AT END OF YEAR		173,077	201,988

Balance sheet

SEK 000s	Note	31 Dec 2015	31 Dec 2014
ASSETS			
Non-current assets			
<i>Property, plant and equipment</i>			
Production equipment		494	743
Office equipment and computers		366	617
<i>Total property, plant and equipment</i>		860	1,360
<i>Financial assets</i>			
Investments in group companies	16	132,938	69,129
Investments in associates	16	8,000	–
Investments in other companies	16	–	4,000
Receivables from group companies	17, 29	55,835	41,013
<i>Total financial assets</i>		196,773	114,142
Total non-current assets		197,633	115,502
Current assets			
Inventories	18	34,137	15,072
<i>Current receivables</i>			
Trade receivables	19	60,550	74,166
Receivables from group companies	20	1,029	–
Current tax assets	21	5,363	–
Other receivables	21	7,003	4,796
Deferred expenses and accrued income	22	11,205	17,037
<i>Total current receivables</i>		85,149	95,999
Short-term investments	23	13	13
Cash and cash equivalents		173,077	201,988
Total current assets		292,377	313,072
TOTAL ASSETS		490,010	428,574

Balance sheet

SEK 000s	Note	31 Dec 2015	31 Dec 2014
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital		17,336	17,271
Other restricted equity		1,253	1,253
		18,589	18,524
<i>Non-restricted equity</i>			
Retained earnings		261,200	182,186
Profit for the year		130,780	149,590
		391,980	331,776
Total equity		410,569	350,300
Liabilities			
<i>Current liabilities</i>			
Other provisions	25	–	3,900
Prepayments from customers		16,762	6,804
Trade payables		20,188	9,527
Liabilities to group companies	20	18,300	21,487
Current tax liability		–	5,827
Other liabilities	26	1,153	7,240
Accrued expenses and deferred income	27	23,038	23,489
<i>Total current liabilities</i>		79,441	78,274
Total liabilities		79,441	78,274
TOTAL EQUITY AND LIABILITIES		490,010	428,574
Pledged assets and contingent liabilities for the Parent Company			
Floating charges	28	2,000	2,000
Contingent liabilities		None	None

Statement of changes in equity

	Share capital	Other restricted equity	Retained earnings incl. profit for the year	Total equity
Opening balance, 1 January 2014	17,271	1,253	303,083	321,607
Dividend			–120,897	–120,897
Profit for 2014			149,590	149,590
Closing balance, 31 December 2014	17,271	1,253	331,776	350,300
Dividend			–86,355	–86,355
New issue of warrants	65		15,779	15,844
Profit for 2015			130,780	130,780
Closing balance, 31 December 2015	17,336	1,253	391,980	410,569

Notes to the financial statements and accounting policies

All figures in SEK 000s unless otherwise specified. Figures in brackets refer to the preceding year.

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Note 1 Accounting policies

Compliance with norms and laws The consolidated financial statements have been prepared in compliance with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and interpretations from the International Financial Reporting Interpretations Committee (IFRIC) that have been approved by the European Commission for application in the EU.

The Parent Company applies the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2, Accounting for Legal Entities, i.e. the same accounting policies as the Group except in cases where the Parent Company's compliance with the Swedish Annual Accounts Act limits the applicability of IFRS in the Parent Company.

New and revised IFRS standards and new interpretations effective for 2015 The new and revised standards and new interpretations have not had any material impact on the consolidated financial statements for 2015.

New and revised IFRS standards and new interpretations not yet effective The new and revised standards and new interpretations that have been issued, but are mandatorily effective for accounting periods beginning on or after 1 January 2016, have not yet been adopted by the Group. Below is a description of those that are assessed to have an impact on the consolidated financial statements in the period when they are applied for the first time.

Standards	Effective for accounting periods beginning:
IFRS 9 Financial Instruments	on or after 1 January 2018
IFRS 15 Revenue from Contracts with Customers	on or after 1 January 2018
IFRS 16 Leases	on or after 1 January 2019

- IFRS 9 Financial Instruments** was issued on 24 July 2014 and will replace IAS 39 Financial Instruments: Recognition and Measurement. The standard has been issued in phases, of which the version issued in July 2014 supersedes all earlier versions. IFRS 9 contains new principles for classification and measurement of financial assets and liabilities. The decisive factors for determining which measurement category a financial asset is attributed to are the entity's objective for holding asset (i.e. the entity's "business model"), and the financial asset's contractual cash flows. The new standard also contains new rules for impairment testing of financial assets, replacing the earlier "incurred loss method" with a new "expected loss method". The new rules for hedge accounting are intended to enable entities to better reflect risk management activities in the financial statements. The standard permits greater scope to hedge risk components of non-financial items and allows more types of instruments to be part of a hedging relationship. Furthermore, the quantitative test for hedge effectiveness is no longer required. IFRS 9 is mandatorily effective for accounting periods beginning on or after 1 January 2018 has not yet been endorsed by the EU. Management's assessment is that the application of IFRS 9 may affect the amounts recognized in the financial statements for the Group's financial assets and liabilities. Management has not yet made a detailed analysis of the impact of the application of IFRS 9 and is therefore not yet able to quantify the effects.
- IFRS 15 Revenue from Contracts with Customers** was issued on 28 May 2014 and will replace IAS 18 Revenue and IAS 11 Construction Contracts. IFRS 15 establishes a model for accounting for almost all revenue that arises through contracts with customers, with the exception of leases, financial instruments and insurance agreements. The core principle of IFRS 15 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Revenue is recognized when control of the goods or services is transferred to the customer. IFRS 15 provides significantly more guidance for specific areas and the disclosure requirements are extensive. IFRS 15 is mandatorily effective for accounting periods beginning on or after 1 January 2018, with earlier application permitted. The standard has not yet been endorsed by the EU. Management has not yet made a detailed analysis of the impact of the application of IFRS 9 and is therefore not yet able to quantify the effects.

- *IFRS 16 Leases* was issued on 13 January 2016 and will replace IAS 17 Leases. IFRS 16 introduces a "right of use model" that requires lessees to recognize assets and liabilities for all leases, for which reason leases are no longer classified as operating or finance leases. The exceptions are leases that have a term of 12 months or less and leases where the underlying asset has a low value. In the income statement, the entity shall recognize depreciation on the asset and interest expenses on the liability. The standard contains more extensive disclosure requirements compared to the current standard. For the lessor, IFRS 16 entails no real changes compared to IAS 17. IFRS 16 is mandatorily effective for accounting periods beginning on or after 1 January 2019, with earlier adoption permitted on the condition that IFRS 15 is also applied. The standard has not yet been endorsed by the EU. Management has not yet made a detailed analysis of the impact of the application of IFRS 9 and is therefore not yet able to quantify the effects.

Management's assessment is that the other new and revised standards and new interpretations that are not yet effective will not have any material impact on the consolidated financial statements when they are applied for the first time.

Basis of preparation The consolidated financial statements have been prepared on the historical cost basis unless otherwise specified.

Non-current assets, non-current liabilities and provisions essentially consist of amounts that are expected to be recovered or settled more than 12 months after the closing date. Current assets and current liabilities essentially consist of amounts that are expected to be recovered or settled within 12 months from the closing date.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the company's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in Note 30.

Basis of consolidation The consolidated financial statements incorporate the operations of the Parent Company and the subsidiaries for the period ended 31 December 2014. The Parent Company controls the subsidiaries, and has the ability to affect returns from its involvement with the subsidiaries through its power over the subsidiaries. All subsidiaries have their balance sheet date on 31 December.

All intragroup transactions and balances are eliminated in full on consolidation, including unrealized gains or losses arising from inter-company transactions. In cases where unrealized losses on intragroup sales of assets are reversed on consolidation, the underlying asset is tested for impairment also from a group perspective. When necessary, amounts reported in the financial statements of subsidiaries have been adjusted to ensure conformity with the accounting policies of the Group.

Profit/loss and other comprehensive income for subsidiaries that are acquired or sold during the year are recognized from the date on which the acquisition or sale went into force, according to what is applicable.

Non-controlling interests, which are recognized as component of equity, represent the share of the subsidiary's profit or loss and net assets that is not held by the Group. The Group attributes comprehensive income for the subsidiaries to owners of the Parent Company and non-controlling interest based on their respective holdings. Transactions involving the acquisition and disposal of shares in companies where there are non-controlling interests are recognized in the cash flow statement in cash flow from financing operations and the statement of changes in equity as transactions with owners

Foreign currency translation

- **Functional currency** The functional currency is the currency of the primary economic environments in which the Group's companies operate.
 - **Transactions** Foreign currency transactions are translated to the functional currency at the rate of exchange ruling on the transaction date. Monetary assets and liabilities in foreign currency are translated to the functional currency at the closing day rate. Exchange differences arising on translation are recognized in profit or loss. Non-monetary assets and liabilities carried at cost are translated at the rate of exchange ruling on the transaction date. Non-monetary assets and liabilities measured at fair value are translated to the functional currency using the rates of exchange ruling on the date when the fair value was determined.
- Foreign exchange gains/losses on operating receivables and liabilities are recognized in operating profit, while foreign exchange gains/losses on financial receivables and liabilities are recognized in net financial items.
- **Derivatives** Growth in sales has also led to increased currency risks, for which reason the company has taken currency hedges in EUR and USD. The company's Board of Directors has issued a policy to hedge approximately 50-60% of projected cash flow 12 months forward and approximately 10-40% of projected cash flow 13-24 months forward in order to spread the risk for exchange rate fluctuations.
- The forward contracts are reported at fair value through profit or loss.
- A financial asset or liability is taken up in the balance sheet when the company becomes party to the contractual terms of the instrument.
- **Financial statements of foreign operations** Assets and liabilities in foreign operations are translated from the foreign operation's functional currency to the Group's presentation currency, SEK, at the closing day rate of exchange. Income and expenses in foreign operations are translated to SEK at an average rate that is a reasonable approximation of actual rates on the respective transaction dates. An

average rate is computed quarterly. Exchange differences arising on translation of foreign operations are recognized in other comprehensive income.

- **Net investments in foreign operations** Receivables from a foreign operation for which settlement is neither planned nor likely occur in the foreseeable future are, in substance, part of the company's net investment in that foreign operation. Exchange differences arising on translation of long-term loans in foreign currency that form part of the net investment in a foreign operation are deferred to a translation reserve in other comprehensive income.

Segment information The company is divided into three business units, Paediatrics, Adult Health and New Business. Support functions have been retained at the central level, but the business units are responsible for product development and sales to their respective target groups.

The Executive Management has analyzed the Group's internal reporting and determined that since the autumn of 2013, the Group's operations are monitored and evaluated based on the following segments:

- **Paediatrics business unit** (drops, digestive health tablets, oral rehydration solution [ORS] and cultures as an ingredient in a licensee's product [i.e. infant formula] and royalties from paediatric health products).
- **Adult Health business unit** (digestive health tablets, oral health tablets, cultures as an ingredient in a licensee's dairy products).
- **New Business business unit** (recognized in the item "other" since it accounts for less than 10% of net sales).
- **Other** (animal health products, etc.).

Sales and gross profit are reported for the above segments. There is no monitoring of the company's total assets and liabilities against the segments' assets.

Revenue recognition BioGaia's revenue comes mainly from the sale of drops, digestive health tablets, oral rehydration solution (ORS) and oral health products to distributors, but also from revenue from the sale of bacteria cultures to be used in a licensee's products (for example infant formula and dairy products), royalty income for the use of *Lactobacillus reuteri* in a licensee's product and sales of packaging systems such as straws and caps.

Revenue from the sale of goods is recognized when the amount can be measured reliably, it is probable that the economic benefits will flow to the company and the criteria have been met for delivery in accordance with the agreed sale and shipping conditions.

Royalty revenue based on the licensee's reporting of units produced or on the sales value of products containing BioGaia's probiotic is recognized quarterly. The presentation of and time for the licensee's reporting is regulated by agreement.

Royalties from the sale of licences (rights), such as the 2012 agreement with Nestlé which gives them the right to use the probiotic *Lactobacillus reuteri* Protectis in infant formula during the remaining term of the patent, are recognized as income directly in cases where there are no remaining conditions to be met and the right is transferred to the customer in connection with signing of the agreement.

Since 2015, royalty revenue attributable to development projects is recognized in pace with completion of the projects. Previously, royalty revenue attributable to development projects was recognized on a straight-line basis over the term of the agreement.

Interest income is recognized in the income statement for the period in which it arises.

Leasing Leased assets are classified as operating leases, since all the risks and rewards incident to ownership have not been substantially transferred to BioGaia. As a result, the lease payments are recognized on a straight-line basis over the term of the lease.

Pensions All employees in Sweden are subject to mandatory retirement in accordance with Swedish legislation, and other employees in accordance with the respective country's legislation. The company has no pension commitments other than payment of annual pension insurance premiums. The pension insurance premiums are of the defined contribution type and are expensed as incurred.

Income taxes Current tax refers to the tax computed on taxable profit for the period. Taxable profit differs from recognized profit in the consolidated income statement in that it has been adjusted for non-taxable income and non-deductible expenses and for items of income and expense that are taxable or deductible in other periods.

Deferred tax refers to the tax computed partly on the basis of temporary differences and partly on tax losses. At every closing date, an assessment is made to determine whether to recognize deferred tax assets not previously recognized in the balance sheet. Such tax assets are recognized to the extent that it is probably that there will sufficient taxable profits against which to utilize these in the future.

Research and development expenses Expenditure on research activities is recognized as an expense in the period in which it is incurred. An internally-generated intangible asset arising from development is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the company's intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probably future economic benefits;

- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset, and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

Other expenditure on development activities is recognized as an expense in the period in which it is incurred. An individual assessment of all ongoing research and development projects is made quarterly to determine which costs are capitalizable. The carrying amount of capitalized expenditure includes all directly attributable costs such as materials, purchased services and employment costs.

BioGaia typically has research activities in the form of clinical studies underway parallel to product development. Much of BioGaia's product development consists of stability tests to ensure that the products remain stable throughout their shelf lives. While the clinical studies and stability tests are in progress, it is often not possible to be certain that the project will be successful and that the product can be sold. The means that projects often do not meet the requirements for capitalization. Other aspects of product development include finding new delivery systems and developing existing products.

Amortization of capitalized development costs is started when the asset can be used and the products begins generating revenue, and is carried out on a straight-line basis over the expected useful life of the asset.

Intangible assets and property, plant and equipment Intangible assets and property, plant and equipment are recognized at cost less accumulated amortization/depreciation and impairment.

Intangible assets are amortized on a straight-line basis over their expected useful lives.

The following depreciation schedules are applied for property, plant and equipment:

Production equipment	5–10 years
Equipment and computers	3–5 years
Buildings	20-60 years

The carrying amounts of the Group's assets are reviewed at each balance sheet date to look for any indication that an asset may be impaired. Incomplete projects are tested for impairment annually. The cash-generating unit is the applicable segment. If impairment is indicated, the recoverable amount of the asset is calculated. If this is lower than the carrying amount, the value is written down to the recoverable amount.

Depreciation of buildings is started when construction is completed. For electrical and internal construction work, etc., the depreciation period is 20-30 years, and for framework and foundation the depreciation period is 60 years.

Inventories Inventories are stated at the lower of cost and net realizable value, including provisions for obsolescence. Cost is measured according to weighted average prices.

Cash and cash equivalents Cash and cash equivalents comprise cash on hand and in banks.

Financial assets and liabilities Financial instruments in the Group are measured and recognized in accordance with the rules in IAS 39.

The financial assets recognized in balance sheet include cash and cash equivalents, short-term investments, and loans and receivables. Financial liabilities and equity include trade payables and prepayments from customers.

Financial assets and liabilities are initially measured at cost, corresponding to fair value including transaction costs for all financial assets and liabilities not measured at fair value through profit or loss. Subsequent measurement depends on how the instruments have been classified according to the following.

Financial assets in the Group refer to shares in a company where the holding is below 20% and the Group does not have control. When the holding exceeds 20% (and control exists), the shares in the company will instead be recognized as interests in associates.

A financial asset or liability is recognized in the balance sheet when the company initially becomes party to the contractual provisions of the instrument. Financial liabilities are recognized when the counterparty has performed and there is contractual obligation to pay, even if no invoice has been received. Trade receivables are initially measured at cost and subsequently at amortized cost less provision for impairment. Impairment losses on trade receivables are recognized in profit or loss. Trade payables are recognized when an invoice has been received.

The purchase or sale of other financial assets is recognized on the trade date, which is the date on which the company commits to purchase or sell the asset.

A financial asset is derecognized from the balance sheet when the company's rights under the agreement are realized, expire or the company has relinquished control of the asset. The same applies to a part of a financial asset. A financial liability is derecognized from the balance sheet when the obligation specified in the agreement is discharged or otherwise extinguished. The same applies to a part of a financial liability.

The company classifies its financial assets and liabilities in the following categories; financial assets and liabilities at fair value through profit or loss, loans and receivables, held-to-maturity investments and other financial liabilities.

In accordance with IFRS 7 Financial Instruments, is it specified in connection with the note, regarding the balance sheet item for all financial instruments measured at fair value, which of the following levels of measurement has been used:

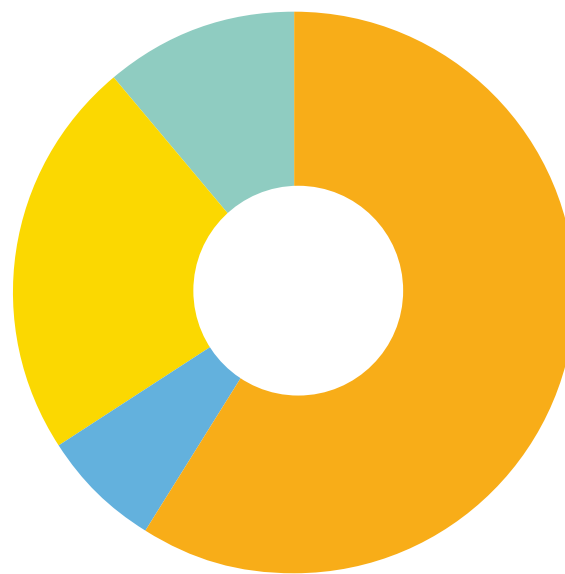
- **Level 1**, fair value is determined based on quoted prices in an active market for the instrument
- **Level 2**, fair value is determined based on a valuation technique using observable market data, either direct (such as prices) or indirect (derived from prices), and which are not included in level 1
- **Level 3**, fair value is determined with the help of valuation techniques, using significant inputs that are not observable in the market data.

Accounting policies of the Parent Company The differences between the accounting policies applied by the Group and the Parent Company are described below. The following accounting policies for the Parent Company have been applied consistently for all periods presented in the Parent Company financial statements.

Revisions in RFR 2 have not had any material impact on the financial statements of the Parent Company for 2015.

- **Presentation** The income statement and balance sheet of the Parent Company are presented in accordance with the schedules in the Swedish Annual Accounts Act.
- **Income taxes** In the Parent Company, untaxed reserves are recognized including the deferred tax liability. In the consolidated financial statements, however, untaxed reserves are divided between the deferred tax liability and equity.
- **Subsidiaries** In the Parent Company, shareholdings in subsidiaries are accounted for on a historical cost basis. The carrying amount is tested regularly against the subsidiaries' consolidated equity.

Sales by geographical market 2015



- = Europe 59% (67%)
- = Rest of world 23% (15%)
- = Asia 11% (10%)
- = USA and Canada 7% (8%)

Note 2 Segment reporting

The Group's operations are monitored and evaluated based on the business units Paediatrics, Adult Health, and New Business. The Paediatrics segment includes sales of drops, oral rehydration solution (ORS), digestive health tablets and cultures as an ingredient in a licensee's product (such as infant formula), as well as royalties pertaining to Paediatrics products. The Adult Health segment mainly includes sales of digestive health tablets, oral health products and cultures as an ingredient in a licensee's dairy product. Other consists of the New Business business unit and a few minor products, such as Animal Health products. Together these account for less than 10% of sales and are therefore not reported separately.

The management monitors net sales and gross profit. Other expenses are not broken down at the segment level, but only at the group level.

NET SALES BY SEGMENT:

Business unit ¹⁾	Group	
	2015	2014
Paediatrics	389,561	301,248
License revenue (Paediatrics) ²⁾	–	95,397
Adult Health	74,667	69,446
Other	19,013	15,711
	483,241	481,802

GROSS PROFIT BY SEGMENT:

Business unit ¹⁾	Group	
	2015	2014
Paediatrics	266,391	195,977
License revenue (Paediatrics) ²⁾	–	95,397
Adult Health	51,907	44,229
Other	18,286	14,861
	336,584	350,464

OPERATING PROFIT BY SEGMENT:

Business unit ¹⁾	Group	
	2015	2014
Paediatrics	152,672	92,460
License revenue (Paediatrics) ²⁾	–	95,397
Adult Health	18,564	12,475
IBT	–20,615	–6,746
Other	1,563	3,298
	152,184	196,884

¹⁾ A minor reallocation between the segments was made in the previous year's sales and gross profit in order to achieve better comparability between years.

²⁾ The license revenue refers to revenue from Nestlé. The license revenue is included in Paediatrics but is reported on a separate line for the sake of comparability.

In 2015, SEK 177.2 million (137.3) or 36.7% (35.5) of revenue excluding license revenue in the Group was attributable to three customers. The two largest of these three customers belong to the Paediatrics segment, and the third belongs to both the Paediatrics and Adult Health segments. In 2015 there were two customers who each accounted for more than 10% of sales. In 2014 there was one customer that accounted for more than 10% of sales.

NET SALES BY GEOGRAPHICAL MARKET:

	Group		Parent Company	
	2015	2014	2015	2014
Europe	284,729	257,808	284,729	257,808
License revenue (Europe) ¹⁾	–	95,397	–	95,397
USA and Canada	35,231	30,273	33,589	29,809
Asia	52,130	38,778	41,143	21,646
Rest of World	111,151	59,546	111,151	59,546
	483,241	481,802	470,612	464,206

¹⁾ The license revenue refers to revenue from Nestlé. The license revenue is included in Europe but is reported on a separate line in order to achieve better comparability between years.

More than 90% of the Group's total assets, amounting to SEK 473,478 thousand (415,608), are located in Europe.

Of the Group's capital expenditure on property, plant and equipment and intangible assets, totalling SEK 27,930 thousand (18,406), more than 90% pertained to Europe.

Sales in Sweden amounted to SEK 13.0 million (12.4), or 2.7% (3.2%) of the sales in the group, excluding the license revenue.

The Group's non-current assets amount to SEK 108.1 million, of which SEK 107.9 million is located in Sweden and SEK 0.2 million in other countries (the USA and Japan).

Note 3 Revenue

	Group		Parent Company	
	2015	2014	2015	2014
Product revenue	442,565	353,640	429,936	336,044
Royalties	40,676	32,765	40,676	32,765
License revenue	–	95,397	–	95,397
	483,241	481,802	470,612	464,206

Note 4 Employees and personnel expenses, remuneration to senior executives

AVERAGE NUMBER OF EMPLOYEES BY COUNTRY:

	2015	of whom, men	2014	of whom, men
<i>Parent Company:</i>				
Sweden	61	22	55	20
<i>Subsidiaries:</i>				
Sweden	32	17	27	16
Japan	6	5	6	5
USA	3	1	2	0
Total subsidiaries	41	23	35	21
Total Group	102	45	90	41

The number of employees in the group at 31 December, 2015 was 105 (95).

SALARIES AND OTHER REMUNERATION DIVIDED BY COUNTRY AND BETWEEN THE BOARD/PRESIDENT AND OTHER EMPLOYEES:

	2015	2014	2015	2014
	Board and President	Board and President	Other employees	Other employees
<i>Parent Company:</i>				
Sweden	3,641	3,601	36,326	32,175
<i>Subsidiaries:</i>				
Sweden	3,447	2,870	9,231	9,606
Japan	2,213	2,067	2,808	2,695
USA	–	–	2,630	1,550
Total subsidiaries	5,660	4,937	14,669	13,851
Total Group	9,301	8,538	50,995	46,026

TOTAL SALARIES AND SOCIAL SECURITY EXPENSES:

	Group		Parent Company	
	2015	2014	2015	2014
Salaries and other remuneration	60,296	54,564	39,967	35,776
Pension expenses for the Board and President	1,575	1,843	734	1,162
Pension expenses for other employees	5,640	5,312	4,679	4,436
Other social security expenses	17,049	15,965	12,468	11,792
	84,560	77,684	57,848	53,166

Pensions and health insurance: All employees in Sweden are subject to mandatory retirement in accordance with Swedish law, currently at the age of 65 years. The company has no pension commitments other than payment of annual pension insurance premiums.

For all employees over the age of 25 years, the following pension insurance premiums are paid in relation to salary:

Pensionable salary within the range:	0–7.5 base amounts	>7.5–30 base amounts	>30 base amounts
Premium	6%	25%	0%

All employees aside from the President (for the President, see below) are covered by health insurance, with benefits. This health insurance is activated after 90 days of sick leave. Together with the employer's health insurance and compensation from the Social Insurance Agency, the employee receives total benefits equal to approximately 65 - 87% of salary after a qualifying period of 3 months (depending on the level of salary).

The company also pays sick pay during the qualifying period (see above), i.e. from day 15 to day 90, when the health insurance is activated. Compensation from the Swedish Social Insurance Agency from day 15 corresponds to just under 80% of salary and is payable in a maximum amount corresponding to an annual salary of 7.5 price base amounts. During this period, the company pays compensation for loss of income so that the employee, regardless of salary level, receives a total of 80% of salary together with compensation from the Swedish Social Insurance Agency.

BioGaia's incentive scheme for the employees In June 2012 BioGaia carried out the warrant programme that was resolved on by the Annual General Meeting on 8 May 2012. A total of 87,000 warrants were subscribed for, of which the management subscribed for 41,000. The warrants were issued at a market price of SEK 14.27 each following valuation according to the Black & Scholes formula. Each warrant entitled the holder to subscribe for one class B share for SEK 241.90 on 1 June 2015. Volatility was estimated at 40%. Of the total of 87,000 subscribed warrants, 65,500 were redeemed on 1 June 2015, which meant that the number of shares in BioGaia increased by 65,500, and that the company was provided with proceeds of SEK 15.8 million.

Remuneration to senior executives Remuneration to the Chairman and members of the Board is paid according to the decision of the Annual General Meeting. The Board has appointed a remuneration committee consisting of Board Chairman David Dangoor and Board member Stefan Elving. The remuneration committee handles matters related to remuneration and other terms of employment of senior executives. The principles for remuneration to senior executives are approved by the Annual General Meeting. The task of the remuneration committee is to prepare recommendations in accordance with these principles. Board member Jan Annwall was Vice President until 1 April 2010 and has since then worked as a consultant for BioGaia to a limited extent.

Remuneration to the President and other senior executives employed by the company consists of basic salary and other benefits. Other senior executives consist of the 11 persons who together with the President make up the Executive Management.

In the event of termination by the company, the President and Vice Presidents are entitled to full salary during an 18-month period of notice. In the event of termination by the company, other senior executives have a statutory notice period of at least 3 months in accordance with the Swedish Employment Protection Act. For the President the company made an extra pension provision of SEK 750,000 in 2014 and SEK 700,000 in 2015. The company has recognized the cost but has not yet paid the amount in full. In 2014 the company paid the cost of health insurance for the President, providing sickness benefits equal to around 75% of salary after a qualifying period of three months. The payment was terminated in 2015 after the company's President turned 65. In other respects, the President has the same benefits as other employees.

Otherwise, no agreements for termination benefits exist for the President or other senior executives.

REMUNERATION AND OTHER BENEFITS DURING THE YEAR:

	Director's fees	Basic salary	Pension insurance incl. health insurance	Other remuneration*)	Total
<i>Board Chairman:</i>					
David Dangoor:	300				300
<i>Board members:</i>					
Jan Annwall	150			225	375
Ewa Björling	150				150
Stefan Elving	150				150
Inger Holmström	150				150
Anthon Jahreskog	150				150
Brit Stakston	150				150
Paula Zeilon	150				150
<i>President: Peter Rothschild</i>		2,291	734		3,025
<i>Other senior executives (11 persons):</i>					
	1,350	12,249	2,808	5,555	21,962

*) Bo Möllstam is Technical Director and a member of BioGaia's Executive Management. He is not employed by the company but is contracted as a consultant and invoices his fees through a company. Bo Möllstam is a partner in Synergon AB, which invoiced an amount of SEK 10.2 million to BioGaia AB during the year, of which SEK 4.7 million referred to consulting fees and SEK 5.5 million referred to forwarded patent expenses.

Helen Olsson is HR Director and a member of the Executive Management. Helen is employed by the company since 1 June 2015. During the period from January to May 2015, Helen Olsson was contracted as a consultant and invoiced the fees through her partly-owned company Spirean AB, which invoiced an amount of SEK 0.6 million to BioGaia AB during the year.

GENDER DISTRIBUTION:

	2015 Women	2014 Women	2015 Men	2014 Men
Board members	4	3	4	5
Management including President	7	7	5	5

Note 5 Operations proposed for distribution

The Board of BioGaia AB (publ) ("BioGaia") has decided to propose that an Extraordinary General Meeting of BioGaia on 18 March 2016 approve the distribution of the shares in the subsidiary Infant Bacterial Therapeutics AB (publ) ("IBT") to the shareholders in BioGaia. Below is a presentation of the profit/loss, assets, liabilities and cash flows from IBT that have affected the Group's income statement, balance sheet and cash flow.

RESULTS FROM THE OPERATIONS PROPOSED FOR DISTRIBUTION

	Jan-Dec 2015	Jan-Dec 2014
Net sales	–	–
Selling expenses	–2,600	–
Research and development expenses	–17,974	–6,592
Other operating income/expenses	–41	–154
<i>Operating profit</i>	–20,615	–6,746
Financial expenses	–9	–2
Profit/loss for the period	–20,624	–6,748

ASSETS ATTRIBUTABLE TO OPERATIONS PROPOSED FOR DISTRIBUTION

	31 Dec 2015	31 Dec 2014
Intangible assets	16,225	6,075
Current assets excl. cash and cash equivalents	1,488	677
Cash and cash equivalents	44,411	1,054
Total assets	62,124	7,806
Trade payables	518	492
Accrued expenses	7,079	2,883
Other current liabilities	138	131
Total liabilities	7,735	3,506

CASH FLOW FROM OPERATIONS PROPOSED FOR DISTRIBUTION

	2015	2014
Operating activities	–30,895	–10,508
Investing activities	–10,150	–6,075
Total cash flow	–41,045	–16,583

Note 6 Auditor's fees

	Group		Parent Company	
	2015	2014	2015	2014
<i>Grant Thornton Sweden AB</i>				
Audit assignments	182	484	108	325
Audit services in addition to audit	58	137	39	120
Audit advice	38	125	33	101
Tax advice	16	16	0	9
Other services	–	–	–	–
<i>Deloitte AB</i>				
Audit assignments	455	–	365	–
Audit services in addition to audit	95	–	95	–
Tax advice	10	–	10	–
Other services	–	–	–	–
<i>Cherry, Bekaert & Holland, L.L.P.</i>				
Audit assignments	70	48	–	–
Other services	201	144	–	–
<i>Grant Thornton Taiyo LLC</i>				
Audit assignments	21	20	–	–
Other services	–	–	–	–

Audit assignments refer to the auditors' work on the statutory audit, other auditing activities and different types of quality assurance services. Other services are such that are not included in the audit assignment, auditing activities or tax advice. Since the 2015 Annual General Meeting, Deloitte is the appointed auditor for the Group.

Note 7 Share of profit of associates

	Group	
	2015	2014
Share of profit of MetaboGen AB	–65	–
	–65	–

Note 8 Other operating income

	Group		Parent Company	
	2015	2014	2015	2014
Exchange gains on operating receivables and liabilities, net	1,732	7,711	1,789	7,851
	1,732	7,711	1,789	7,851

Note 9 Operating expenses allocated by type of cost

	Group		Parent Company	
	2015	2014	2015	2014
Cost of sales	146,657	131,338	157,364	139,971
Personnel expenses	87,922	78,733	60,827	54,016
Depreciation/amortization	6,548	5,652	560	867
Other operating expenses	91,598	76,908	87,525	75,259
	332,725	292,631	306,276	270,113

Operating expenses include lease payments of SEK 177 thousand (167).

The total amount of minimum future lease payments falls due as follows

- Within one year: SEK 48 thousand
- Within two to five years: SEK 145 thousand

The Group's future payment commitments for rents amount to SEK 23.0 million, of which SEK 21.5 million refers to the Parent Company. The Group's rents fall due for payment in an amount of SEK 4.6 million within one year and SEK 16.7 million within two to five years.

Note 10 Financial income

	Group		Parent Company	
	2015	2014	2015	2014
Exchange gains, forward exchange contracts	5,107	–	5,107	–
Interest income	331	2,382	1,014	3,096
	5,438	2,382	6,121	3,096

Note 11 Financial expenses

	Group		Parent Company	
	2015	2014	2015	2014
Exchange losses, forward exchange contracts	–	6,592	–	6,592
Other financial expenses	269	148	193	116
	269	6,740	193	6,708

At 31 December 2015 the Parent Company and the Group had outstanding foreign exchange contracts for EUR 11.8 million (13.3) at an average exchange rate of SEK 9.31 and USD 1.0 million (0.0) at an average exchange rate of SEK 8.50. Foreign exchange contracts amounting to EUR 8.3 million and USD 1.0 million will mature in 2016 and the remaining EUR 3.5 million in 2017. The unrealized foreign exchange gain/loss is reported in financial income/expense.

Note 12 Tax on profit for the year

	Group		Parent Company	
	2015	2014	2015	2014
Current tax	–35,903	–44,643	–34,847	–43,035
Deferred tax	–159	107	–	–
	–36,062	–44,536	–34,847	–43,035

DEFERRED TAX IN UNTAXED RESERVES

	Group		Parent Company	
	2015	2014	2015	2014
Deferred tax attributable to untaxed reserves	351	192	–	–
	351	192	–	–

CHANGES IN DEFERRED TAX

	Group		Parent Company	
	2015	2014	2015	2014
Opening balance, deferred tax	192	85	–	–
Provisions for deferred tax	159	107	–	–
Closing balance, deferred tax	351	192	–	–

RECONCILIATION OF NOMINAL TAX AND ACTUAL TAX EXPENSES:

	Group		Parent Company		Capitalized development expenditure	Licenses and brands	Total intangible assets
	2015	2014	2015	2014			
Reported profit before tax	157,353	192,525	165,627	192,625	26,875	2,528	29,403
Tax rate	22.0%	22.0%	22.0%	22.0%			
Anticipated tax expense, 22%	-34,617	-42,355	-36,438	-42,378			
Tax effect of other non-deductible and non-taxable items	-767	-5,554	3,127	-859			
Tax effect of non-capitalized loss carryforwards	863	3,167	-	-			
Tax effect due to changed tax, opening balance	-1,536	-	-1,536	-			
Other tax adjustment	-5	206	-	202			
Actual tax expense	-36,062	-44,536	-34,847	-43,035	26,875	2,528	29,403

The Group's loss carryforwards amounted to a total of SEK 31.3 million (35.2) at 31 December 2015. Loss carryforwards of SEK 0 thousand (0) are attributable to the Swedish companies. No deferred tax has been recognized on loss carryforwards amounting to SEK 31.3 million (35.2). These carryforwards are attributable to the Japanese subsidiary and will expire as follows: SEK 2.8 million in the financial year 2018, SEK 11.0 million in 2019, SEK 4.1 million in 2020, SEK 4.9 million in 2021 and SEK 8.5 million in 2022.

The company has had a tax matter related to a write-down of receivables from the Japanese subsidiary. At the end of 2015, the Administrative Courts ruled against BioGaia AB. The Parent Company was not allowed a deduction for the write-down of receivables from the Japanese subsidiary. BioGaia therefore recognized the expense of SEK 3.0 million in the fourth quarter of 2015. In the first quarter of 2015, the Parent Company received SEK 1.5 million in refunded tax from previous fiscal years attributable to correction of previous years' tax returns with regard to exchange losses on loans to the subsidiary in Japan. As a result, profit for the year was charged with a total of SEK 1.5 million in tax expenses attributable to previous years.

Note 13 Non-controlling interests

	2015	2014
At beginning of year	99	-484
Profit for the year attributable to non-controlling interests	-117	583
At end of year	-18	99

The non-controlling interests refer to a 9.9% stake in the subsidiary CapAble AB that is held by its President Staffan Pålsson and a 5.5% stake in the subsidiary IBT that is held by the company's Managing Director Staffan Strömberg (2.5%), its Research Director Eamonn Connolly (2.5%) and boardmember Anders Ekblom (0.5%).

Note 14 Intangible assets

GROUP:

	Capitalized development expenditure	Licenses and brands	Total intangible assets
<i>Accumulated cost:</i>			
Opening balance, 1 January 2014	26,875	2,528	29,403
Additions	6,075	-	6,075
Closing balance, 31 December 2014	32,950	2,528	35,478
Opening balance, 1 January 2015	32,950	2,528	35,478
Additions	10,150	-	10,150
Closing balance, 31 December 2015	43,100	2,528	45,628
<i>Accumulated amortization</i>			
Opening balance, 1 January 2014	26,875	2,528	29,403
The year's amortization	-	-	-
Closing balance, 31 December 2014	26,875	2,528	29,403

TOTAL RESEARCH AND DEVELOPMENT EXPENDITURE:

	Group		Parent Company	
	2015	2014	2015	2014
Total R&D expenditure excl. amortization	80,869	59,668	53,890	40,169
The year's capitalization of development expenses	-10,150	-6,075	-	-
Uncapitalized R&D expenses	70,719	53,593	53,890	40,169
Amortization component of R&D expenses *)	538	274	182	292
R&D expenses with an effect on profit/loss	71,257	53,867	54,072	40,461

*) This amount refers only to that portion of depreciation on property, plant and equipment attributable to the Research and Development function in the income statement classified by function. No amortization on capitalized development expenses has been recognized during the year.

Note 15 Property, plant and equipment

GROUP:

	Land and buildings	Production equipment	Work in progress	Office equipment	Total property, plant and equipment
				and computers	
<i>Accumulated cost:</i>					
Opening balance, 1 January 2014	39,828	23,320	11,458	14,974	89,580
Additions	10,070	1,708	5,750	883	18,411
Sales and disposals	-	-1,006	-	-12	-1,018
Reclassifications	-	2,428	-2,428	-	-
Exchange differences	-	-	-	210	210
Closing balance, 31 December 2014	49,898	26,450	14,780	16,055	107,183

	Land and buildings	Production equipment	Work in progress	Office equipment and computers	Total property, plant and equipment
Opening balance, 1 January 2015	49,898	26,450	14,780	16,055	107,183
Adjustment of opening balance	–	–775	–	–	– 775
Additions	12,577	3,413	2,243	321	18,555
Sales and disposals	–	–	–	–910	–910
Reclassifications	–	6,499	–6,499	–	–
Exchange differences	–	–	–	128	128
Closing balance, 31 December 2015	62,475	35,587	10,524	15,594	124,181

Accumulated depreciation

Opening balance, 1 January 2014	1,243	14,879	–	13,172	29,294
Depreciation	1,285	3,139	–	1,233	5,657
Impairment losses	–	307	–	–	307
Sales and disposals	–	–1,006	–	–12	–1,018
Exchange differences	–	–	–	191	191
Closing balance, 31 December 2014	2,528	17,319	–	14,584	34,431

Opening balance, 1 January 2015	2,528	17,319	–	14,584	34,431
Adjustment of opening balance	–	– 775	–	–	– 775
Depreciation	1,798	3,656	–	910	6,363
Impairment losses	–	959	–	–	959
Sales and disposals	–	–	–	–839	–839
Exchange differences	–	–	–	106	106
Closing balance, 31 December 2015	4,326	21,159	–	14,761	40,245

Carrying amounts:

At 1 January 2014	38,585	8,441	11,458	1,802	60,286
At 31 December 2014	47,370	9,131	14,780	1,471	72,752
At 31 December 2015	58,150	14,429	10,524	833	83,936

PARENT COMPANY:

	Production equipment	Office equipment and computers	Total property, plant and equipment
<i>Accumulated cost:</i>			
Opening balance, 1 January 2014	3,559	11,254	14,813
Additions	–	169	169
Sales and disposals	–	–12	–12
Closing balance, 31 December 2014	3,559	11,411	14,970

Opening balance, 1 January 2015	3,559	11,411	14,970
Additions	–	60	60
Sales and disposals	–	–	–
Closing balance, 31 December 2015	3,559	11,471	15,030

Accumulated depreciation:

Opening balance, 1 January 2014	2,510	10,245	12,755
Depreciation	306	562	868
Sales and disposals	–	–12	–12
Closing balance, 31 December 2014	2,816	10,795	13,611

Opening balance, 1 January 2015	2,816	10,795	13,611
Depreciation	249	310	559
Sales and disposals	–	–	–
Closing balance, 31 December 2015	3,065	11,105	14,170

	Production equipment	Office equipment and computers	Total property, plant and equipment
<i>Carrying amounts:</i>			
At 1 January 2014	1,049	1,009	2,058
At 31 December 2014	743	616	1,359
At 31 December 2015	494	366	860

Depreciation on property, plant and equipment is recognized on the following lines in the income statement:

	Group		Parent Company	
	2015	2014	2015	2014
Cost of sales	4,240	3,294	–	–
Selling expenses	1,265	1,565	305	498
Administrative expenses	505	519	73	131
Research and development expenses	538	274	182	238
	6,547	5,652	560	867

Note 16 Financial assets

PARENT COMPANY

Participations in group companies	2015	2014
At beginning of year	69,129	52,394
Group contribution paid to CapAble AB	2,374	2,874
Group contribution paid to TriPac AB	8	5
Group contribution paid to IBT AB	20,601	6,730
Impairment loss on shares in IBT AB	–20,601	–
Impairment loss on shares in CapAble AB	–2,374	–2,874
New share issue in IBT AB	52,800	–
Shareholder contribution paid to IBT AB	11,000	10,000
Carrying amount at end of year	132,937	69,129

SPECIFICATION OF THE PARENT COMPANY'S EQUITY HOLDINGS IN GROUP COMPANIES:

Subsidiary/corp. reg.no./Domicile	No. of shares	Holding, %	Book value
Biogaia Biologics Inc. /-/Raleigh, NC, USA	100,000	100	0
TriPac AB /556153-2200/Stockholm	10,000	100	3,590
CapAble AB /556768-3601/Stockholm	9,010	90.1	6,901
BioGaia Japan Inc. /-/Hiroshima, Japan	180	100	0
TwoPac AB /556591-9767/Eslöv	10,000	100	40,641
Infant Bacterial Therapeutics AB (IBT AB) /556873-8586/Stockholm	85,050	94.5	81,805
			132,937

The assets and liabilities of the American subsidiary Biogaia Biologics Inc. have been translated at the closing day rate of exchange, SEK 8.42 (7.80). All items in the income statement have been translated at the average exchange rate during the year, SEK 8.42 (6.86). The assets and liabilities of the Japanese subsidiary BioGaia Japan Inc. have been translated at an exchange rate of SEK 0.070 (0.065). All items in the income statement have been translated at an exchange rate of SEK 0.070 (0.065). The resulting translation differences have been recognized in consolidated comprehensive income.

CapAble AB was formed in 2008. BioGaia owns 90.1% of the company. CapAble's President, Staffan Pålsson, owns 9.9% of the company. The non-controlling interests' share in equity of CapAble amounts to SEK -18 thousand.

TwoPac AB was formed in 2002 and is 100% owned by BioGaia since 1 July 2013.

Infant Bacterial Therapeutics (IBT) AB was formed in 2011. BioGaia owns 94.5% of the company. IBT's President, Staffan Strömberg, IBT's Research Director, Eamonn Connolly, and board member Anders Ekblom together own 5.5% of the company. The non-controlling interests' share in equity of IBT amounts to SEK 3 thousand. Of total purchases made by the Parent Company, 19.5% (17.8) was attributable to group companies. Of total sales made by the Parent Company, 2.2% (0) was attributable to group companies.

INVESTMENTS IN ASSOCIATES

	Group		Parent Company	
	2015	2014	2015	2014
At beginning of year	0	–	0	–
Reclassification of MetaboGen AB to associate	8,000	–	8,000	–
Share of profit for the year	–65	–	–	–
Carrying amount at end of year	7,935	–	8,000	–

SPECIFICATION OF THE PARENT COMPANY'S EQUITY HOLDINGS IN ASSOCIATES

Associated company/Corp. ID no./Domicile	No. of shares	Holding, %	Carrying amount
MetaboGen AB/556872-7142/Göteborg	208	27	8 000

INTERESTS IN OTHER COMPANIES

	Group		Parent Company	
	2015	2014	2015	2014
At beginning of year	4,000	–	4,000	–
Acquisition of shares in MetaboGen AB	4,000	4,000	4,000	4,000
Reclassification of Metabogen AB to associate	–8,000	–	–8,000	–
Carrying amount at end of year	–	4,000	–	4,000

Note 17 Non-current receivables from subsidiaries

NON-CURRENT RECEIVABLES FROM SUBSIDIARIES:

	Parent Company	
	2015	2014
At beginning of year	41,013	29,513
Payment of loan to BioGaia Japan Inc.	4,052	2,835
Payment of loan to TwoPac AB	15,844	11,500
Repayment of debt from CapAble	–1,022	–
Exchange difference related to loan to BioGaia Japan Inc.	4,181	–6,075
Provisions for net receivable ¹⁾	–8,233	3,240
	55,835	41,013

¹⁾ Due to uncertainty as to whether the receivable from the subsidiary in Japan will be repaid within the foreseeable future, a provision has been made for the net amount.

NON-CURRENT RECEIVABLES FROM GROUP COMPANIES AT 31 DECEMBER 2015:

	Parent Company	
	2015	2014
CapAble AB	–	1,022
TwoPac AB	55,835	39,991
Closing balance at end of year	55,835	41,013

Note 18 Inventories

	Group		Parent Company	
	2015	2014	2015	2014
Raw materials and consumables	6,396	4,310	–	–
Finished goods and goods for resale	37,150	16,838	34,137	15,072
	43,546	21,148	34,137	15,072

The Group's provisions for obsolescence amount to SEK 3,362 thousand (1,698) at 31 December 2015. Expenses related to impairment losses on inventory and scrapping amount to SEK 3,690 thousand (3,624) at 31 December 2015. The increase in inventories of finished goods is mainly attributable to stockpiling in preparation for orders for delivery at the beginning of 2016 and to a certain extent also due to management's assessment that higher inventory levels of cultures and semi-finished goods are necessary to maintain delivery times and high service for the customers.

Note 19 Trade receivables

The Group has recorded a loss of SEK 1,152 thousand (268) for impairment losses its trade receivables in 2015. Provisions for bad debt losses amounted to SEK 1,899 thousand (487) at 31 December 2015.

At 31 December 2015, trade receivables of SEK 13,435 thousand (17,816) were overdue without any assessed grounds for impairment. Of the overdue receivables, all had been recovered as of the closing date.

AGE ANALYSIS:

	Group		Parent Company	
	2015	2014	2015	2014
Less than 3 months	12,414	17,356	12,414	17,356
3-6 months	1,021	460	1,021	460
	13,435	17,816	13,435	17,816

THE CARRYING AMOUNTS, BY CURRENCY, ARE AS FOLLOWS:

	Group		Parent Company	
	2015	2014	2015	2014
SEK	14,169	17,327	14,169	17,327
EUR	28,864	36,345	28,363	36,345
USD	17,981	18,692	17,981	18,509
GBP	7	–	7	–
NOK	–	76	–	76
DKK	30	1,909	30	1,909
JPY	4,886	1,562	–	–
	65,937	75,911	60,550	74,166

Note 20 Related party transactions

Group Annwall & Rothschild Investment AB holds 740,668 class A shares and 759,332 class B shares, corresponding to 8.6% of the share capital and 34.0% of the votes. Annwall & Rothschild Investment AB is owned by Peter Rothschild, President of BioGaia AB, and Jan Annwall, a member of the Board of the Parent Company. The only transaction that took place during 2015 was a dividend of SEK 5.00 per share.

Bo Möllstam is Technical Director and a member of BioGaia's Executive Management. He is not employed by the company but is contracted as a consultant and invoices his fees through a company. Bo Möllstam is a partner in Synergon AB, which invoiced an amount of SEK 10.2 million to BioGaia AB during the year. Of this total, SEK 5.5 million refers to forwarded patent expenses and the remainder consists of consulting fees.

Helen Olsson is HR Director and a member of the Executive Management. Helen Olsson is employed by the company since 1 June 2015. During January-May 2015 Helen Olsson was contracted as a consultant and invoiced her fees through her partly-owned company Spirean AB, which invoiced an amount of SEK 0.6 million BioGaia AB during the year. Note 20, cont'd.

Parent Company The Parent Company owns 100% of TwoPac AB, BioGaia Biologics Inc., USA, BioGaia Japan Inc. and Tripac AB. The Parent Company owns 90.1% of the shares in CapAble AB. The Parent Company owns 94.5% of the shares in Infant Bacterial Therapeutics (IBT) AB.

THE FOLLOWING TRANSACTIONS HAVE TAKEN PLACE WITH TWOPAC AB (INCLUDING TWOPAC'S WHOLLY OWNED SUBSIDIARIES):

	Parent Company	
	2015	2014
Interest income	683	696
Loan paid	–15,844	–11,500
Purchase of services	–1,601	–
Purchase of goods	–50,561	–44,689

Goods are purchased on a cost plus basis.

THE FOLLOWING TRANSACTIONS HAVE TAKEN PLACE WITH BIOGAIJA JAPAN INC.:

	Parent Company	
	2015	2014
Interest income	942	1,323
Loan paid ¹⁾	-4,052	-2,835
Sale of goods ²⁾	11,455	6,145
Marketing contribution paid	-10,727	-7,468

¹⁾ Due to uncertainty as to whether the loan to BioGaia Japan will be recovered within the foreseeable future, a provision has been made for the net amount.

²⁾ BioGaia has delivered products but only invoiced a small amount in 2015, since the bulk refers to marketing contributions during the start-up phase. In 2014, all deliveries referred to marketing contributions.

THE FOLLOWING TRANSACTIONS HAVE TAKEN PLACE WITH BIOGAIJA BIOLOGICS INC.:

	Parent Company	
	2015	2014
Purchase of services	-5,476	-3,259

THE FOLLOWING TRANSACTIONS HAVE TAKEN PLACE WITH CAPABLE AB:

	Parent Company	
	2015	2014
Interest income	-	25
Repayment of loan	1,022	-
Sale of services	148	163
Group contribution paid	-2,374	-2,874

THE FOLLOWING TRANSACTIONS HAVE TAKEN PLACE WITH TRIPAC AB:

	Parent Company	
	2015	2014
Group contribution paid	-8	-5

THE FOLLOWING TRANSACTIONS HAVE TAKEN PLACE WITH IBT AB:

	Parent Company	
	2015	2014
Group contribution paid	-20,601	-6,730
Conditional shareholder contribution	-11,000	-10,000
New share issue	-52,800	-
Sale of services	481	-
Purchase of services	-220	-408

THE CLOSING BALANCE AT THE END OF THE PERIOD WAS AS FOLLOWS:

	Parent Company	
	31 Dec, 2015	31 Dec, 2014
Non-current receivables from subsidiaries		
Non-current receivables, TwoPac AB	55,835	39,991
Non-current receivables, CapAble AB	-	1,022
	55,835	41,013
Current liabilities from subsidiaries		
Current liabilities, BioGaia Biologics Inc.	-1,627	-930
Current liabilities, CapAble AB	-3,700	-4,793
Current liabilities, Tripac AB	-4,670	-4,662
Current liabilities, IBT AB	-	-6,956
Current liabilities, TwoPac AB	-8,303	-4,146
	-18,300	-21,487

Current receivables from subsidiaries

Current receivables, IBT AB	180	-
Current receivables, BioGaia Japan Inc.	849	-
	1,029	-

See also Note 4 for other related party transactions.

Note 21 Other receivables

	Group		Parent Company	
	2015	2014	2015	2014
VAT refund	4,948	4,322	4,402	4,030
Current tax asset	7,127	-	5,363	-
Other receivables	2,654	2,402	2,601	766
	14,729	6,724	12,366	4,796

Note 22 Deferred expenses and accrued income

	Group		Parent Company	
	2015	2014	2015	2014
Accrued income	9,022	15,955	9,022	15,955
Prepaid rents	1,141	1,117	879	879
Other deferred expenses	3,791	1,225	1,304	203
	13,954	18,297	11,205	17,037

Note 23 Financial assets and liabilities

The Group classifies its financial assets and liabilities in the following categories; financial assets at fair value through profit or loss, held-to-maturity investments, loans and receivables and other financial liabilities.

Financial assets measured at fair value through profit or loss The Group's financial assets at fair value through profit or loss consist of cash and cash equivalents and short-term investments. The financial assets are recognized in the balance sheet and are valued at the closing day rate of exchange.

	Fair value		Carrying amount	
	31 Dec, 2015	31 Dec, 2014	31 Dec, 2015	31 Dec, 2014
Cash and cash equivalents in SEK	172,449	194,618	172,449	194,618
Cash and cash equivalents in EUR	23,322	927	23,322	927
Cash and cash equivalents in USD	27,446	13,083	27,446	13,083
Cash and cash equivalents in JPY	1,783	1,985	1,783	1,985
Cash and cash equivalents in DKK	1,882	53	1,882	53
Short-term investments	13	13	13	13
Total assets	226,895	210,680	226,895	210,680

Short-term investments refer to listed securities. The shares are recognized at historical cost less accumulated impairment. The fair value refers to the bid price on the balance sheet date. The intention is to sell the shares when an appropriate occasion arises.

The company has taken forward currency hedges in EUR and USD. The forward currency hedges have been recognized at their fair value at 31 December 2015. This value is included in other liabilities – see Note 21. In BioGaia's measurement of fair value, the fair values of financial assets and financial liabilities are determined according to level 2.

Held-to-maturity investments The Group has no held-to-maturity investments.

Loans and receivables The Group's trade receivables amount to SEK 65,937 thousand (75,911). Fair value corresponds to the carrying amount.

Other financial liabilities The Group's other financial liabilities consist of trade payables and prepayments from customers. Financial liabilities are valued at the closing day rate of exchange.

	Fair value		Carrying amount	
	31 Dec, 2015	31 Dec, 2014	31 Dec, 2015	31 Dec, 2014
Trade payables	23,638	16,952	23,638	16,952
Prepayments from customers	16,762	6,804	16,762	6,804
Total other financial liabilities	40,400	23,757	40,400	23,757

Note 24 Equity

The objective of the Group's capital management is to safeguard the Group's ability to continue as a going concern and to provide a good return to the shareholders.

The share capital in BioGaia AB consists of 740,668 class A shares, carrying 10 votes each, and 16,595,794 class B shares, carrying one vote each. The class A and B shares grant equal entitlement to the company's assets and profits. Both the A shares and B shares have a quota value of SEK 1 each. All shares are fully paid-up and no shares are reserved for transfer. No shares are held in treasury by the company itself or by its subsidiaries.

Other contributed capital consists of payments made by the shareholders in excess of the quota value.

The foreign currency translation reserve arises in translation of the net assets of foreign operations according to the acquisition method.

Retained earnings consist of other equity. The Parent Company's dividend for 2014, as resolved on by the 2015 AGM, was SEK 86.4 million, equal to SEK 5.00 per share. For 2015 the Board and President propose that the company pay an ordinary dividend of SEK 3.03 per share and an extraordinary dividend of SEK 1.97 per share, amounting to a total dividend of SEK 5.00 per share. This is equal to a total dividend of SEK 86.7 million.

Non-controlling interests account for 9.9% of equity in the subsidiary CapAble and 5.5% of equity in the subsidiary Infant Bacterial Therapeutics AB.

Equity in the BioGaia Group consists of the sum of equity attributable to owners of the Parent Company and equity attributable to non-controlling interests. At 31 December 2015, total consolidated equity amounted to SEK 395.8 million (344.6) and equity attributable to owners of the Parent Company amounted to SEK 395.9 million (344.5).

BioGaia's dividend policy is to pay a shareholder dividend equal to 40% of profit after tax.

KEY RATIOS

	2015	2014
Number of shares at 31 Dec., thousands	17,336	17,271
Average number of shares, thousands	17,309	17,271
Number of outstanding warrants, thousands	–	87
Number of outstanding warrants with a dilutive effect, thousands	–	–
Number of outstanding shares including outstanding warrants with a dilutive effect, thousands	17,309	17,271
Earnings per share, SEK	7.01	8.53
Earnings per share after dilution, SEK	7.01	8.53
Equity per share, SEK	22.87	19.95
Equity per share after dilution, SEK	22.87	19.95
Return on equity, %	33	45
Share price on closing day, SEK	281.50	179.50
Dividend per share, SEK	5.00 ¹⁾	5.00

¹⁾ Dividend proposed but not yet approved. The Board and President propose that the company pay an ordinary dividend of SEK 3.03 per share and an extraordinary dividend of SEK 1.97 per share, equal to a total dividend of SEK 5.00 per share.

Note 25 Other provisions

	Group		Parent Company	
	2015	2014	2015	2014
Carrying amount at 1 January	3,900	–	3,900	–
Reversal of provisions	–3,900	–	–3,900	–
The year's provisions	–	3,900	–	3,900
Carrying amount at 31 December	–	3,900	–	3,900

These provisions relate to BioGaia's estimated cost for development projects to which it is committed in accordance with the collaboration agreement with Nestlé (for more information, see the administration report). The provisions were settled during the year.

Note 26 Other liabilities

	Group		Parent Company	
	2015	2014	2015	2014
Employee withholding tax	1,572	1,278	1,153	941
Other current liabilities	3,182	7,713	–	6,299
	4,754	8,991	1,153	7,240

Other current liabilities above include forward exchange contracts with a fair value of SEK 6.3 million in 2014. All forward exchange contracts are attributable to level 2 of the fair value hierarchy.

Note 27 Accrued expenses and deferred income

	Group		Parent Company	
	2015	2014	2015	2014
Accrued holiday pay	6,829	6,210	4,916	4,745
Accrued social security expenses	1,580	1,308	957	796
Other accrued expenses	23,431	20,832	17,165	17,949
	31,840	28,350	23,038	23,490

Note 28 Pledged assets and contingent liabilities

	Group		Parent Company	
	2015	2014	2015	2014
Pledged assets				
Floating charges	2,000	2,000	2,000	2,000
Assets pledged for construction of a facility for the subsidiary TwoPac AB	690	–	–	–
	2,690	2,000	2,000	2,000
Contingent liabilities	None	None	None	None

The floating charges relate to credit for credit cards.

Note 29 Policy for financial risk management

The overall objective of the Group's finance function is to secure cost-effective financing for the Group's operations and group companies and to provide secure cash management with a market-based return on investment. The overall objective of financial risk management is to minimize the risk for negative effects on the Group's earnings. Consequently, the Group's financial investments must have a low risk profile. Below is a description of the Group's assessed risk exposure and the related risk management:

Currency risk BioGaia has revenue primarily in EUR, but also in USD, SEK, CHF and JPY, and expenses primarily in SEK, EUR, JPY and USD. The breakdown of net sales in 2015 was approximately:

EUR 49%
 USD 28%
 SEK 15%
 JPY 4%
 Other currencies 4%

In 2015 the company had a cash flow surplus of approximately EUR 14.5 million (25.9) (2014 including the payment of EUR 10.8 million from Nestlé), a cash flow deficit of JPY -62.0 million (-76.8) and a cash flow surplus of USD 12.8 million (3.5).

Growth in sales has also led to increased currency risks, for which reason the company has taken currency hedges in EUR and since 2015 also in USD. The company's Board of Directors has issued a policy to hedge approximately 50-60% of projected cash flow 12 months forward and approximately 10-40% of projected cash flow 13-24 months forward in order to spread the risk for exchange rate fluctuations. At 31 December 2015 the company had outstanding forward exchange contracts for EUR 11.8 million at an average exchange rate of SEK 9.31 and USD 1.0 million at an average exchange rate of SEK 8.50. Forward exchange contracts amounting to EUR 8.3 million and USD 1.0 million will mature for payment in 2016 and EUR 3.5 million in 2017. The

actual exchange gain/loss depends on the exchange rate on the maturity date of the contracts. For more information, see Notes 10, 11, 23 and 26.

The average exchange rate for EUR/SEK in 2015 was 9.35. If the EUR/ SEK rate had been SEK 0.10 higher, BioGaia's net sales would have been approximately SEK 2.5 million higher and operating profit would have been SEK 1.4 million higher. The average exchange rate for USD/SEK in 2015 was 8.43. If the USD/ SEK rate had been SEK 0.10 higher, BioGaia's net sales would have been approximately SEK 1.6 million higher and operating profit would have been around SEK 1.2 million higher. A stronger SEK rate, primarily against the EUR and USD, will decrease the value of BioGaia's sales and profit, but through forward exchange transactions and by trying to reallocate a portion of expenses to EUR, the company is trying to minimize the impact on profit. BioGaia is also trying to reallocate a portion of revenue from EUR to other currencies.

Interest rate and liquidity risk The Group has no external loans. Excess liquidity is invested mainly in bank accounts. For cash and cash equivalents, the company has a liquidity policy in which the basic principles are that investment risks should always be minimized and investments should be made primarily in Swedish kronor. To minimize currency risk, other currencies may also be considered. The company's excess liquidity may be invested only in bank accounts, commercial paper or other fixed income securities with very limited risk. This means that no investments may be made in shares, equity funds, options, etc.

Credit risks BioGaia's credit risks are attached to trade receivables and, for the Parent Company, also loans to subsidiaries. When signing agreements with new customers, BioGaia always carries out an assessment of the customer's financial position. The company has routines for collection of past due trade receivables and additional evaluation of the customers' financial position is carried out when needed in order to minimize risks.

The loan from the Parent Company to the subsidiary TwoPac AB has been used mainly for construction of a new production facility in Eslöv. The first facility was completed and taken into operation in 2012. In 2014 and 2015, additional loans were paid for expansion of the production facility, which was underway during the year. The expansion is expected to be completed 2016. The company's assessment is that the credit risk on the loan is low

Cash flow risk Cash flow for the period amounted to SEK 15.1 million (-25.0). Cash flow included license revenue from Nestlé of SEK 0 million (95.4), dividends of SEK 86.4 million (120.9) and tax payments of SEK 50.1 million (66.8).

Because cash and cash equivalents at 31 December 2015 amounted to SEK 226.9 million (210.7), no infusion of capital is necessary during the coming 12-month period.

Price risk BioGaia buys most of its goods on the international market and has several alternative suppliers, which reduces the company's price risk. BioGaia's price to distributors is largely the same for all, but can vary with respect to the order volume. Certain markets are subject to aggressive price competition towards consumers. However, BioGaia's strategy is not to compete in terms of price but to instead convince doctors of the effectiveness and safety of the products by showing the results of clinical studies.

Note 30 Critical accounting estimates and assumptions

Certain sources of uncertainty in accounting judgements and assumptions are described below.

BioGaia's venture in Japan The Japanese subsidiary has operated at a loss since the start in 2006. On the balance sheet date, assets in the Japanese subsidiary were reported at SEK 15.6 million in the Group. BioGaia's assessment is that there is no indication of impairment of these assets. In the Parent Company, the loan to the Japanese subsidiary and the participations in the company have been written down to zero.

Investments in group companies CapAble, which is 90.1% owned by BioGaia AB, was started in November 2008 to manufacture and sell the patented LifeTop Cap. The shares in the subsidiary CapAble amount to a total of SEK 6.9 million in the Parent Company. CapAble has operated at a loss since the start in 2008. Profit before tax for 2015 amounted to SEK -3.5 million (-2.9). BioGaia made total conditional shareholder contributions of SEK 6 million to CapAble in 2009 and 2010. BioGaia AB made total group contributions of SEK 15.1 million during the period from 2010 to 2015. On the balance sheet date, assets in CapAble were reported at SEK 3.1 million in the Group. BioGaia's assessment is that CapAble will show profitability in coming years, for which reason there was no indication of impairment on the balance sheet date.

Development of drug to treat NEC Infant Bacteria Therapeutics AB (IBT), which is 94.5% owned by BioGaia, was established in November 2013. At that time, the Board of BioGaia made a decision to invest in phase one of a long-term project aimed at developing a drug with rigorous hygiene, analysis and documentation requirements, to treat the highly fatal disease Necrotizing Enterocolitis (NEC), which affects premature infants. BioGaia's total investment in IBT amounts to SEK 81.8 million. On the balance sheet date, assets in IBT were reported at SEK 62.1 million in the Group. BioGaia's assessment is that IBT and the research and development projects currently underway in the company will show profitability in the future, for which reason there was no indication of impairment on the bal-

ance sheet date. The project represents a major opportunity, but also a significant risk. In the event that the drug development is not realized, BioGaia intends to market the formulation under another product category. In February 2016 the Board of BioGaia resolved to distribute the shares in IBT to the company's shareholders in connection with IBT's application for listing on the First North marketplace.

Associated company MetaboGen AB Since 1 December 2015, BioGaia owns 27% of MetaboGen AB (for more information, see above). The remaining shares are held by the researchers who founded the company. So far, MetaboGen has shown a loss. On the balance sheet date, assets in MetaboGen were reported at SEK 7.9 million in the Group. BioGaia's assessment is that MetaboGen will show profitability in the future, for which reason there was no indication of impairment on the balance sheet date.

The Board of Directors and the President hereby give their assurance that the consolidated financial statements and annual report have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and generally accepted auditing practices, and give a true and fair view of the financial position and results of operations of the Group and the Parent Company. The administration report for the Group and the Parent Company gives a true and fair view of the business activities, financial position and results of operations of the Group and the Parent Company, and describes the significant risks and uncertainties to which the Parent Company and the Group companies are exposed.

Stockholm, 24 February 2016

David Dangoor <i>Chairman</i>	Peter Rothschild <i>President</i>
Jan Annwall <i>Member of the Board</i>	Ewa Björling <i>Member of the Board</i>
Stefan Elving <i>Member of the Board</i>	Inger Holmström <i>Member of the Board</i>
Anthony Jahreskog <i>Member of the Board</i>	Brit Stakston <i>Member of the Board</i>
Paula Zeilon <i>Member of the Board</i>	

My audit report was submitted on 18 March 2016
Deloitte AB

Birgitta Löf
Authorized Public Accountant

Auditor's report

To the annual meeting of the shareholders of BioGaia AB (publ)
Corporate identity number 556380-8723

Report on the annual accounts and consolidated accounts

We have audited the annual accounts and consolidated accounts of BioGaia AB (publ) for the financial year 2015-01-01 – 2015-12-31. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 2–25.

RESPONSIBILITIES OF THE BOARD OF DIRECTORS AND THE PRESIDENT FOR THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of these annual accounts in accordance with the Annual Accounts Act and of the consolidated accounts in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the Managing Director 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.

AUDITOR'S RESPONSIBILITY

Our responsibility is to express an opinion on these annual accounts and consolidated accounts based on our audit. We conducted our audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and consolidated accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and consolidated accounts 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. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the annual accounts and consolidated accounts.

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

OPINIONS

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 the parent company as of 31 December 2015 and of its financial performance and its cash flows 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 2015 and of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the annual meeting of shareholders adopt the income statement and balance sheet for the parent company and the group.

OTHER MATTERS

The audit of the annual accounts for the financial year 2014-01-01 – 2014-12-31 were performed by another auditor who submitted an auditor's report dated 20 February 2015, with unmodified opinions in the Report on the annual accounts.

Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the Managing Director of BioGaia AB (publ) for the financial year 2015-01-01 – 2015-12-31.

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, and the Board of Directors and the Managing Director are responsible for administration under the Companies Act.

AUDITOR'S RESPONSIBILITY

Our responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on our audit. We conducted the audit in accordance with generally accepted auditing standards in Sweden.

As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss, we examined the Board of Directors' reasoned statement and a selection of supporting evidence in order to be able to assess whether the proposal is in accordance with the Companies Act.

As a basis for our opinion concerning discharge from liability, in addition to our audit of the annual accounts and consolidated accounts, we examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the Managing Director is liable to the company. We also examined whether any member of the Board of Directors or the Managing Director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

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

OPINIONS

We recommend to the annual meeting of shareholders that the profit 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.

Stockholm, 18 March 2016

Deloitte AB

Birgitta Löf

Authorized Public Accountant

Corporate governance report BioGaia AB 2015

Compliance with the Swedish Code of Corporate Governance The purpose of the Code is to strengthen confidence in Swedish listed companies by promoting positive development of the companies' corporate governance. The Code is based on the "comply or explain" principle, which means that a company may deviate from the Code but that any such deviations must be explained.

BioGaia has not deviated from any of the rules set out in the Code.

Corporate governance in BioGaia BioGaia is a Swedish public limited company whose class B shares are listed on the Mid Cap list of the NASDAQ OMX Nordic Exchange Stockholm. The company's corporate governance is exercised through the General Meeting of Shareholders, the Board of Directors, the President and the Executive Management in accordance with the Swedish Companies Act, the Articles of Association and the Swedish Code of Corporate Governance.

The share capital consists of 740,668 class A shares carrying 10 votes each and 16,595,794 class B shares carrying one vote each.

Articles of Association According to BioGaia's Articles of Association, the company, directly or through subsidiaries or other forms of co-ownership or partnership, shall engage in the development, production, marketing and sale of health-enhancing products in the form of pharmaceuticals, natural health products, dietary supplements, additives for food products and animal feed, suitable delivery systems for these products and other activities compatible therewith. The company is domiciled in Stockholm, Sweden. The Articles of Association can be viewed on BioGaia's website under the heading "Investors/Corporate Governance".

General Meeting of Shareholders The General Meeting of Shareholders is the company's highest decision-making body. The Annual General Meeting (AGM) elects the members of the Board of Directors. In addition, the responsibilities of the AGM include adoption of the company's income statements and balance sheets, approval of the appropriation of disposable profits and discharge from liability for the members of the Board and the President. The AGM also elects the company's auditors.

One shareholder, Annwall & Rothschild Investment AB, holds 8.6% of the share capital and 34.0% of the votes in the company. Other individual shareholders hold less than 10% of the share capital and votes each.

2015 AGM BioGaia's AGM was held on 7 May 2015 and was attended by shareholders representing 59.9% of the total number of votes in the company. The AGM was also attended by the company's President, the Board members elected by the previous AGM except for Brit Stakston, Jan Litborn and Jörgen Thorball, and all of the Board members elected by the year's AGM except for Brit Stakston, as well as the company's elected auditor.

The AGM resolved on the following proposals, among others:

- Adoption of the annual report
- Discharge from liability for the Board of Directors and the President
- A dividend of SEK 5.00 per share
- Re-election of sitting Board members Jan Annwall, David Dangoor, Stefan Elving, Inger Holmström, Brit Stakston and Paula Zeilon
- Election of Anthon Jahreskog and Eva Björling as new Board members
- Re-election of David Dangoor as Board Chairman
- Election of the registered auditing firm of Deloitte AB
- Board fees of SEK 300,000 to the Board Chairman and SEK 150,000 to each of the other Board members not employed by the company
- Payment of auditor's fees according to approved account
- Principles for remuneration and other terms of employment for senior executives in accordance with the Board's proposal
- Appointment of the Nominating Committee in accordance with the Nominating Committee's proposal

2016 AGM The 2016 AGM will be held at 4:00 p.m. on Thursday, 10 May, at Lundqvist & Lundqvist Klara Strand, Klarabergsviadukten 90, in Stockholm.

Notice of the AGM Notice of the AGM is given through an announcement in the Official Gazette (Post- och Inrikes Tidningar) and on the company's website. An announcement that notice has been given is published in Svenska Dagbladet.

Nominating Committee The task of the Nominating Committee is to prepare recommendations regarding election and remuneration for decision by the AGM.

The 2015 AGM resolved that the Nominating Committee would be appointed according to the following: "The Board Chairman shall convene the three largest shareholders in the company in terms of voting power, each of which has the right to appoint a member to the Nominating Committee together with the Board Chairman. In determining the composition of the Nominating Committee, the largest shareholders in terms of voting power shall be based on the ownership conditions at 30 June 2015. The Nominating Committee shall be chaired by the member representing the largest shareholder at that time. If any of the three largest shareholders should waive its right to

appoint a member to the Nominating Committee, the next largest shareholder in order of voting power shall be given the opportunity to appoint a member. The names of the three shareholder representatives shall be made public as soon as they have been appointed, but no later than six months before the 2016 AGM. The term of office shall extend until a new Nominating Committee has been appointed.

In the event that the shareholder represented by a member is no longer one of the three largest shareholders in terms of voting power, and if the Nominating Committee deems it appropriate, the member can resign and a representative for the next largest shareholder in order of voting power can be given the opportunity to replace this member. In the event that an appointed member of the Nominating Committee resigns from the Nominating Committee for some other reason, the shareholder who has appointed the member in question has the right to appoint a new member to the Committee. If this shareholder waives its right to appoint a new representative, the Nominating Committee, if it deems so appropriate in respect of the remaining mandate period, shall ask the next largest shareholder in terms of voting power if it wishes to appoint a representative to the Nominating Committee."

In accordance with the AGM's resolution, the Nominating Committee was appointed and consists of the Chairman of BioGaia AB, David Dangoor, together with Per-Erik Andersson, representing Annwall & Rothschild Investment AB, the company's largest shareholder, Sebastian Jahreskog, who through direct and indirect ownership is the company's second largest shareholder, and Jannis Kitsakis, representing the company's third largest shareholder, Fjärde AP-Fonden. All four members of the Nominating Committee are independent in relation to the company and its management.

The Nominating Committee shall prepare recommendations for the following matters to be put before the 2016 AGM for resolution:

- a) appointment of the Chairman of the AGM
- b) election of the Board of Directors
- c) election of the Board Chairman
- d) election of auditors
- e) fees for members of the Board
- f) fees for the auditors
- g) appointment of the Nominating Committee ahead of the 2017 AGM.

All shareholders have the opportunity to contact the Nominating Committee with recommendations for Board candidates for further evaluation within the framework of the Committee's work. No suggestions or proposals have been submitted to the Nominating Committee as of today's date.

The Nominating Committee presents a written motivation to the AGM for election of Board members. In its motivation, the Nominating Committee gives consideration to diversity and breadth of experience on the Board and strives for an even gender distribution.

Board of Directors According to BioGaia's Articles of Association, the Board shall consist of at least five and at most eight members with no more than three deputies. The Board is elected yearly by the AGM to serve for the period until the end of the following AGM. In 2015 the Board consisted of eight members elected by the AGM, with no deputies. One Board member, Jan Annwall, has been a member of the Board since 1990 and is a major shareholder in the company. Jan Annwall was previously employed by the company as CFO and Executive Vice President, but retired on 1 April 2010. However, Jan Annwall works to a limited extent as a consultant to the company. The seven remaining members are independent in relation to both the company and its management. A presentation of the Board is provided on page 32-33.

BioGaia's legal counsel has been appointed to serve as Secretary at Board meetings. The President is not a member of the Board but is co-opted to attend all Board meetings. Other executives in the company take part in Board meetings in order to present reports. The Board has adopted rules of procedure that include instructions for the separation of duties between the Board and President and the structure of Board activities during the year. In addition to the responsibilities that are generally applicable pursuant to Swedish Companies Act, the Articles of Association and the Swedish Code of Corporate Governance, the following are regulated by the Board's rules of procedure:

- At least 5 Board meetings during the year, in addition to the statutory meeting.
- Establishment of the overall objectives for the company's operations and decision on the company's strategy.
- Approval of budgets and similar long-term plans, including the investment budget.
- Matters related to investments and similar in amounts of more than SEK 2 million.
- Decision on the purchase and sale of real estate, shares or the acquisition of another company's operations in amounts of more than SEK 2 million.
- Decision on the formation and capitalization of subsidiaries in amounts of more than SEK 2 million.
- Adoption of the annual report, administration report and interim reports.
- Raising of loans
- Signing of agreements with a term of more than five years.
- Launching of large-scale lawsuits and settlement of disputes of material significance.
- Other matters of material financial or other significance.

Furthermore, the Board has adopted instructions for the President, authorization instructions including instructions for liquidity management and a policy for foreign exchange management. The rules of procedure, President's instructions and authorization instructions are reviewed at least once a year.

Board attendance during 2015¹⁾

Members elected by the AGM	Elected in	Born in	Board meetings Attendance/total no. of Board meetings	Remuneration Committee Attendance/ total no. of committee meetings
Board Chairman David Dangoor ⁴⁾	2003	1949	13/13	2/2
Board member Jan Annwall	1990	1950	13/13	
Board member Ewa Björling ^{2) 4)}	2015	1961	8/8	
Board member Stefan Elving ⁴⁾	2001	1941	12/13	2/2
Board member Inger Holmström ⁴⁾	2007	1948	13/13	
Board member Anthon Jahreskog ^{2) 4)}	2015	1980	8/8	
Board member Jan Litborn ^{3) 4)}	2014	1951	4/5	
Board member Brit Stakston ⁴⁾	2014	1961	11/13	
Board member Jörgen Thorball ^{3) 4)}	2008	1962	4/5	
Board member Paula Zeilon ⁴⁾	2003	1962	12/13	

¹⁾ All members of the Board who have been prevented from participating in a Board meeting have been given the opportunity to present their views to the Chairman prior to the meeting.

²⁾ Elected in connection with the 2015 AGM.

³⁾ Resigned in connection with the 2015 AGM.

⁴⁾ Independent in relation to the major shareholders, the company and the company's management.

At the Board meetings, the following are dealt with as needed:

- Business plans
- Business performance monitoring
- Investments
- Strategic matters
- Financial reports
- Major agreements
- Budgetary matters
- Accounting matters

The Board of Directors continuously evaluates its own performance through both open discussions and a written self-assessment. The results of the written assessment are submitted to the Nominating Committee.

Board fees The 2015 AGM resolved that Board fees would be paid in an amount of SEK 300,000 to the Board Chairman and SEK 150,000 to each of the other Board members not employed by the company.

Board Chairman The Chairman supervises the work of the Board and is responsible for ensuring that the Board carries out its duties in accordance with the Swedish Companies Act and the rules of procedure. Through ongoing contact with the President, the Chairman continuously monitors the company's development and ensures that the Board is provided with the information necessary to carry out its duties. David Dangoor has been Board Chairman since the 2007 AGM.

President The President is responsible for overseeing the company's business development and for supervising and coordinating its day-to-day operations. The Board has established instructions for the President that among other things regulate his management and development of the company and the provision of reports and decision data to the Board. The President prepares the requisite information and decision data such as reports on the company's finances, the order situation, significant business matters and strategic issues prior to Board meetings, as well as presenting reports and motivating proposals for decision. Furthermore, the President continuously informs the Board Chairman about the company's financial and business situation. Every year the Board carries out an evaluation of the President's performance in which no member of the Executive Management is present.

Executive Management BioGaia's Group Executive Management consists of the eleven individuals who are presented in Appendix 2. In October 2015, BioGaia's Board of Directors decided to appoint Axel Sjöblad as the new Managing Director with effect from 1 March 2016. The company's former President Peter Rothschild was then appointed as Group President.

The Group's Executive Management is headed by the President and is responsible for planning, supervising and monitoring the company's day-to-day operations. Minuted meetings are normally held once a month. The responsibilities and powers of the President are regulated by the Swedish Companies Act and by the instructions that are adopted by the Board. The responsibilities and powers of the Executive Management are defined in the established job descriptions and authorization instructions.

Remuneration Committee The Board has appointed a Remuneration Committee consisting of Board Chairman David Dangoor and Board member Stefan Elving. The task of the Remuneration Committee is to prepare recommendations for the remuneration and other terms of employment of the President and other senior executives who together make up the Executive Management. The principles for remuneration to senior executives are resolved on by the AGM. The Remuneration Committee prepares its recommendations based on these principles.

Auditors BioGaia's independent auditors are normally appointed by the AGM to serve for a period of four years. The 2015 AGM resolved on election of the registered auditing firm of Deloitte AB to serve for the period until the end of the AGM to be held in 2016. The auditing firm appointed Birgitta Löf as Auditor in Charge. By decision of the AGM, auditing fees are paid according to approved account.

The auditors examine the administration of the company by the Board of Directors and the President and the quality of the company's financial reporting. At the request of the Board, the auditors also review the semi-annual report and the year-end report.

The auditors report the results of their review to the shareholders through an audit report, which is presented to the AGM. In addition, the auditors submit written and oral reports to the Executive Management and the Board. The auditors take part in the Board meeting preceding publication of the year-end report to present the results of their audit of the annual accounts and observations from ongoing examination of the company's internal control during the financial year.

The auditors also submit an auditor's statement on the corporate governance report and a report on the examination of remuneration to senior executives.

Deloitte (and for 2014 Grant Thornton) has provided certain tax-related advice and performed other audit-related services. Information about remuneration to the auditors can be found in Note 6 of the annual report.

Due to the fact that independent Board members have accounting expertise and in view of the Board's ongoing examination of the financial reporting and the company's limited size and transaction volume, the Board has decided not to set up any audit committee. Furthermore, the entire Board of Directors meets with the auditors at least once a year without the presence of the President or other members of the Executive Management.

The Board's report on internal control over financial reporting for the 2014 financial year 2015

Introduction As stated in the Swedish Companies Act, the Swedish Annual Accounts Act and the Swedish Code of Corporate Governance, the Board of Directors is responsible for establishing and maintaining adequate internal control. This description has been prepared in accordance with these rules and provisions and is thereby limited to internal control over financial reporting.

Internal control over financial reporting The Board is responsible for ensuring that the company's organization is suitably structured so that the financial accounts, cash management and other financial conditions can be controlled satisfactorily.

Every year, the Board of Directors adopts rules of procedure for the Board's activities and instructions regulating the division of responsibilities between the Board and the President. The rules of procedure state which matters require approval or authorization from the Board. At Board meetings, the President reports on matters requiring treatment by the Board.

The President ensures that the Board is provided with the objective, detailed and relevant information needed for the Board to make well founded decisions and that the Board is continuously informed about the company's business development and financial position.

Aside from the rules of procedure between the Board and the President, BioGaia's control structure is based on the company's organization and way of conducting operations, where roles and responsibilities are defined. There is a high level of employee awareness about the importance of maintaining good control over financial reporting. The company's financial development is assessed and monitored monthly. Financial reports and summaries are prepared by the Group's finance department and are presented to the Board quarterly and to the Executive Management monthly.

The company's values BioGaia also has a set of shared values and the company's employees are well aware of these (see below). This is ensured through interviews in connection with new hires and through regular workshops with each department.

BioGaia's values:

- My personal commitment is vital for BioGaia's success.
- We are innovative and action-oriented.
- We are business-minded and deliver on our promises.
- We are honest, respectful and selfless in what we do and say.

Risk assessment The company works continuously with risk assessment and risk management to ensure that the risks to which the company is exposed are handled within the limits ultimately established by the Board. The Executive Management continuously analyses the company's business processes with regard to efficiency and risks.

This work includes identifying significant risks for misstatements and deficiencies in the financial reporting and ensuring that there are suitable processes and controls in the company's operations to limit these risks. The most critical business processes and the absolutely largest values, in terms of both assets and business/product development, are found in the Parent Company. In addition, the bulk of sales take place in the Parent

Company. Processes that are deemed to be of special importance to BioGaia are sales including quality assurance, R&D and manufacturing.

Control activities The risks identified in the financial reporting are managed through a number of control activities in the company's processes. Processes and controls are reviewed and updated regularly in order to detect, prevent and correct any errors or deficiencies. The control structure also includes the division of powers and responsibilities and the Executive Management's monthly review of the company's financial information.

Information and communication BioGaia has information and communication paths that are designed to promote the completeness and accuracy of the financial reporting. Authorization instructions and policies are distributed to all employees and can be viewed on the company's intranet. Once or twice a year, all of BioGaia's employees meet to increase their knowledge about the company's processes and goals and to exchange information and experiences. In 2015 the company's employees met for two days in September.

Monitoring The Executive Management performs a yearly evaluation of the effectiveness of internal control. Every year, the company's elected auditing firm, Deloitte AB, also audits a selection of BioGaia's routines and internal controls. The Board then evaluates this information and ensures that measures are taken in respect of the identified deficiencies and resulting recommendations.

The company has no special internal audit function. In light of the company's size and the volume of transactions, together with the expertise in this area possessed by the Board of Directors and the Board's meeting with the independent auditor, the Board has determined that there is no reason to set up a formal internal audit function.

Stockholm, 24 February 2016

Board of Directors of BioGaia AB

Auditors' statement on the corporate governance report

To the general meeting of the shareholders in BioGaia AB (publ.), corporate identity number 556380-8723

The Board of Directors is responsible for the corporate governance report for the year 2015 (on pages 27-29) and for ensuring that it has been prepared in accordance with the Annual Accounts Act.

We have read the corporate governance report and based on this reading and our knowledge of the company and the Group we believe we have sufficient grounds for our statement. This means that our statutory review of the corporate governance report has a different focus and scope compared to the focus and scope of an audit according to the International Standards on Auditing and generally accepted accounting principles in Sweden.

In our opinion, a corporate governance report has been prepared and its statutory information is consistent with the annual report and the consolidated accounts.

Stockholm, 18 March 2016

Deloitte AB

Birgitta Lööf

Authorized Public Accountant

The BioGaia share

Figures in brackets refer to the preceding year

Trading volume BioGaia AB's class B share has been quoted on the OMX Nordic Exchange Stockholm since May 1998. On 1 January 2012 the share was moved from the Small Cap list to the Mid Cap list.

In 2015 BioGaia shares were traded for a total of around SEK 1,335 million (1,172), corresponding to approximately 5.3 million shares (6.0).

The number of shareholders at 31 December 2015 was 7,272 (7,136).

The total registered share capital of BioGaia AB consists of 740,668 class A shares and 16,595,794 class B shares.

Share price development In 2015 the share price increased from SEK 179.50 to SEK 281.50. The highest closing price during the year was SEK 315.50 and the lowest was SEK 175.00. Market capitalization at 31 December 2015 was approximately SEK 4,880 million (3,100).

Dividend policy BioGaia's policy is to pay a shareholder dividend equal to 40% of profit after tax.

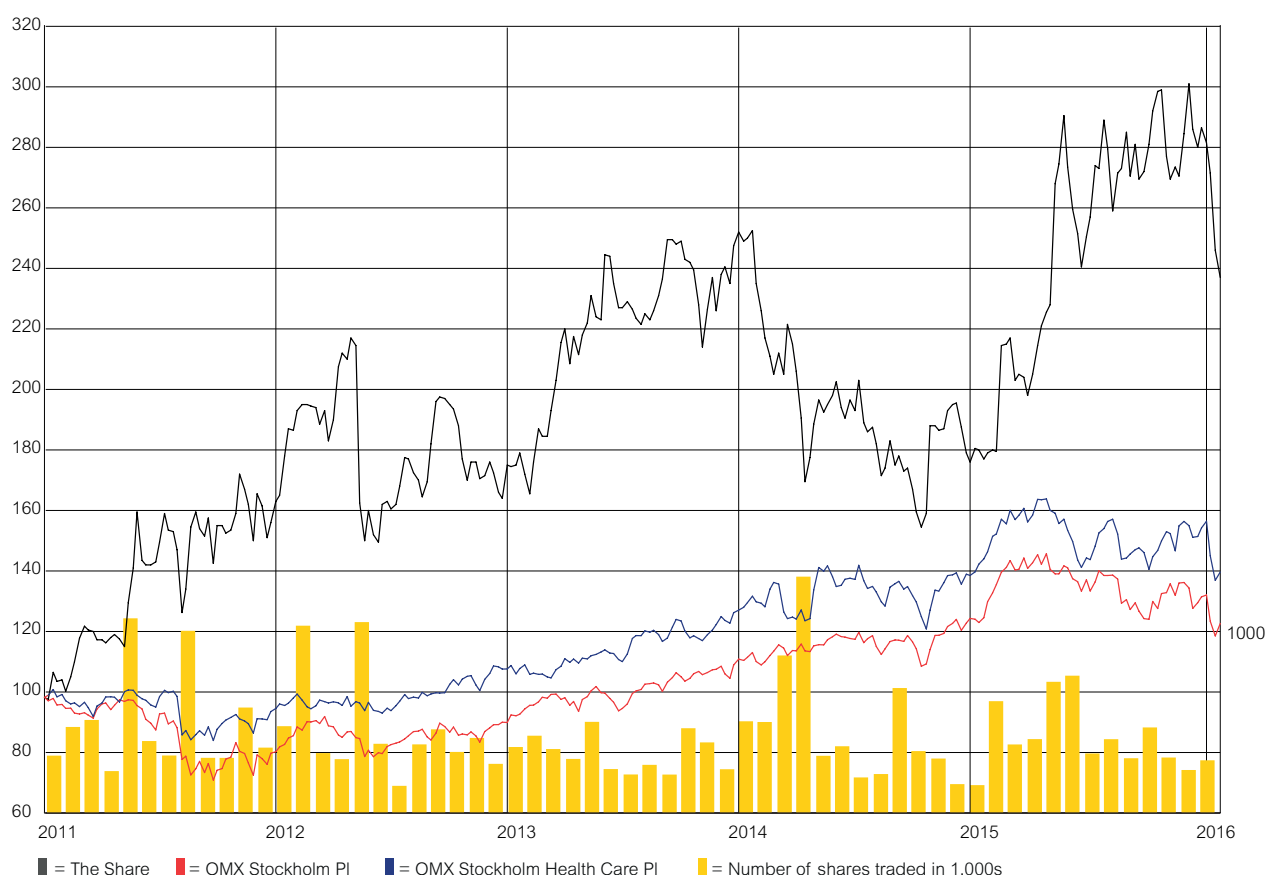
Incentive scheme The warrant programme for the employees that was resolved on by the Annual General Meeting on 8 May 2012 expired on 1 June 2015. A total of 65,500 warrants were redeemed and the share capital now amounts to SEK 17,336,462. The number of class B shares now amounts to 16,595,794 and the number of class A shares is unchanged at 740,668. The subscription price for the share was SEK 241.90 and the company was thus provided with proceeds of SEK 15.8 million in the second quarter. expenses

The company now has no ongoing share-based incentive schemes.

Distribution of ownership

Number of shares	Total number of shareholders	
	31 December 2015	31 December 2014
1–500	6,039	5,832
501–1,000	580	641
1,001–5,000	447	475
5,001–10,000	73	65
10,001–15,000	15	21
15,001–20,000	14	16
20,001–	104	86
Total number of shareholders:	7,272	7,136

The BioGaia share



Largest shareholders in BioGaia at 31 December 2015 (source: Eurocle ar Sweden AB)

	A shares, 000's	B shares, 000's	Share capital, SEK 000's	No. of votes, 000's	Holding, %	Votes, %
Annwall & Rothschild Inv. AB	741	759	1,500	8,166	8.6	34.0
Banque Öhman S.A		1,271	1,271	1,271	7.3	5.3
Fjärde AP-fonden		775	775	775	4.5	3.2
Handelsbankens Fonder AB		651	651	651	3.8	2.7
David Dangoor (incl. company)		569	569	569	3.3	2.4
Livförsäkringsaktiebolaget Skandia		532	532	532	3.1	2.2
CBNY Norges Bank		494	494	494	2.8	2.1
Mingdale Company		462	462	462	2.7	1.9
State Street Bank & Trust com., Boston		436	436	436	2.5	1.8
Swedbank Robur fonder		395	395	395	2.3	1.6
SSB and Trust company, Boston		319	319	319	1.8	1.3
Caroline Hamilton		303	303	303	1.7	1.3
AMF-Försäkring och fonder		284	284	284	1.6	1.2
Banque Carnegie Luxembourg SA		276	276	276	1.6	1.1
Hanvad Invest Aktiebolag		268	268	268	1.5	1.1
Credit Suisse AG Zurich		265	265	265	1.5	1.1
Nordea Investment Funds		240	240	240	1.4	1.0
JP Morgan Chase N.A		238	238	238	1.4	1.0
Sten Irwe		224	224	224	1.3	0.9
Skandinaviska Enskilda Banken S.A		212	212	212	1.2	0.9
CF Ruffer Investment Funds		200	200	200	1.2	0.8
SSB Client Omnibus Account, Abu Dhabi		189	189	189	1.1	0.8
Nordnet Pensionsförsäkring AB		171	171	171	1.0	0.7
Försäkringsaktiebolaget Avanza Pension		162	162	162	0.9	0.7
SEB Investment Management		149	149	149	0.9	0.6
Other		6,752	6 752	6 752	38.9	28.1
Total	741	16,596	17,336	24,002	100.0	100.0

Changes in share capital since the company's formation

Year	Transaction	Increase in no. of shares	Increase in share capital, SEK	Total share capital, SEK	Total no. of A shares	Total no. of B shares	Quota value, SEK	Issue proceeds, SEK
1990	Company founded			150,000		30,000	5.00	–
1991	New share issue	12,857	64,285	214,285		42,857	5.00	4,500,000
1993	New share issue	12,554	62,770	277,055		55,411	5.00	4,394,341
1995	New share issue	2,303	11,515	288,570		57,714	5.00	806,009
1996	Bonus issue/Split	60,541,986	5,771,400	6,059,970	4,740,278	55,859,422	0.10	–
1996	New share issue	18,200,000	1,820,000	7,897,970	4,740,278	74,059,422	0.10	15,320,000
1997	New share issue Banco Fonder	2,608,696	260,870	8,140,840	4,740,278	76,668,118	0.10	5,760,000
1997	New share issue BioGaia Fermentation	4,400,000	440,000	8,580,840	4,740,278	81,068,118	0.10	7,469,000
1997	New share issue	21,452,099	2,145,210	10,726,050	5,925,347	101,335,148	0.10	38,597,265*
1998	New share issue	5	1		5,925,350	101,335,150	0.10	20
1998	Reverse split				592,535	10,133,515	1.00	–
1998	New share issue (IPO on SSE)	2,681,512	2,681,512	13,407,562	740,668	12,666,894	1.00	57,934,131*
2000	New share issue November	3,275,000	3,275,000	16,682,562	740,668	15,941,894	1.00	73,031,886*
2000	New share issue December	425,000	425,000	17,107,562	740,668	16,366,894	1.00	11,505,294*
2004	New share issue Industrifonden	100,000	100,000	17,207,562	740,668	16,466,894	1.00	100,000
2010	New share issue warrant programme	63,400	63,400	17,270,962	740,668	16,530,294	1.00	4,862,780
2015	New share issue warrant programme	65,500	65,500	17,336,462	740,668	16,595,794	1.00	15,844,450

* Excluding underwriting costs

Executive Management



PETER ROTHSCHILD

Born in 1950. M.B.A. President, founder and principal shareholder. Board assignments in Looft Industries AB. Holds 370,334 class A shares and 379,666 class B shares via Annwall & Rothschild Investment AB.

MARGARETA HAGMAN

Born in 1966. M.B.A. Executive Vice President Accounting, Finance and Investor Relations. Employed by the company since 1996, in current position since 2010. Holds 7,000 class B shares.

NIGEL TITFORD

Born in 1973. MSc Business Administration and Business Law. Head of Business Unit Adult Health. Employed by the company since 1999, in current position since 2014. Holds 540 class B shares.

JESSICA EIDEMO

Born in 1974. MSc Biology, education in business economics and marketing. Head of Business Unit Paediatrics. Employed by the company since 2012, in current position since 2014. Holds 6,000 class B shares.

BO MÖLLSTAM

Born in 1952. M.B.A. Director of Intellectual Property. Employed by the company since 1990, on a consulting basis since 2003. Holds 44,000 class B shares.

HELEN OLSSON

Born in 1965. Studies in Human Resources Management. Human Resources Manager. Employed by the company on a consulting basis since 2013, in current position since 2015. Holds 0 shares.

Board of Directors



DAVID DANGOOR

Born in 1949. Board Chairman. Elected to the Board in 2003. M.B.A. Marketing and PR consultant. President of Innoventive Partners LLC. Former Vice President and Marketing Director at Philip Morris USA and Philip Morris International. Other board assignments: Lifetime

Brands, Inc., New York, City Ballet Inc., BAM, Brooklyn, School of Creative Leadership, Berlin University and Swedish-American Chamber of Commerce (SACC NY, chairman 1997–2001), among others. Holds 518,918 class B shares directly and 50,000 class B shares via private company.

INGER HOLMSTRÖM

Born in 1948. Elected to the Board in 2007. MA in Language and Linguistics and a degree in journalism. Senior Partner, Priority. Former Corporate Communications Director at Coop Norden, Posten and Vattenfall. Other board assignments: Järna akademi. Holds 500 class B shares.

ANTHON JAHRESKOG

Born in 1980. Elected to the Board in 2015. MSc Financial Management. Former Chief Operating Officer Fund Linked Products at Credit Suisse Investment Bank, London. Holds 0 shares.

EWA BJÖRLING

Born in 1961. Elected to the Board in 2015. Doctor of Dentistry, Doctor of Medicine and Associated Professor at the Karolinska Institute. Former member of the Swedish Riksdag and Minister for Trade in the Swedish Government from 2007 to 2014. Minister for Nordic Cooperation from 2010 to 2014. Other board assignments: Mobilaris AB, KAK, Rehman & Partners Global Assessment advisory board. Holds 0 shares.



SEBASTIAN SCHRÖDER

Born in 1973. M.B.A. Vice President Marketing and Business Development. Employed by the company since 2015. Holds 0 shares.

ULRIKA KÖHLER

Born in 1966. BSc Biology with extended studies in microbiology. Head of Business Unit New Business. Employed by the company since 2013. Holds 0 shares.

KRISTINA SILVERIO

Born in 1964. MSc Engineering. Vice President Production and Supply. Employed by the company since 2003, in current position since 2005. Holds 0 shares.

KRISTINA MAGNUSSON BORG

Born in 1961. MSc Nutrition/Biochemistry, Ph. Lic. Clinical Physiology, Executive MBA. Clinical Research Director Paediatrics and Female Health. Employed by the company since 2015. Holds 1,500 class B shares.

KATAYOUN WELIN-BERGER.

Born in 1968. PhD Pharmacology. Vice President Sourcing and Supply. Employed by the company since 2014. Holds 600 class B shares.

URBAN STRINDLÖV

Born in 1964. Mechanical Engineering. Executive Vice President and Marketing Director. Employed by the company since 2004, in current position since 2010. Holds 0 shares.



STEFAN ELVING

Born in 1941. Elected to the Board in 2001. Former Marketing Director and Executive Vice President of Icahandlarnas AB. Other board assignments: Arcus AS. Holds 0 shares.

BRIT STAKSTON

Born in 1961. Elected to the Board in 2014. Studies in Media and Communications. PR and Communications Consultant, Media Strategist and owner of Stakston AB. Member of Presstödsnämnden. Holds 0 shares.

PAULA ZEILON

Born in 1962. Elected to the Board in 2003. MSc Engineering. Partner in Conlega affärskonsultbolag. Former President of Life Science Foresight Institute and former Marketing Director at Amersham Biosciences AB. Holds 1000 Class B shares.

JAN ANNWALL

Born in 1950. Elected to the Board in 1990. M.B.A. Former Executive Vice President and CFO of BioGaia AB. Founder and principal shareholder in BioGaia AB. Holds 370,334 class A shares and 379,666 class B shares via Annwall & Rothschild Investment AB.

Definitions and Glossary

Definitions

Basic earnings per share

Profit after tax attributable to owners of the Parent Company divided by the number of shares.

Cash flow from operating activities per share

Cash flow from operating activities divided by the number of shares.

Cash flow from operating activities per share after dilution

Cash flow from operating activities divided by the number of shares plus the number of outstanding warrants with a dilutive effect.

Capital employed

Balance sheet total less interest-free liabilities.

Current ratio

Total current assets divided by current liabilities.

Diluted earnings per share

Profit after tax attributable to owners of the Parent Company divided by the number of shares plus the number of outstanding warrants with a dilutive effect

Diluted equity per share

Shareholders' equity attributable to the owners of the Parent Company divided by the number of shares plus the number of outstanding warrants with a dilutive effect.

Equity/assets ratio

Shareholders' equity attributable to the owners of the Parent Company divided by total assets.

Equity per share

Shareholders' equity attributable to the owners of the Parent Company divided by the number of shares.

Growth

Sales for the current year less sales for the previous year divided by sales for the previous year.

Operating margin

Operating profit in relation to net sales.

Profit margin

Profit before tax in relation to net sales.

Return on capital employed

Profit before financial items plus financial income, divided by average capital employed.

Return on equity

Profit after tax equity attributable to the owners of the Parent Company divided by average shareholders' equity attributable to the owners of the Parent Company.

Glossary

Antibiotics

Compounds that kill or inhibit the growth of microorganisms.

Helicobacter pylori

Very commonly occurring bacteria in many parts of the world. Resides in the stomach and may lead to peptic ulcers and gastric cancer.

Clinical research

Research conducted in humans.

Lactobacillus

Lactic acid bacteria. A collective name for a group of microorganisms that occur naturally in various foods such as yogurt, olives and pickled vegetables. In the past, we ingested a great deal of lactic acid bacteria, but today our diet lack these beneficial bacteria. Some lactic acid bacteria are also present in the human commensal flora.

Lactic acid bacteria have different properties and may thus provide different health effects when consuming them. There are a large number of lactic acid bacteria, for example *Lactobacillus reuteri* and *Lactobacillus acidophilus*.

Lactobacillus reuteri (L. reuteri)

Species within the genus *Lactobacillus*. The vast majority of BioGaia's patented probiotics are different strains of *Lactobacillus reuteri*, for example, *Lactobacillus reuteri* Protectis.

Lactobacillus reuteri Gastrus

Combination of two strains of *Lactobacillus reuteri*, used in BioGaia's digestive health product for use in connection with *Helicobacter pylori* infection.

Lactobacillus reuteri Prodentis

Combination of two strains of *Lactobacillus reuteri*, used in BioGaia's oral health products.

Lactobacillus reuteri Protectis

Strain of *Lactobacillus reuteri*, used in BioGaia's digestive health products for children and adults.

Partner

The companies distributing and selling BioGaia's products.

Probiotics

Live microorganisms that, when administered in adequate amounts, confer a health benefit on the host.

Resistant bacteria

Bacteria that have become resistant to one or several antibiotics.





Experts at bacteria

BioGaia is an innovative Swedish health care company and has been a world-leader in dietary supplements with probiotics for more than 25 years. The products are based mainly on different strains of *Lactobacillus reuteri* and are sold by local distribution partners in around 90 countries.

The annual report will be distributed only to those who have ordered it.
Printed copies can be ordered by calling BioGaia's head office, +46 8-555 293 00, or via info@biogaia.se.
The annual report is also published on biogaiaannualreport.com.

