# BioGaia<sub>®</sub>

ANNUAL REPORT 2012

Record number of clinical studies published	14
BioGaia's products now in 80 countries	18
Major partnership agreement with Nestlé	28



HIGHLIGHTS OF 2012

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# 2012

BioGaia 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.

**FINANCIAL TARGETS** 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. The financial target is a sustainable operating margin (operating profit in relation to sales) of at least 30 per cent with continued strong growth and increased investments in research, product development and brand building. BioGaia's previous policy was to pay a shareholder dividend equal to 30 per cent of profit after tax. At the beginning of 2013, the Board decided to change the policy so that shareholder dividends amount to 40 per cent of profit after tax in the future.

**VISION** BioGaia's vision is to improve the health of people around the world by offering first class probiotic products.

**STRATEGY** BioGaia's strategy is based on three main pillars:

- 1 Performance of high quality clinical studies.
- 2 Development of innovative new products and packaging solutions.
- 3 Powerful support to the company's partners, among other things through a presence at international medical conferences and seminars, training of sales staff and online marketing.

**CLINICAL STUDIES** The results of 19 studies on *Lactobacillus reuteri* were published in 2012 (eight gastrointestinal and immune studies in children, four gastrointestinal and immune studies in adults and seven oral health studies). Below are some of the most significant results:

- Study confirming that *Lactobacillus reuteri* Protectis reduces colic in infants.
- Two studies on premature infants showing effects on intestinal inflammation.
- Results of study showing that Lactobacillus reuteri Protectis reduces diarrhoea in children.
- Study showing that Lactobacillus reuteri Prodentis reduces pocket depth in patients with periodontitis.

#### NEW AGREEMENTS FOR LACTOBACILLUS REUTERI PROTECTIS WITH

- Nestlé regarding the acquisition of the rigths to use Lactobacillus reuteri
  Protectis in infant nutrition products during the remaining term of the
  patent, which resulted in license revenue of SEK 356 million in 2012.
- Gerber (subsidiary of Nestlé) for the sale of drops in the USA.
   Nestlé for the sale of drops in Mexico.
- United Laboratories Group for the sale of drops and digestive health tablets in Taiwan.
- Ferozon for the sale of drops and digestive health tablets in Pakistan.

#### NEW AGREEMENTS FOR LACTOBACILLUS REUTERI PRODENTIS WITH

- Next Force in the Czech Republic.
- Ivodent in South Africa.
- Oral Company in the Benelux countries.
- Pharmaforte in Singapore.
- Dexcel in Israel.

#### LAUNCH OF

- Drops in Bolivia, Colombia, Hong Kong, Indonesia and Taiwan.
- Gut health tablets with lemon flavour in Bolivia and Taiwan.
- Gut health tablets with strawberry flavour in Romania and the USA.
- Oral rehydration solution in Greece.
- Oral health tablets in the Benelux countries, Canada, Croatia, Poland, Serbia, Slovenia and the Czech Republic.
- Infant formula with *Lactobacillus reuteri* Protectis in Bangladesh, Burma, Cambodia, the Caribbean, Laos, Puerto Rico, Singapore, Sri Lanka and the USA.

2012	2011	2010	2009	2008
645.2	315.0	236.0	203.5	145.2
237.6	215.4	165.6	147.7	106.3
406.6	97.7	68.6	53.8	36.9
428.1	103.2	56.3	47.7	25.8
442.2	108.9	69.7	53.1	24.0
329.9	79.5	47.2	36.0	36.1
105	33	16	40	36
66	33	24	23	18
88	82	82	90	86
70	61	45	43	39
	237.6 406.6 428.1 442.2 329.9 105 66	237.6 215.4 406.6 97.7 428.1 103.2 442.2 108.9 329.9 79.5 105 33 66 33	237.6         215.4         165.6           406.6         97.7         68.6           428.1         103.2         56.3           442.2         108.9         69.7           329.9         79.5         47.2           105         33         16           66         33         24           88         82         82	237.6         215.4         165.6         147.7           406.6         97.7         68.6         53.8           428.1         103.2         56.3         47.7           442.2         108.9         69.7         53.1           329.9         79.5         47.2         36.0           105         33         16         40           66         33         24         23           88         82         82         90





#### BioGaia in 30 seconds

1990 Peter Rothschild and Jan Annwall acquire the rights for the probiotic use of Lactobacillus reuteri and found the company BioGaia Biologics. The duo also acquires the laboratory operations in Raleigh, USA. The focus is on reducing the need for antibiotics in animal feed. An interest is awakened in human health and so-called functional foods. The first brand for BioGaia's products is BRA milk and fermented milk.

 $1994^{\,\,\text{ICA}}$  acquires the BRA trademark and concept.

1996 Introduction on IM, Innovationsmarknaden.

1997 The fermentation facility Multi Ferm in Lund is acquired and becomes BioGaia Fermentation AB. The aim is to gain greater knowledge about the fermentation process and how to extend the shelf life of the bacterial cultures.

 $1998\,{}^{\rm Introduction}$  on the O list, which is today OMX NASDAQ.

2001 Price pressure and daunting regulatory hurdles lead to a decision to abandon activities in the animal health area. The main focus is now on probiotic dietary supplements for humans.

2002 BioGaia Fermentation AB is sold at a profit. The Parent Company has acquired the necessary knowledge and can retain parts of the staff in a production and development unit that becomes the current BioGaia Lund. TwoPac (50 per cent-owned) in Eslöv is formed together with a couple of entrepreneurs to develop a concept for straws containing Lactobacillus reuteri.

 $2006 ^{\, \text{The first year that the company makes}}_{\, \text{a profit.}}$ 

2008 CapAble is founded and is responsible for development of caps containing

 $2009^{\,\text{Net sales exceed SEK 200 million.}}$ 

2010 BioGaia celebrates 20 years as a successful probiotics company.

2011 Net sales of over SEK 300 million.
BioGaia's 50 per cent-owned subsidiary
TwoPac builds a new production facility in Eslöv to meet
demand for increased volumes.

2012 BioGaia extends and deepens its collaboration with Nestlé. TwoPac's new production facility is completed.

MESSAGE FROM THE PRESIDENT MESSAGE FROM THE PRESIDENT

very year is special, but I think perhaps 2012 will go down in history as an exceptionally special year. There are several reasons. We signed a series of major agreements with our customer Nestlé in February that are affecting us in several ways, and we have also changed or are in the process of changing our distribution partners in a number of markets. In addition, the EU introduced new rules for health claims at the same time that economic development in the

EU was the weakest we have seen in a very long time. But in spite of these challenges, I would say that 2012 was a fantastic year.

LET ME START WITH THE NESTLÉ DEAL. To provide some background, in 2008 we signed a long-term contract with Nestlé that gave them virtually global rights to use Lactobacillus reuteri Protectis in their infant formula. To gain better control over this business, Nestlé wished to buy a perpetual license covering the entire term of the patent. For this they paid a sum of SEK 356 million in February and will pay an additional EUR 10.8 million on the achievement of certain milestones during the period until 2017. From our side, one condition for the contract was to formalise a number of business initiatives and development projects that we have already started with Nestlé. The content of these agreements will be announced

non-recurring revenue our profit is "only" SEK 72 million. But this doesn't tell the whole story either, since part of the revenue from Nestlé is attributable to 2012. Our own calculations show that the amount should be around SEK 40 million, which gives us a total operating profit of around SEK 112 million and an improvement of around 9 per cent compared to 2011.

IN 2012 WE WORKED intensively to change our distribution partners in a number of markets. Since this involves markets where we sell under the BioGaia brand, it has gone relatively smoothly, although it did affect growth in the past year. We have not lost sales, but our growth fell short of the level we are used to. Finished consumer products have risen by around 12 per cent including foreign exchange effects, which is significantly weaker than our five-year average of around 30 per cent. The change of partners is naturally motivated by our belief that this will accelerate growth. As an example, we have fairly high expectations for what Nestlé can do for our drops in the US market.

THE NEW EFSA RULES have been given a lot of media coverage, but have not affected us to any great extent since our products are marketed to doctors and other healthcare professionals and we have no need to attract consumers with "forbidden" health claims. Our foremost marketing tool is our clinical studies and 2012 was dependent on success in every one of these.

economic situation in Europe would have positive consequences are also continuing to build our brand. Sales of products under for us, but we do not depend on a few individual countries and are able to spread our risks across the 80 or so markets where we are active.

IN THE PAST YEAR, TWOPAC, our 50 per cent-owned manufacturing company in Eslöv, Sweden, built a new state-of-the-art factory that will enable us to take on whole new challenges with regard to demands on production quality. It is also satisfying to see that TwoPac is highly profitable, in spite of the considerable energy and resources devoted to the construction project.

The rising sales trend for our oral health products in Japan has continued and we are convinced that the business model we use there, based on sales through dentists, can be exported to other countries, which we also plan to test in the coming year. In time we are convinced that these products will account for a significant share of our sales.

Aside from our ongoing activities in the oral health area, in PETER ROTHSCHILD, 2013 we will focus on the BRIC countries and the US market. We FOUNDER AND PRESIDENT, BIOGAIA

the BioGaia brand are showing favourable development and in 2012, 45 per cent of the finished products were sold under our own brand. The target for 2014 is 60 per cent.

IN 2012 WE STRENGTHENED our management by recruiting a new Vice President Development and Regulatory Affairs, a new Sales Director and a Marketing Director, all highly qualified and with experience from the pharmaceutical industry. We have also reinforced the sales department with new talents. All in all, our organisation is now more competitive and I am certain that we have the right team team to develop our existing products and create new product solutions that enable us to maintain high sales growth in the future.



# **ProBiotics**

Probiotics are live microorganisms that provide health benefits. The effects of probiotics are best documented with regard to diarrhoea and other gastrointestinal disorders, but continuous advances are being made in this research. Our intestinal microflora is an extremely complex system and the central role of bacteria in maintaining physical well-being is being mapped out in increasing detail. BioGaia focuses on well documented dietary supplements, such as tablets and drops, that are recommended by healthcare professionals and sold to consumers via drug stores and pharmacies.

BIOGAIA ANNUA

# Healthy microorganisms

Probiotic means "for life", in contrast to antibiotic which means "against life". WHO/FAO (2001) defines probiotics as "live microorganisms which when administered in adequate amounts confer a health benefit on the host". Two important criteria for qualifying as probiotic are that the microorganisms are alive and have proven health effects in clinical studies. To be called probiotic, the product must also contain the same probiotic strain (or strains) and the same dose that was used in the studies. The most common types of microorganisms used in probiotics are lactic acid bacteria, such as Lactobacillus reuteri, and bifidobacteria.

**IGESTIVE HEALTH.** *Lactobacillus reuteri* is well researched in the digestive health area. A large number of clinical studies have shown positive effects on conditions like antibiotic-associated diarrhoea, acute diarrhoea and Helicobacter pylori infection, as well as colic and digestive problems in infants.

**ROTAVIRUS IS ONE OF** the most prevalent causes of acute diarrhoea in small children worldwide. By the age of five, it is estimated that all children, regardless of their homeland, have had one rotavirus infection. In the USA rotavirus is behind 45 per cent of all cases of acute diarrhoea in children. Antibiotic-associated diarrhoea (AAD), i.e. diarrhoea as a side effect of antibiotic therapy, affects up to 25 per cent of all patients treated with antibiotics. The risk of AAD is increased by factors such as the intake of several different types of antibiotics over a long period of time, gastrointestinal surgery and long-term hospital stays.

THE RATE OF CONSTIPATION among children varies between 7 per cent and 30 per cent depending on the country. A full 40 per cent develop symptoms already during the first year of life and these often persist for a long time. Many children with constipation have continued problems as teens and adults.

HELICOBACTER PYLORI infection is one of the world's most widespread. At least half of the earth's population is infected, but its incidence varies from over 80 per cent of all adults in developing regions such as Asia and Latin America to between 20 per cent and 50 per cent in the industrialised world. However, the majority of infected individuals are unaware of this fact and only around 20 per cent have symptoms.

**COLIC IS A CONDITION** that affects up to 26 per cent of

crying, mainly in the evening, for at least three hours per day, at least three days per week and for at least three weeks in an otherwise healthy infant.

**REGURGITATION** is defined as the passage of refluxed gastric content into the throat, while vomiting is defined as expulsion of refluxed gastric content from the mouth. The frequency of regurgitation varies with age, but infants up to the age of one month are more frequently affected.

**ORAL HEALTH** is a relatively new area for probiotics. Lactobacillus reuteri Prodentis is currently the only clinically documented probiotic with positive results from studies on conditions like bleeding and inflammation of the gums (gingivitis) and periodontal disease.

**GINGIVITIS** (inflammation of the gums) is very common and is found in more than half of the adult population. Gingivitis is caused by dental plaque and the first signs of the illness are irritated, swollen and bleeding gums. In one third of all adults the inflammation has advanced to periodontitis, which in many cases could lead to loss of teeth. ■



all infants in the West. Colic is defined as recurrent

BIOGAIA ANNUAL REPORT 2012

PROBIOTICS

#### Focus on

# finished products

Finished products currently account for around 80 per cent of BioGaia's sales, and this is also where the company's focus lies. The main market is therefore defined as "probiotic dietary supplements that are sold in pharmacies and similar retail outlets". The finished products are sold in more than 60 countries and BioGaia is represented in a total of around 80 countries.

he biggest product is BioGaia ProTectis drops, which are sold in over 50 countries. The drops previously required refrigeration, but in 2011 BioGaia launched drops that can be stored at room temperature. These new drops have been launched in Sweden, the USA and a couple of other markets and have been well received. In the past year drops with vitamin D were also launched in a few countries such as Italy, Sweden and Poland.

BioGaia ProTectis digestive health tablets are sold in close to 50 countries. In 2011 they were launched in a strawberry flavour (the original flavour is lemon) and these are currently sold in close to ten markets.

Other key consumer products are BioGaia Pro-Tectis oral rehydration solution, which is available in both neutral and orange flavours, and ProDentis oral health tablets. In 2013 the company will launch BioGaia Gastrus, a digestive health tablet for control of *Helicobacter pylori* infection.

BIOGAIA HAS HAD its own consumer brand since 2006 and the strategy is to successively increase sales under this brand, which in 2012 accounted for 45 per cent of finished product sales. Including products with a combination of the partner's own and BioGaia's brand, so-called co-branding, the figure is 51 per cent. The goal for 2014 is to achieve 60 per cent of sales under the BioGaia brand.

In 2012, sales growth for finished products was roughly equal in markets where the BioGaia brand

is used and those where the partner's own brand is used.

**COMPONENT PRODUCTS** are bacterial cultures of *Lactobacillus reuteri* Protectis that are used as ingredients in infant formula and infant cereal products, yoghurt and other dairy products. Here, Nestlé is the largest customer. ■



Children are BioGaia's largest and most important segment. Drops, oral rehydration solution and cultures that are used in infant formula together account for around 70 per cent of total sales.

# 286 patents

Issues related to patents and trademarks are of central importance for BioGaia. This is an area known as IPR (intellectual property rights), which includes patents, brands and trademarks, copyrights and other rights. An approved patent is normally valid for around 20 years.

n BioGaia's business model, the company functions as a hub in the network of researchers that together with BioGaia contribute to developing knowledge about and use of the company's probiotic strains and technologies.

The advantages of working with independent researchers is that this leads to a more creative research climate and enables BioGaia to form ties with the top experts in each area.

The one possible drawback is the time-consuming and continuous work surrounding administration of patents and contracts with different researchers.

There are no global patents. BioGaia applies for and holds patents in the countries where it is commercially relevant to do so and where there are a functioning regulatory framework for patents.

**APPLYING FOR PATENTS** is a cumbersome process that requires extensive documentation. BioGaia handles the fundamental aspects of the process and then uses local representatives for contacts with each country's

patent authorities. Thanks to BioGaia's forefront position when it comes to new knowledge in the field of probiotics, it has been possible to patent specific new strains and indications/areas of use.

**IN 2011 A DECISION** was made to add product names to the various products. In pace with the growing number of products being launched, there is a need to more effectively differentiate between them while at the same time strengthening the BioGaia brand. Previously, all of the products were called BioGaia in combination with the formulation, such as BioGaia probiotic chewable tablets. In the new system, all products based on the Lactobacillus reuteri Protectis strain have been given the product name ProTectis. As a result, the digestive health tablets are now called BioGaia ProTectis followed by "tablets" to clarify that this refers to tablets and not drops, which instead have the addition "drops". Products based on Lactobacillus reuteri Prodentis are called BioGaia ProDentis, followed by "tablets" or "drops." ■

57
INTERNET DOMAINS

REGISTERED TRADEMARKS IN

57
COUNTRIES

286
GRANTED PATENTS I
27 PATENT FAMILIES



## BioGaia a world-leader with unique products



2000 Launch of the world's first probiotic chewable tablet. 2001

The first probiotic infant formula is introduced

**2002**Launch of the first probiotic straw.



Launch of the world's first probiotic drops for infants.



Launch of the world's first probiotic oral health products for adults.



Over 50 studies performed on more than 4,000 individuals. Global agreement with Nestlé Nutrition for infant formula.



Launch of the first probiotic oral rehydration solution (ORS) containing zinc.



Three billion doses sold globally. BioGaia's products are sold in more than 60 countries. 2011

Launch of oral health tablets, drops with vitamin D and digestive health tablets with strawberry flavour. Drops that can be stored at room temperature are also launched.

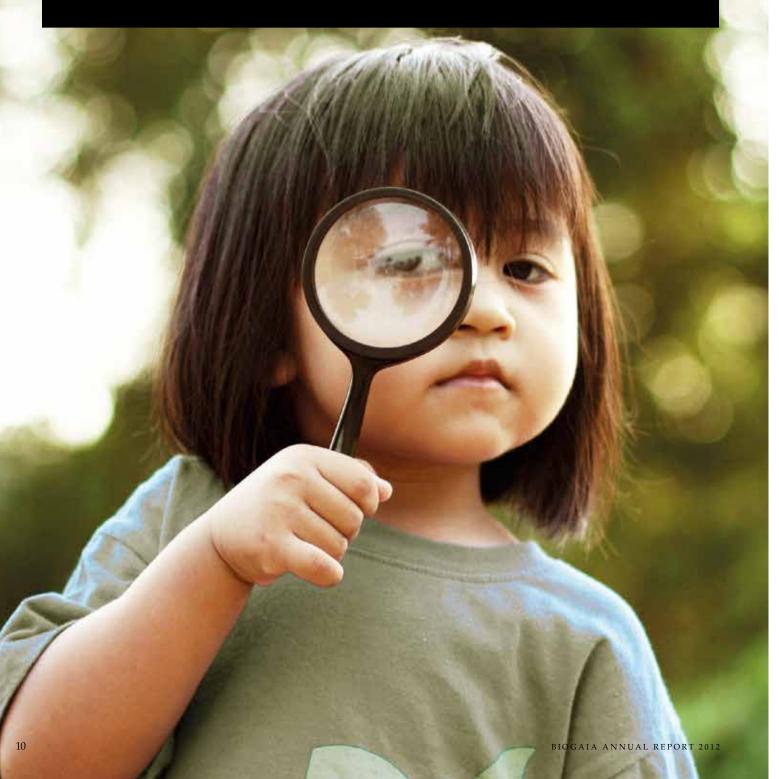


2012
Publication of 19 clinical studies with *Lactobacillus* reuteri. more than in any

previous year.

# Research

As a research-driven probiotics company, BioGaia is at the leading edge when it comes to scientifically-based research and unique packaging solutions. In addition to in-house experts, the company has built up a global network of leading independent researchers and specialists in this area. Some studies are initiated by BioGaia itself, but many are initiated and conducted by one of BioGaia's partners. Furthermore, a number of studies are initiated and conducted entirely independently from BioGaia. A total of 30 clinical and preclinical studies on BioGaia's strains of Lactobacillus reuteri were published in 2012.



# Sights set on the unexplored

Research is one of BioGaia's core areas. For the past few years, Senior Vice President Research Eamonn Connolly and his staff work according to a four-stage model.

THE FIRST INVOLVES the discovery of a health effect in a clinical study.

TO CONFIRM these results it is desirable to then reproduce the first study, which is stage two in the model. The goal is for two or three independent studies of high quality and with the same protocol to be published in well reputed scientific journals. Preferably, the studies should also be performed at different clinics. As an example Eamonn mentions colic, where there are now three studies showing that crying time in the infants with colic is reduced with supplementation of *Lactobacillus reuteri* Protectis.

"Although there are additional studies underway in this area, we at BioGaia are satisfied as we have proven the efficacy of our probiotic on infantile colic.

3 "INSTEAD, OUR NEXT TASK IS to explain how it works, the modes of action behind the effect," according to Eamonn.

Here, BioGaia collaborates with some of the world's foremost preclinical researchers in the field of probiotics. Topics currently being studied include

the connection between gut motility and pain in the gastrointestinal tract.

Another example is preventative treatment of diarrhoea. In this area there will soon be three independent studies showing the same effect, that patients who were supplemented with *Lactobacillus reuteri* Protectis had fewer episodes of diarrhoea than those who were given a placebo. Two such studies have already been published and a third is in the analysis phase. Several preclinical studies have also been carried out on diarrhoea caused by rotavirus that explain the modes of action of *Lactobacillus reuteri* Protectis on this condition.

THE FOURTH AND FINAL STAGE of the model is to investigate whether it is possible to improve the existing therapy or find new application areas for a therapy. For this is it necessary to find researchers who are specialists in their areas and are able to think along new lines. In combination with the in-house expertise and experience at BioGaia, it is possible to together develop new products or new areas of use for existing products.

"It's a privilege to cooperate with these highly competent researchers in new and unexplored areas," says Eamonn. "And even though it is a challenging and time-consuming process, I have high hopes for the future." ■

"It's a privilege to cooperate with these highly competent researchers in new and unexplored areas,"

EAMONN CONNOLLY, SENIOR VICE PRESIDENT RESEARCH



# We are more than just people

BioGaia works in a young field of research, probiotics, where there is still much to be discovered. In 2012, an article in The Economist shed light on the symbiosis between microorganisms and their human hosts. In the future, this may open new doors to finding cures for chronic diseases.

human being is not simply a biological entity, but also a habitat for a dazzling multitude of organisms. Our bodies are home to hundreds of billions of microbes. They are found in our intestines, in our mouths, on our skin – and everywhere else that our bodies come in contact with the outside world. They are collectively known as the microbiome and in most cases, they are our best friends. They have been reviewed in many studies, some of which have been recently published in leading scientific journals like Nature and Science.

Microbes in the human body are specialised to handle different tasks, but they are able to adapt to their environment. Studies on infants in Malawi and rural Venezuela show that their microbiomes contain more riboflavin-producing organisms than those of infants in North America. They are also better at extracting nutrients from mother's milk because they produce large amounts of an enzyme called glycoside hydrolase that converts carbohydrates in the milk into usable sugars. For human enzymes, carbohydrates of this type are indigestible. Only bacterial enzymes can accomplish this, which is an excellent example of co-evolution.

The latest research shows that when the microbiome is in disarray, these micro-organisms can instead become our worst enemies. Researchers have discovered links between such disruptions and many common maladies, such as obesity, malnutrition, diabetes, cardiovascular disease, diseases of the intestine and autism. It appears that the organisms sometimes get their signals crossed, and that disease is a consequence of this.

One example is *Clostridium difficile*, an intestinal bacterium that multiplies when the gut microflora is disrupted by antibiotic treatment and causes severe diarrhoea. Recently performed treatments show that enemas containing the faeces of healthy individuals, known as "stool transplants", can eliminate this condition. Apparently, the good bacteria from a healthy individual are able to drive out the harmful ones.

Many of the cells that make up our immune system live in the gut wall, where their role is to identify suspicious bacteria. Sometimes things go awry and an immune response is triggered by the wrong signals, as in the case of diabetes type 1 where the immune system attacks insulin-secreting cells. The precise details are not known, but the microorganisms seem to be somehow confusing the immune system so that body cells are damaged.

This is a puzzle for researchers and it is difficult to identify which genes are involved. Many such genes appear to cooperate like in families, but some of the genes may not be found in the human genome. It is possible that certain apparently genetic diseases are not inherited, but instead caused by bacteria. This may mark the emergence of a whole new approach to treatment of diseases that were previously incurable. ■

Source: The Economist, 18-24 augusti 2012

# BioGaia's research network growing stronger

BioGaia collaborates with specialists at around 40 research institutes and clinics in a unique global research network. To maintain a position at the leading edge, it is of the utmost importance to work with and inspire the top researchers in the various indication areas. Vice President Research Eamonn Connolly and his colleagues function as the pivotal link and engine.

AUSTRALIA Royal Children's Hospital & Murdoch Children's Research Institute.

**BELGIUM** Catholic University.

**BULGARIA** University Hospital S:t Marina.

CANADA The Hospital for Sick Children.

McMaster University.

CHILE Pontificia Universidad Católica de Chile.

**CROATIA** University Hospital "Sestre Milosrdnice", Zagreb. Sveti Duh Hospital.

**DENMARK** University of Copenhagen.

**EGYPT** Zagazig University.

FRANCE University Hospital Robert Debré.

INDONESIA Medical Faculty University of Indonesia.

ISRAEL Shaare Zedek Medical Center. Ben-Gurion University. Lily Safra Children's Hospital.

TALY University of Bari, Clinica Pediatrica"B. Trambusti". Regina Margherita Children's Hospital.

MALAYSIA University Kebangsaan.

MEXICO National Insitute of Pediatrics. University Autónoma de Nuevo León.

**PERU** Johns Hopkins School of Public Health and Hygiene Satellite laboratory.

**POLAND** Medical University. Children's Health Memorial Institute.

**SINGAPORE** Singapore Polytechnnic, School of Chemical and Life Sciences.

SLOVAKIA Gastroenterology Hepatology Center Thalion.

**SLOVENIA** University Children's Hospital Ljubljana, University Medical Centre Ljubljana.

SPAIN University Hospital Ramón y Cajal.

**SWEDEN** Uppsala University. Swedish University of Agricultural Sciences. Umeå University. Karolinska Institute, Karolinska University Hospital. University of Örebro. Linköping University. Sahlgrenska University Hospital. Lund University.

**TURKEY** Yeditepe University Dental School.

USA Case Western Reserve University. University of Nebraska. Women's Hopsital of Greensboro. Tulane University. Texas Children's Hospital. University of Texas Medical Center. Michigan State University. Children's Investigational Research Program. University of Miami. Emory University. St Luke's Hospital.



In 2012, the The Economist magazine shed light on the symbiosis between microbes and humans. In the future, it may be possible to find cures for chronic diseases in this field.



# International medical conferences in 2012

In 2012 BioGaia took part in several international medical conferences. Products were displayed and scientific symposia were held at a few of these.

- ISTANBUL, TURKEY IS3P 2012 International Symposium of Probiotics and Prebiotics in Pediatrics
- STOCKHOLM, SWEDEN ESPGHAN 2012
- MOSCOW, RUSSIA Global Congress for Consensus in Pediatrics & Child Health
- VIENNA, AUSTRIA Europerio 7 The European Federation of Periodontology
- SARAWAK, MALAYSIA 14<sup>th</sup> Asia Pacific Congress of Pediatrics (APCP)
- HELSINKI, FINLAND PER/IADR 2012 The International Association for Dental Research's (IADR)/ Pan European Region (PER)
- AMSTERDAM, THE NETHERLANDS
   United European Gastroenterology Week (UEGW)
- TAIPEI, TAIWAN World Congress of Pediatric Gastroenterology, Hepatology and Nutrition (WCPGHAN)

# High quality research

Lactobacillus reuteri is one of the world's most well researched probiotics, especially in young children. To date, 108 clinical studies using BioGaia's human strains of Lactobacillus reuteri have been performed on more than 8,600 individuals of all ages. The results have been published in 71 articles in scientific journals (January 2013).

he majority of clinical studies carried out with BioGaia's products are randomised, double-blind and placebo-controlled, and are thus 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 founded and scientifically-based articles. As a result, BioGaia actively supports publication of the results in well-reputed scientific journals.

one fourth of all studies are initiated by BioGaia itself, to investigate product safety and health benefits in a specific area, and are monitored by BioGaia's research supervisor. However, there is a widespread interest in research on *Lactobacillus reuteri* and another fourth of the studies are initiated and conducted by independent researchers. Aside from requesting the researcher's resume and study protocol and requiring ethical approval (these criteria apply to studies), BioGaia has no insight into or influence over these studies.

Around half of all studies are initiated and conducted by BioGaia's partners. ■

# Preclinical studies

Preclinical studies include in vitro (laboratory) studies and animal trials. In 2012, Geoffrey Preidis and his colleagues at Baylor College of Medicine in Houston, Texas, USA, published two articles showing that *Lactobacillus reuteri* affects the composition of the gut microflora and has a novel mechanism for the effect on acute diarrhoea. Another research team showed a reduced incidence of necrotising enterocolitis in an animal trial for premature infants (Liu et al.).

#### Effect already after one day

PROBIOTICS STIMULATE enterocyte migration and microbial diversity in the gastrointestinal tract of newborn mice. The study showed that already 24 hours after a single administration of the probiotic, the composition of the gut microbiata had improved. Rapid effects were also seen in the cells of the intestinal lining. The results suggest novel mechanisms for different probiotic strain-specific effects, for example in protection from gut pathogens. The strains tested in the study were Lactobacillus reuteri DSM 17938 and Lactobacillus reuteri ATCC PTA 6475. ■

# Response to probiotics determined by nutritional status

THE RESPONSE TO PROBIOTICS is determined by the nutritional status of the rotavirus-infected mice. According to a new study, two strains of *Lactobacillus reuteri* appear to strengthen the intestinal anatomical structure. The formation of virus-specific antibodies also contributes to diarrhoea resolution. Furthermore, the data suggests that the nutritional status of the mouse influences its response to both beneficial bacteria and pathogens. *Lactobacillus reuteri* also restored intestinal microbiata diversity after rotavirus infection. ■

# Probiotic strain inhibits intestinal tissue death

LACTOBACILLUS REUTERI DSM 17938 reduced both the incidence and severity of gut inflammation and tissue death in a mouse model for necrotising enterocolitis (NEC). This strain also had a positive effect on the milder form of gut inflammation caused by formula feeding (based on cow's milk). The mechanisms involved are explained by the bacterial strain's regulation of gene expression in the intestinal cells and production of immune-modulating substances. ■



In 2012, the results of several interesting studies on *Lactobacillus reuteri* Protectis were published in well renowned journals such as Pediatrics in the USA and BMC Pediatrics in the UK. Dr. Rina Agustina's study on Indonesian children was part of her doctoral dissertation and was published in Pediatrics in the autumn of 2012.

**TWO STUDIES ON** premature infants were also published. Mary-Ann Dimaguila in Greensboro, North Carolina, USA, published a retrospective analysis on the rate of NEC in premature infants born with a weight below 1000 grams. Mario Rojas performed a multi-centre study at nine neonatal intensive care units in four cities in Colombia. This is the largest probiotic study to date, although the number of infants included was considerably lower than planned.

A confirmatory study on infants with colic was also published in the autumn of 2012. Read more about this on pages 16−17. ■



#### ii p Pl re et

In 2012, among others, Geoffrey Preidis and his colleagues at Baylor College of Medicine in Houston, USA, published a study showing how strains of *Lactobacillus* reuteri affect the composition of the microflora.

# Reduction of intestinal inflammation in premature infants

**PROPHYLACTIC SUPPLEMENTATION** of *Lactobacillus reuteri* Protectis to premature infants has a positive effect, among other things on necrotising enterocolitis (NEC). NEC is an inflammation that leads to death of intestinal tissue and is the most common gastrointestinal cause of death and illness in premature infants, with a death rate of 20–30 per cent.

The rate of NEC is highest in the smallest neonates, those with a birth weight below 1000 grams. In a retrospective sequential analysis of 311 premature infants with this low birth weight, the incidence of NEC was only 2.5 per cent among the infants who received *Lactobacillus reuteri* Protectis, compared to 15.1 per cent in the untreated infants.



#### World's largest probiotic study

PROBIOTICS HELP premature infants. This was shown by the world's largest probiotic study in premature infants, which was carried out by independent researchers. 751 infants were enrolled in a double-blind, placebo-controlled study whose primary goal was to investigate whether probiotics can reduce the mortality rate among infants and the incidence of infections during hospitalisation. For this, 1,110 infants were needed to participate in the study, which was performed at nine neonatal intensive care units. Unfortunately, the study was terminated early due to a drop in recruitment and funding restrictions from the independent funding institute.

However, the study showed that feeding intolerance in the infants with a birth weight below 1500 grams was reduced by 43 per cent. ■

# Diarrhoea among children reduced with the right probiotic

CHILDREN LIVING in impoverished areas are often undernourished and vulnerable to infection. In Indonesia, where 25 per cent of all deaths among small children are caused by diarrhoea, treatment strategies are needed to increase the children's resistance to disease. In a six-month, double-blind, placebo-controlled study, 494 apparently healthy children between the ages of one and six years were randomly assigned to four groups, of which one received supplements of Lactobacillus reuteri Protectis. For the children in this group, the incidence of diarrhoea was reduced by 32 per cent compared to the placebo. In this case, diarrhoea is defined as two or more loose or liquid stools per day. The supplement was especially effective among children with lower nutritional status (below median height and weight for their age). Another probiotic strain from another company that was also included in the study showed no positive effects on the children. ■



"I give Interlac (BioGaia ProTectis in Indonesia) to infants with colic and it can help to reduce pain among the infants."

Widodo Judarwanto, Paediatrician at Bunda Hospital, Djakarta, Indonesia

"Most of my patients that need supplements, particularly those with eczema and diarrhoea, find that BioGaia's drops help the children to recover more quickly. As a regular dietary supplement, it keeps the intestines in good condition and provides a healthy gut."

VK Pradeepkumar, Paediatric Consultant at Kinder Clinic Pte Ltd, Singapore

"BioGaia is a product to restore balance in the gut microflora and prevent colic. I like BioGaia since it works, and parents appreciate the quality and effectiveness. The effects of the drop normally appear after 6–7 days of use."

V. Velicko, Paediatrician at Odessa Children's Hospital No. 1, Odessa, Ukraine

# Relief for children and families

In 2012 one of the world's leading researchers on probiotics, Hania Szajewska, Professor and Chair of the Department of Paediatrics at the Medical University of Warsaw, Poland, performed a double-blind, placebo-controlled study on 80 infants with colic. Recently home from a conference in Brazil, where she among other things presented the results of the study, she talks about her expectations before undertaking the study.

Hania Szajewska, Professor at the Medical

University of Warsaw.

arlier studies on colic seemed too good to be true. It is always useful to conduct a study that confirms these results – one that is performed by an independent team and with a different setup," says Hania Szajewska. The results of the new study showed that crying time was significantly reduced among the infants supplemented with drops of the probiotic *Lactobacillus reuteri* Protectis compared to those in the placebo group.

For the fist time in a probiotic study on colic, quality of life for the family was also measured. In the study, the parents' perceptions of the change were recorded and the results show that the parents of

children who were supplemented with *Lactobacillus reuteri* Protectis perceived a significantly greater improvement compared to the placebo group.

# Why did you decide to include quality of life for the family in your study?

"We discussed this in our team and agreed that the irritation of the parents and family is often greater than the child's pain, and in view of this we felt it was important to include the family's quality of life in the study. Parents of colicky babies can find themselves in serious and strained situations.

"This is particularly common with the first child,

when the parents find it difficult to distinguish between hunger cries and crying for other reasons. In many functional disorders like this, it is important to measure the parent's quality of life. Frustration in the family should always be addressed."

# Are there other parameters that would be interesting to study in connection with colic?

"From a clinical perspective our study covers the most important parameters, but it would be interesting to look at how probiotics that are administered early in life function in a longer time perspective. This is very difficult to study since there are so many factors that play in."

# Given the overall picture from your own and earlier studies, would you recommend that paediatricians give *Lactobacillus reuteri* Protectis to infants with colic?

"Based on the data we have today, it really appears that *Lactobacillus reuteri* Protectis can help both colicky babies and their families."

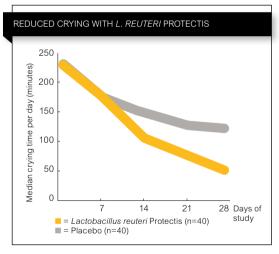
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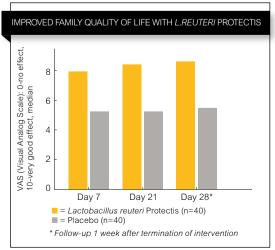
Colic is a condition that affects up to 26 per cent of all infants in the West.

# Earlier studies on colic

For a period of 28 days, 83 colicky infants aged 11 to 80 days were given supplements of the probiotic *Lactobacillus reuteri* Protectis or the pharmaceutical simethicone. After one week, crying time for the children who received *Lactobacillus reuteri* Protectis was reduced by 51 minutes per day. At the end of the study, crying time was reduced by 74 per cent in the probiotic group and by 26 per cent in the simethicone group.

A double-blind, placebo-controlled study on 50 infants with colic. The results showed that after only one week of supplementation with *Lactobacillus reuteri* Protectis, the reduction in crying time was 74 per cent among the infants receiving *Lactobacillus reuteri* Protectis, compared to 38 per cent for those in the placebo group. At the end of the study, which lasted a total of 21 days, crying time among the infants receiving *Lactobacillus reuteri* Protectis was reduced by 84 per cent. ■





# Market BioGaia's products are sold in some 80 countries worldwide. Europe is the largest market and

accounts for around 70 per cent of sales. Italy is still the leader in terms of sales, followed by Finland, Japan and South Africa. In Italy, Finland and South Africa, the products are sold under the partners' brands, since

sales of these products were started before BioGaia established its own brand. Of the partners added

after 2006, most use the BioGaia brand or a combination of their own and BioGaia's brand. Today, BioGaia-branded

products are sold in close to 50 countries. The target for 2014 is to achieve 60 per cent of finished

product sales under the BioGaia brand. The figure in 2012 was 45 per cent.

# EUROPE

In Europe, BioGaia's largest market, acceptance and understanding of probiotics are relatively high 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 markets where probiotics are regularly recommended and used.



The decrease in sales in Europe for 2012 is due to lower sales of component products following the sale of a perpetual license to Nestlé.

\*Excluding license revenue from Nestlé

## Sweden

**Partners:** Semper (drops, strawberry tablets, oral rehydration solution) and Medhouse (tablets). Population: 9.5 million.

Births per year: 85,500.

**Maturity level:** Probiotics relatively well-known among paediatricians and the public.

**Products:** Digestive health drops (2004), Vitamin D drops (2011), Digestive health tablets (2011), Oral rehydration solution + (2009), BioGaia ProTectis tablets (2012).

IN SWEDEN PROBIOTICS are relatively well known among paediatricians but are still unknown to many other categories of doctors. Among the public, more and more people are aware of the health benefits of probiotics. The best known products are yoghurt and beverages supplemented with probiotics. There are some ten probiotic dietary supplements in the form of chewable tablets, capsules and drops on the market.

BioGaia's drops are sold by Semper under the name Magdroppar. The drops are well established and sales are increasing by the year. Over 140,000 packages were sold in 2012, which is equal to around 1.7 bottles per child born. Since the oral rehydration solution was launched three years ago, sales of this product have risen steadily. Today it is the only oral

rehydration solution on the market for children under the age of three years.

In 2012 BioGaia changed its partner for the digestive health tablets. The new partner Medhouse relaunched the tablets in October under BioGaia's own brand. They are currently sold by the Medstop and Vårdapoteket pharmacy chains, the natural health chains Life and Hälsokraft and at www.apotea.se. In early 2013 the oral health tablets will be relaunched by BioGaia under the BioGaia ProDentis brand. The product will be available for sale at selected dental clinics and at www.apotea.se. ■



# Spain

Partners: Casen Fleet, Sunstar and Nestlé.

**Population:** 46.2 million. **Births per year:** 508,200.

**Market maturity:** Probiotics relatively unknown among the public but starting to become established among paediatricians.

**Products:** Reuteri drops (end of 2011), CasenBiotic tablets (2007), CasenBiotic sachets (2009), Bio Oral Suero ORS beverage (2004), Bio Oral Suero ORS Baby sachets (2009), GUM PerioBalance (2007), Nestlé infant formula (2010).

**ALTHOUGH PROBIOTICS** are still relatively unknown among the public in Spain, interest and knowledge are rising and the market grew by more than 15 per cent in 2012. Casen Fleet markets its products primarily to doctors and has good relations above all with paediatricians and gastroenterologists. They also collaborate with medical associations and take part in local conferences and similar scientific events. Pharmacists are another important target group. The partnership with BioGaia started back in 2004 with the launch of an oral rehydration solution with a straw containing Lactobacillus reuteri Protectis. The portfolio was then expanded to include CasenBiotic tablets and sachets (single-portion bags with probiotic culture), also they containing Lactobacillus reuteri Protectis. In 2011 Casen Fleet also incorporated BioGaia's drops, which were previously sold by another distributor. There are many advantages to gathering all of the products with a single partner and sales of the drops are already on the rise again after a falling trend in 2010. In 2012 sales of the drops were up by close to 10 per cent. At the end of the year Casen launched drops that can be stored at room temperature and the company hopes for continued strong sales growth in 2013.

Overall, BioGaia's products have the number three position with a share of around 16 per cent of the probiotics market.

# Portugal

Partners: Casen Fleet and Nestlé

**Population:** 10.6 million. **Births per year:** 106,000.

**Market maturity:** Probiotics relatively unknown among the public but starting to become established among paediatricians.

**Products:** BioGaia ProTectis drops (2013), Bio Oral Suero ORS beverage (2009), CasenBiotic sachets (2009), Nestlé infant formula (2010).

PREVIOUSLY, CASEN FLEET and another distributor were BioGaia's partners in Portugal. This company sold the drops and Casen Fleet sold the sachets (single-portion bags containing probiotic culture) and oral rehydration solution with BioGaia's straw. In 2012 the collaboration with the other distributor was terminated and Casen

Fleet will take over and relaunch the drops in 2013. Spanish Casen Fleet is well established among healthcare professionals in both Spain and Portugal and it is hoped that synergy effects can be realised between the countries.

The probiotics market in Portugal shrank by close to 8 per cent in 2012. Virtually all of the ten or so products saw a drop in sales except for CasenBiotic, which grew by more than 35 per cent over the year before. However, CasenBiotic is still a very small product in a market that is dominated by UL-250 (the probiotic *Saccharomyces boulardii*). The drops are the second largest product, with a market share of around 10 per cent, which gives Casen Fleet good potential to improve its position in the Portuguese market. ■

# United Kingdom

Partner: Under BioGaia's own management.

Population: 62.6 million.
Births per year: 813,800.

 $\textbf{Market maturity:} \ \textbf{Probiotics like yoghurt well-known}$ 

among the public.

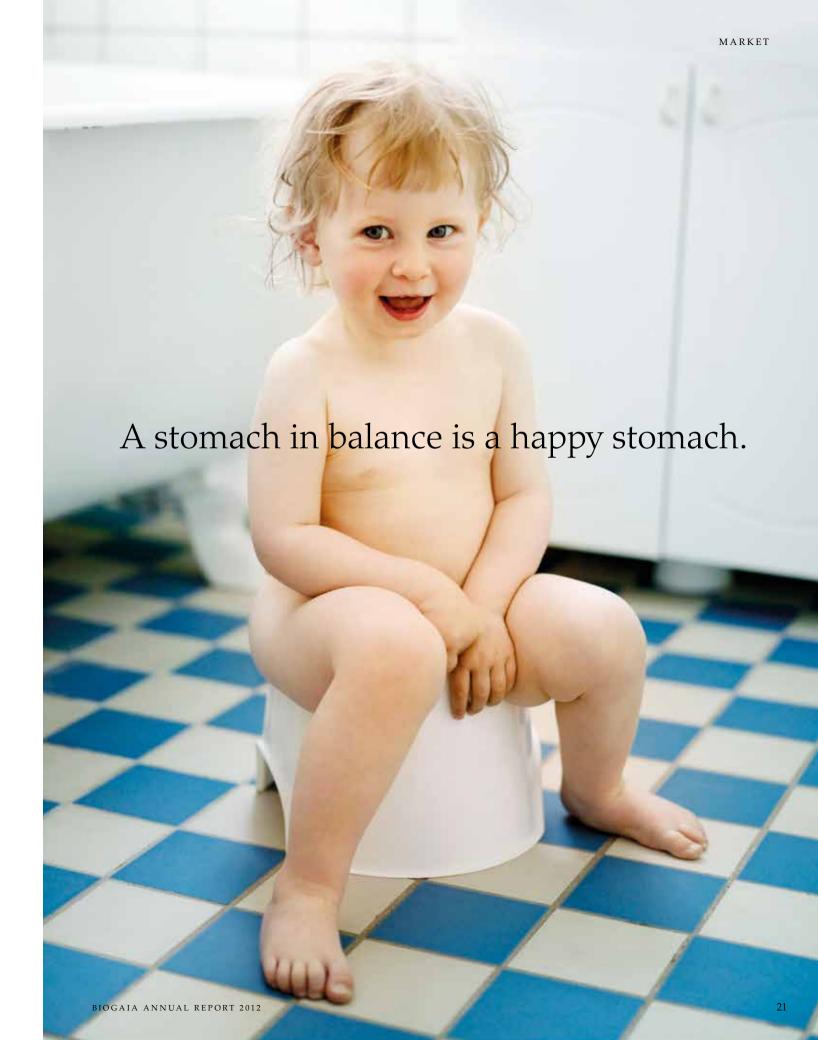
**Products:** BioGaia ProTectis drops and tablets (2012).

IN THE UK BioGaia has decided to sell its products under its own management for the time being. The drops and tablets were launched on a small scale in April 2012, mainly via hospital pharmacies and patient care wards at children's hospitals in Sheffield and Manchester. The products are also sold via BioGaia's own website biogaia.co.uk.

Probiotics in tablet or drop form are not customary in the UK. If you visit a pharmacy, there are a handful of probiotic products. For food supplemented with probiotics, the situation is different and yoghurts like Activia are well known among the public.

Although sales are still modest, they have risen steadily since the launch and it is hoped that this trend will continue in 2013. In order to influence healthcare professionals, BioGaia is collaborating with opinion leaders. In addition, the first clinical study in the UK recently commenced. In 2013 BioGaia is also starting a process to establish a new sales channel through dispensing doctors (family doctors in primary care who also dispense pharmaceuticals). The plan also includes participation in trade shows for midwives and doctors who make house calls.

The competitor product Infacol is covered by the National Health Service (NHS), and to a large extent has therefore been the only one recommended. Although it is generally known that this product is not particularly effective, doctors, nurses and midwives have clear guidelines from the NHS to only recommend products that are covered by the system. After having studied clinical data for *Lactobacillus reuteri* Protectis, however, healthcare professionals that BioGaia has been in contact with can often consider recommending the drops. ■





## Croatia

Partner: Ewopharma. **Population:** 4.4 million. Births per year: 44,000.

Market maturity: Probiotics known both among the public and doctors.

**Products:** ProTectis drops and tablets (2010),

BioGaia ProDentis (2012).

**EWOPHARMA LAUNCHED** the tablets and drops on the Croatian market at the beginning of 2010. At that time the market was dominated by two main competitors, Sandoz with Linex and JGL with Prolife and Normia. Since then the Croatian market has grown dramatically and at present there are more than 33

probiotic products available, including BioGaia ProDentis which was launched in May 2012. In December 2012 Ewopharma reached a market share of 14 per cent.

The main competitors use major media campaigns that communicate directly with consumers. Ewopharma has decided to focus its resources on doctors and pharmacists, and in less than three years has succeeded in securing a strong position in this target group. They have continued to expand and in 2012 showed growth of over 50 per cent. To maintain this growth in 2013 they are launching BioGaia's oral rehydration solution and will begin marketing directly to consumers. ■

## Serbia

Partner: Ewopharma. Population: 7.3 million. Births per year: 65,700

Market maturity: Probiotics relatively unknown among the public but relatively well-known among paediatricians and doctors.

Products: ProTectis drops and tablets (2010),

BioGaia ProDentis (2012).

WHEN EWOPHARMA established a subsidiary in Serbia in 2010, they also launched BioGaia's drops and tablets here. The competitive situation is the same as in the neighbouring countries, with around 35 probiotic products. In the child segment, the drops are now the preferred choice for colic and are ranked as the number two product in the entire segment. Ewopharma cooperates with midwives and the local association for nurses at children's health clinics, among others.

Competition in the tablet market is fierce. There are many products and the marketing is of varying quality. In addition, the laws regulating dietary supplements are unclear since Serbia is not part of the EU.

BioGaia is the fourth largest brand on the market, with a market share of 14 per cent.

Since the launch of BioGaia ProDentis early last autumn, reactions from dentists have been positive. They appreciate the availability of a new, natural product that is easy for patients to use, but, as in most countries, the market for probiotics for oral health is immature and will take time to build up. ■

### Slovenia

Partner: Ewopharma. Population: 2.1 million. Births per year: 23,100.

Market maturity: Probiotics well known among

both the public and doctors.

Products: ProTectis drops and tablets (2008),

BioGaia ProDentis (2012).

**IN SLOVENIA** there are more than 30 competing brands. Despite this, in just four years BioGaia has succeeded in climbing to the number three position in the drops market with a market share of around 10 per cent. The most important indications for children are colic, antibiotic-associated diarrhoea and use of the drops to strengthen the immune defence. Today, more than 1.5 bottles of drops are sold for each child born.

As in the other countries, Ewopharma focuses its resources on healthcare professionals, mainly paediatricians, gastroenterologists and pharmacy staff.

BioGaia ProDentis was launched in the spring of 2012 and the oral rehydration solution is planned to launch in 2013. ■



is Marketing and Sales Manager at Ewopharma in Croatia

#### Successful marketing strategy

Ewopharma Croatia increased its sales by over 50 per cent this year and Ewopharma in Slovenia and Serbia also grew dramatically. What are the key success factors?

"First of all, we saw that we couldn't spend our limited resources on advertising in the mass media. So we decided to treat BioGaia's products as prescription drugs and therefore focus our resources on developing relationships with opinion leaders among paediatricians and gastroenterologists," says Marketing and Sales Manager Jasna Mijalić.

Segmentation and a focus on healthcare professionals with the greatest potential in term of both volume and patient dialogue is another success factor.

"And thirdly, we have grown dramatically by positioning our products based on indications, since we want to avoid being seen as just another probiotic by healthcare personnel. For example, our largest competitor is marketed for a wide range of indications but mostly acute and antibioticassociated diarrhoea, and they have been on the market for many years. We decided to instead link a product to a specific indication and thereby differentiate BioGaia from other probiotics."

#### Croatia, Slovenia and Serbia are fairly small countries and you cooperate with each other. In what ways and what are the advantages of this strategy?

"We have no language barriers and can arrange activities across national borders. One example this year is that we held BioGaia Academy CRO - SLO. The idea is for this to be a recurring event every other year and to also include Serbia next time?

Joint regional meetings at least once a year make it possible to share best practices and learn from each other. but the marketing management also meets in other ways.

"We have management meetings where we discuss plans and strategies for all three markets. The advantages of this cooperation are many. It promotes our development since we learn from each other, and in many cases we save both time and resources. The meetings also help us when we review and validate our plans and strategies."

#### In which indication areas do you see the greatest potential for future growth?

"For diarrhoea, both acute and as a side effect of antibiotics. We will meet the needs for patients with acute diarrhoea with BioGaia's oral rehydration solution and for antibiotic-associated diarrhoea by improving our focus on BioGaia's digestive nealth tablets." ■

MARKET

## **ASIA**

Asia offers major potential for BioGaia's products, since this continent is densely populated. The understanding of what probiotics are

varies widely between countries and, as a result, so does demand. In the small and prosperous country of Singapore, one package of ProTectis drops is sold for every second child that is born. Its heavily populated and relatively poor neighbour to the south, Indonesia, is characterised by a low level of knowledge among the public but enormous opportunities.



The decrease in Asia is due to lower sales of component products, which is partly explained by a sharp drop in sales to a dairy in South Korea during 2012 and partly by the fact that the figures for 2011 included non-recurring income.

# Singapore

Births per year: 46,800.

**Partners:** Age D'or and Nestlé. **Population:** 5.2 million.

Market maturity: Probiotics well known among doctors

**Products:** BioGaia ProTectis drops and tablets (2006), BioGaia ProTectis oral rehydration solution, neutral and orange flavoured (2012), Nestlé infant formula (2011).

singapore is a small country with a high standard of living. The Singapore ans are well educated and dedicated to their families' quality of life. They are generally aware of probiotics and their positive effects on health. Paediatricians recommend drops mainly for children suffering from colic or diarrhoea. Other common indications are constipation and general digestive health. The drops are used to cure and the tablets to maintain a healthy bacteria culture.

BioGaia has a market share of around 19 per cent and the largest competitors are Lacto GG, Pro-Guard and vsl3. The brand is positioned in the premium class and has the advantage of having entered the market at an early stage.

The future plan for BioGaia's partner Age D'Or is to launch additional products. ■

## Indonesia

Partners: Interbat (drops), Kalbe (tablets)

and Nestlé (infant formula). **Population:** 242.3 million. **Births per year:** 4.4 million.

Market maturity: Some knowledge of probiotics

in the major cities.

**Products:** Rillus tablets (2007), Interlac drops (2012), Nestlé infant formula (2011).

INDONESIA IS A CHILD-DENSE COUNTRY where families have low incomes. In rural areas there is a low awareness of probiotics and the consumers are found in the major cities, which are also home to a growing middle class. The most common area of use for probiotics is diarrhoea. BioGaia's new partner in Indonesia, Interbat, started the year by launching the drops under the Interlac brand. The marketing is directed primarily to paediatricians and the expectations for Interbat are high. Interbat has a large sales force and longstanding contacts with doctors. In competition with brands like Lacto-B and L-Bio, they see both the reasonable price and strong clinical studies as success factors for BioGaia's drops.

To establish the drops on the market, Interbat is taking part in many local events. Their future plan is to expand the product range in order to also offer BioGaia's probiotics to older children. The other partner, Kalbe, sells the digestive health tablets under the Rillus brand. This is the fourth best selling probiotic dietary supplement in the country. The marketing is targeted primarily toward specialised physicians and the tablets are sold mainly as a probiotic product for diarrhoea and general digestive health.

# NORTH AMERICA

The US probiotics market is growing, driven by a greater interest among consumers in health-enhancing products in general. Probiotics are now relatively well-known and widely used in the form of yoghurt, beverages and dietary supplements.

In 2012 the market for dietary supplements with probiotics, prebiotics and vitamins (and combinations of these) grew by 17 per cent to nearly USD 570 million. In Canada, on the other hand, public knowledge about probiotics remains low.



#### Canada

**Partners:** Ferring and Sunstar. **Population:** 34.5 million. **Births per year:** 379,500.

Market maturity: Probiotics unknown among the public. Products: BioGaia ProTectis drops (2006) and tablets

(2008), GUM PerioBalance (2012)

knowledge about probiotics, but are eager to learn more. They want clinical proof before introducing new products. As a result, clinical data is critical in this market. The sales force at Ferring distributes the Canadian Probiotic Clinical Guide to healthcare professionals as a means for differentiating BioGaia from other probiotics companies. Ferring awards educational grants to healthcare professionals with probiotic expertise to study Health Canada-approved Canadian probiotics. The Guide contains published clinical studies that clearly position the various probiotic products.

Ferring also uses probiotics experts to train health-care professionals through programmes for continuing medical education. Consumers are educated through a tool that healthcare professionals can provide to patients or parents to assure them that BioGaia is the best alternative. To raise public awareness that not all probiotics are the same and that the benefits they provide vary, Ferring supports probiotics experts who are visible in the media.

The greatest obstacle in Canada is not the competitors, but the low level of knowledge about probiotics among both consumers and healthcare professionals. The competing products include Simethicone, Florastor, Bio-K, DanActive yoghurt and Culturelle. ■

## USA

Partners: Everidis (tablets with lemon flavour), Fleet Laboratories (tablets with strawberry flavour), Gerber (drops), Sunstar (oral health tablets) and

Gerber (infant formula). **Population:** 314 million. **Births per year:** 4.4 million.

**Market maturity:** Probiotics relatively well known among both paediatricians and general practitioners, with regional differences.

**Products:** BioGaia ProTectis drops (to be relaunched in 2013), BioGaia ProTectis tablets (2008), Pedia-Lax Probiotic Yums (2012), BioGaia probiotic straws (2007), GUM PerioBalance (2011), Gerber infant formula (2012).

**INTEREST IN PROBIOTICS** is on the rise in the USA. Many doctors recommend them to treat diarrhoea, both acute and antibiotic-associated. There are a number of competing brands, such as Culturelle, Nature's Bounty, Pure Life and the drug store chains' own private labels.

It is common to offer a combination of probiotics and fibre, as well as probiotics targeting different age groups.

Although doctors and nurses are becoming more aware of the possibility to treat colic with probiotic drops, it is still most common to start with soy-based formula for lactose intolerance.

The drops are sold by Everidis but in mid-2013 will be launched by Gerber under its own brand, although with distinct features of BioGaia's brand. Gerber is the USA's most well known brand of child nutrition and infant formula products, and expectations are high. ■



There are high expectations for increased sales of the drops in the USA. Gerber is Nestlé's subsidiary in the USA. Read more on page 28.



In Singapore, many parents give BioGaia's drops to their babies with colic.

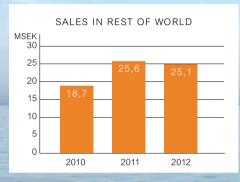
MARKET MARKET

# REST OF WORLD

CFR Pharmaceuticals\* is a multinational pharmaceutical corporation with a focus on speciality products and complex injectables. The company has operations in 15 Latin American countries - mainly Chile, Peru, Argentina and Colombia - but

also countries like Vietnam, Canada, India and the United Kingdom. In 2007 BioGaia and CFR signed an exclusive license agreement for distribution of BioGaia's products in six markets in Latin America. The launch has taken place in four of these and the registration process is still underway in two.

S.A., Parmindustria S.A., Ph.
Laboratorios Synthesis S.A.



\* The corporation includes Laboratorios Recalcine S.A., Farmindustria S.A., Pharmatech S.A. and

## Bolivia

Partner: Pharmatech S.A. Population: 10.1 million. Births per year: 262.600.

Market maturity: Probiotics are relatively unknown among paediatricians and gastroenterologists Products: BioGaia ProTectis drops and tablets (2012).

## Colombia

Partner: Laboratorios Synthesis S.A.

Population: 46.9 million. Births per year: 938.000

Market maturity: Probiotics are relatively unknown among paediatricians and gastroenterologists. Products: BioGaia ProTectis drops (2012).

BIOGAIA'S DROPS were launched in both Colombia and Bolivia during 2012. In Bolivia, the tablets were also introduced. The launches took place in connection with medical conferences and the products have attracted widespread interest among doctors. In both countries, probiotics are relatively unknown among both doctors and the public, and BioGaia is thus contributing to building the market. The competitors have focused exclusively on treatment of diarrhoea and the clinical studies on BioGaia's products in a number of other areas have given the products a unique position that is hoped will contribute to growth in sales. ■



## Chile

Partners: Laboratorios Recalcine S.A. and Nestlé.

Population: 17.3 million. Births per year: 242,200.

Market maturity: Probiotics are becoming more well known among both paediatricians and the public. Products: BioGaia ProTectis drops and tablets (end of

2008), Nestlé infant formula (2010).

THE CHILEAN MARKET has shown continued strong growth and increased by 25 per cent in 2012. The product Perenteryl is the market-leader, while BioGaia's products have a market share of around 24 per cent. Sales of Perenteryl have fallen somewhat, while BioGaia's products are among the few brands that are rising.

Marketing in Chile and Peru is targeted exclusively to doctors and other healthcare professionals, and the key advantage that is emphasised is scientific proof of the products' efficacy. Through research results, the products are differentiated from the majority of other probiotic preparations in a positive way.

In the next few years, sales of probiotics will continue to increase in both Peru and Chile. New products will be launched and their use will be expanded into new indication areas.

## Peru

Partners: Farmindustria S.A. and Nestlé

Population: 29.4 million. Births per year: 588,000.

Market maturity: Probiotics are somewhat known among paediatricians and gastroenterologists **Products:** BioGaia ProTectis drops and tablets (end of 2010), Nestlé infant formula (2010).

THE PERUVIAN MARKET is expanding steadily, by 28 per cent in 2011 and a somewhat slower 12 per cent in 2012. The fastest-growing products are Floratil, Enterogermina and BioGaia's drops, and there is wide potential for further development of the market. BioGaia has good growth opportunities in the paediatric segment where competitors like Enterogermina and Floratil are strong. In the gastroenterology segment, BioGaia is already the leading probiotic brand. Farmindustria also sees favourable scope for growth in the next few years by launching more of BioGaia's products, such as drops that can be stored at room temperature, oral rehydration solution and oral health products. ■

Marketing in Chile and Peru is targeted exclusively to doctors and other health care professionals, and the key advantage that is emphasised is scientific proof of the products' efficacy.



Nicolás Weinstein, Marketing Director at CFR Pharmaceuticals, BioGaia's partner in Latin America.

## **Clinical evidence** strengthening BioGaia

#### How familiar are patients in Latin America with probiotics?

"As our understanding of the human microflora increases (see page 12 "We are more than just people"), both doctors and patients are recognising probiotics as a tool to balance our microbiome and for effective treatment and prevention of certain

People in Latin America are rapidly adopting new technology. Physicians often talk about encountering "Google patients" who come to their doctor with a self-diagnosis and think they know what ailment they are suffering from and how it should be treated.

The countries in Latin America still have a relatively low rate of Internet usage, but for example in Chile there are 54 Internet users for every one hundred people (2011).

#### What role do you think probiotics can play?

"That probiotics prevent disease is of enormous value, since this widens the market in a way that pharmaceuticals are not capable of. Together with a more relaxed regulatory framework, I am convinced that probiotics can play a vital role in Latin America where acute illnesses caused by bacterial or viral nfections are very common."

#### How can BioGaia best support you?

"We are involved developing treatments for these infections and have seen enormous success in BioGaia's regional expansion. BioGaia is a phenomenal partner that provides us with constant support and clinical data when we visit doctors. They complement our prescription drugs with their premium

> products. They also assure patients of the efficiency of the products. Peter Rothschild knows what needs to be done to gain support from the medical disciplines, and in my experience this is not the norm."



# BioGaia ProDentis taking off

BioGaia ProDentis is currently sold in 20 countries and in 2012 was launched in Canada, the Netherlands, Belgium, Serbia, Croatia, Slovenia, Poland and the Czech Republic. The majority of sales come from BioGaia's subsidiary in Japan, which sells the oral health tablets via dental clinics.

ioGaia has learned two valuable lessons from earlier years' sales of BioGaia ProDentis. Firstly, consumers are often unaware that they are suffering from periodontal disease despite the fact that this condition affects nearly 20 per cent of the population. Secondly, if dental professionals don't see the advantages of BioGaia ProDentis and recommend the product to their patients, sales will not increase.

BioGaia ProDentis was launched in a number of trial markets in 2012 through partners who collaborate closely with dental clinics and have experience of medical products. With experience from these reference markets, BioGaia intends to initiate collaborative efforts in more and larger markets. Parallel to the international expansion, seven new studies were published that confirm the beneficial effects of the oral health tablets on gingivitis and periodontal

In 2012 BioGaia took part in several highly regarded international scientific conferences for dental professionals, including EuroPerio7 and IADR/PER. ■



BioGaia ProDentis has shown positive effects on gingivitis and periodontal disease in a large number of studies.

# Fruitful collaboration with Nestlé

The researchers and product developers at Nestlé had had their eye on BioGaia for some time. They were impressed by both the number and quality of studies on *Lactobacillus reuteri* Protectis, particularly in children and infants. In 2008 they contacted BioGaia to explore the possibilities for collaboration. Their main area of interest was the studies on infants with colic.

estlé already had an infant formula with probiotics in its product range, so knowledge and experience of products containing beneficial bacteria were well established in the company.

The first partnership agreement was signed the same year and meant that Nestlé purchased cultures (probiotic in powder form) of *Lactobacillus reuteri* Protectis that they added to some of their infant formula products.

NESTLÉ FRANCE FIRST OUT At the end of 2009 France was the first country where Nestlé launched its infant formula with BioGaia's probiotic, under the Guigoz brand. Since then the product has spread quickly and it is now found in over 40 markets worldwide. The marketing is targeted primarily to healthcare professionals and the product has become a sales success in most countries where it has been launched.

The success of the product led to continued cooperation between BioGaia and Nestlé. In recent years this partnership has been both deepened and widened, among other things through the signing of an agreement in February 2012 that gave Nestlé a perpetual license to use BioGaia's *Lactobacillus reuteri* Protectis in the infant formula area for the entire term of the patent. This was followed by several additional agreements. One of these is with Nestlé's US subsidiary, Gerber, and applies to BioGaia's baby drops, marking the first time that the partnership does not concern probiotic culture but one of BioGaia's finished consumer products.

The drops will be marketed under the Gerber brand, but with clear features of BioGaia's brand, and the launch is planned for the second quarter of 2013. Gerber is the USA's best known brand in the child nutrition area and expectations are high. The drops will also be launched in Mexico during 2013, here under BioGaia's brand but with features of Nestlé's brand.

LONG-TERM COLLABORATION It is common and often a successful model for multinational corporations to collaborate with small companies in development projects. In this case the collaboration is long term, based on multi-year agreements and projects of varying types, and Nestlé is also one of BioGaia's largest customers today. ■



# Sustainability and ethics

BioGaia has a fundamentally ethical vision, namely to improve the health of people around the world by offering first class probiotic products. When health is improved through the use of natural organisms, without side effects, it is hopefully possible to reduce the use of medications and antibiotics. In the long term, this will also have positive effects on the environment.

In 2009 BioGaia asked the Swedish Environmental Research Institute (IVL) to calculate and compare the environmental effects of the company's different packages. This study will be repeated in 2013, partly to determine if any changes have taken place and partly to include new products. At the beginning of 2013 BioGaia has started an effort to measure its climate impact by calculating the company's greenhouse gas emissions related to for example heating, business trips and transports. The areas where improvements can be made will then be remeasured after one or two years.

For areas where no improvement is possible, BioGaia will instead take climate compensation measures.



# Can we do this? The question is irrelevant

# We have to do it

People take antibiotics too often and in many cases without any need. In some parts of the world they are even sold without a doctor's prescription. The situation is becoming alarming as more and more bacteria develop antimicrobial resistance. By strengthening the human immune defence, we can decrease the use of antibiotics.

ince antibiotics were discovered more than 70 years ago, the use of antibiotics and vaccinations has extended the human life span by an average of 20 years. These are encouraging figures for mankind.

"Antibiotics are a revolutionary discovery and the solution to a vast range of problems. They are a powerful weapon against bacteria and should be used wisely," says Peter Rothschild, a long time contributor to the debate surrounding antibiotic resistance.

In fact, this is one of the reasons why he initially started BioGaia together with Jan Annwall. They saw probiotics as an alternative to antibiotics in animal feed, which at that time were routinely added to feed as a growth-promoting ingredient and are unfortunately still used in many countries around the world, including major producers like the USA and China.

In Europe antibiotics are prescribed fairly indiscriminately to animals and – incredibly – are sold to people without a prescription in certain countries. The World Health Organization, who, reports that two of three countries in Eastern Europe sell antibiotics over the counter without a prescription. This also takes place in many other countries around the world.

Antibiotics kill bacteria, but have no impact on the flu and rarely have any effect on throat infections or colds, which are caused by viruses.

"Earlier, doctors routinely prescribed antibiotics for children with ear infections, but now studies show that the infection will clear up without medication and that doing nothing actually works better."

The WHO confirms that antibiotics are being misused. Over half of all medicines in the world, including antibiotics, are prescribed and sold inappropriately and, unfortunately, half of the patients are taking the medicine wrongly. Why is it so important to take the entire course of antibiotics?

"Because when you break off treatment, the strongest bacteria survive and are able to withstand the antibiotic. They become resistant."

**PETER ROTHSCHILD IS CONCERNED** about the situation. In Europe alone, upwards of 80,000 people develop antibiotic-resistant tuberculosis. Treating resistant infections can be up to 100 times more expensive and the health consequences for those affected are serious.

"We are being thrown back to the 1940s when people went to sanatoriums in the mountains. I believe that in five years, we will have virtually nothing with which to treat certain bacterial infections."

One reason for this frightening state of affairs is that no new antibiotics have been discovered in the past 25 years despite wide-scale research efforts. In 2009, when Professor Otto Cars, who has been chairman of Strama (the Swedish strategic programme against antibiotic resistance) for many years, performed an analysis among 90 antibacterial agents, he did not find a single one that fought multi-resistant bacteria via new mechanisms.

"There is still a lot we can do. One obvious step is to stop the unregulated sale of antibiotics, but we also need to reduce prescription of antibiotics, particularly broad spectrum agents. We should also do what we can to alleviate the side effects of treatment so that patients complete the full course. Here, BioGaia can make a contribution."

Probiotics provide relief for those who are sick by adding friendly bacteria, but they can also help people to avoid infection. A study (Weizman Z, Pediatrics 2005) among children showed that use of antibiotics was significantly reduced among the subjects who were given *Lactobacillus reuteri* Protectis.

**THIS IS HOW PETER ROTHSCHILD** would like to turn things around. To reorient the entire medical system from primarily curing illness to primarily preventing it.

"With few exceptions, there are no doctors today who recommend that their patients avoid illness by building up their immune defence. They are trained to treat sick people. Doctors and other healthcare professionals need to learn how they can strengthen the body's own defence system."

From a concrete perspective they can recommend preventative measures such as probiotics, but also vitamin D, vitamin C and omega-3. We will naturally still need antibiotics in the future, and this will help to preserve them as an effective weapon.

The main challenge will be to change people's behaviour.

"Swedish doctors write some 4.5 million prescriptions for antibiotics every year. I think the key to changing our lifestyle is to present clinical studies showing that measures to strengthen the immune defence also lead to reduced use of antibiotics, and to market preventative care directly to consumers."

Can we do this? Peter Rothschild believes that unfortunately, the question is irrelevant. We have to do it. ■ AV HELENA THORÉN "Probiotics provide relief for those who are sick by adding friendly bacteria, but they can also help people to avoid infection."

PETER ROTHSCHILD, PRESIDENT



# Organisation

Despite having sales in 80 countries, BioGaia has only 76 employees. The explanation lies in the business model, which is based on strong collaboration in the company, which uses a flat and effective organisation.



# A flat organisation with short decision-making paths

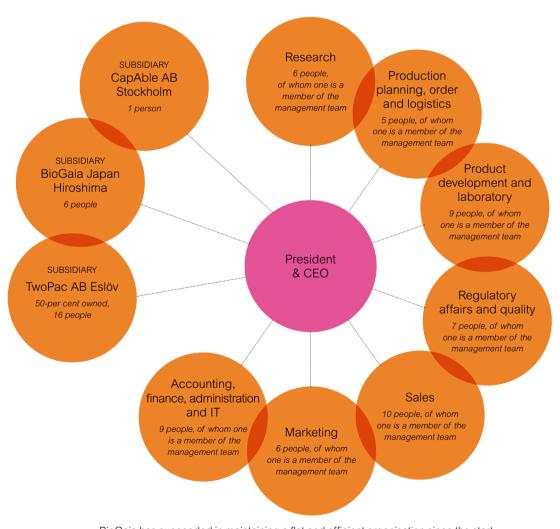
**FLAT ORGANISATION** BioGaia has a flat organisation **NEW EMPLOYEES** 14 people were hired in 2012 and with short decision-making paths. The ambition is to maintain this even when the organisation grows.

**EQUALITY** Of the total number of employees, 41 are women and 35 are men. Among senior executives, four are men and four are women.

company is low, and in 2012 the employees had an average of three sick days (aside from one longterm sickness absence).

two left the company. There are a total of 76 employees, of whom 16 work in the 50-per cent owned subsidiary TwoPac AB. The average term of service is six years and the average age is 42

**HIGH LEVEL OF EXPERTISE** The level of expertise is **LOW SICKNESS ABSENCE** Sickness absence in the high: 45 employees have a university education or the equivalent, and four of these hold a doctor's degree. The company promotes continuing education in order to meet future competency needs.



BioGaia has succeeded in maintaining a flat and efficient organisation since the start. The ambition is to preserve this even when the company grows.

BIOGAIA ANNUAL REPORT 2012

# BioGaia's global network

BioGaia's business model is based on three external networks: distribution, research and production. The distribution network is made up of some 40 partners with sales in around 80 different countries. In the research area, BioGaia collaborates with over 40 hospitals and universities around the world. The products are manufactured and packaged at six different units in Europe and the USA.

#### BioGaia

product development product strategies quality systems marketing support

NETWORK

Partners

pharmaceutical

and health companies with sales forces

Suppliers manufacturing and packaging

NETWORK Researchers

preclinical and clinical studies are onducted at hospitals

= BioGaia

= Universities and hospitals where research is conducted

= Manufacturing and packaging units

= Partners with sales of component products

= Partners with sales of finished products

# Employee voices

needed to ensure that the business model BioGaia's high quality standards. Another for BioGaia's global network is effective is to develop products and packaging (pages 34–35). One of these lies in choosing solutions, often in collaboration with the which clinical studies to pursue and ensuring suppliers, and make sure that the products

**THE COMPANY HAS** the core competencies that these are carried out according to are protected by patents that are controlled by BioGaia. An additional core competency is the ability to support partners in their marketing primarily to physicians, but also via the Internet and other activities. ■

"The products and packaging solutions we develop should be practical for consumers, but should also feel innovative and modern. Our drops are an excellent example. When they were launched in 2004 there was nothing similar on the market."

ELISABETH SJÖBERG, PRODUCT DEVELOPER, LUND "The success of our company relies on science of the highest quality. We therefore focus on collaborating with leading researchers and institutions around the world."

ANDERS ZACHRISSON, VICE PRESIDENT, CLINICAL RESEARCH, LUND



# Financial information and notes

**BioGaia** 

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2012 was a special year. The major deal with Nestlé and change of distribution partners have created the conditions for new success. Now it's full speed ahead!

Margareta Hagman, Executive Vice President Accounting & Finance

# Administration report

Figures in brackets refer to the previous year

The Board of Directors and President of BioGaia AB (publ), corporate identification number 556380-8723, hereby submit their annual report and consolidated accounts for the financial year 2012.

The financial statements were approved for publication by the Board of the Parent Company on 19 February 2013.

#### BioGaia

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 76 employees, of whom 29 are based in Stockholm, 22 in Lund, 16 in Eslöv, two in Raleigh, USA, six in Hiroshima, Japan, and one in Shanghai, China.

#### Business model

BioGaia's revenue comes mainly from the sale of finished consumer products (digestive health tablets, drops, oral rehydration solution (ORS) and oral health products) to distributors, but also from component products such as reutericultures, straws and caps.

The products are sold through nutrition, food, natural health and pharmaceutical companies in some 80 countries.

BioGaia holds patents for the use of *Lactobacillus reuterl* 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 package as the licensor/patent holder.

#### Key events in 2012

#### SALES AGREEMENTS

Extended collaboration with Nestlé Since 2008, BioGaia and Nestlé have collaborated in the field of infant nutrition products. After the signing of several new agreements in mid-February 2012, the parties have further extended this collaboration. The agreements include the acquisition of a perpetual licence to use BioGaia's patented *Lactobacillus reuterl* in infant nutrition products for EUR 50.8 million. The initial payment of EUR 40 million (SEK 356 million) was made and recognised in the first quarter of 2012. Additional payments of EUR 10.8 million will be paid and recognised over a five-year period on the achievement of certain milestones. In such case, the payment of EUR 10,8 million will be made during the period 2014-2017. The company assesses a high probability of achieving these milestones, but it is still too early to comment on this with certainty.

In addition, Nestlé has signed an option agreement with BioGaia to extend the use of *Lactobacillus reuterl* Protectis to other product areas.

Furthermore, Nestlé and BioGaia are working on several other projects, including the development of innovative products in the infant nutrition and other nutrition categories and the distribution of BioGaia-branded products in new markets. These further developments will be announced at an appropriate time closer to launch. Two of the agreements were announced in 2012. The first agreement, which was announced in June, is the agreement with Gerber for the sale of BioGaia's probiotic baby drops on the US market (see below). The second agreement refers to the sale of drops in Mexico (see below).

BioGaia's revenue from Nestlé in 2012 (excluding license revenue) was equal to approximately 58 % of the value of sales to Nestlé during 2011. BioGaia's assessment is that revenue from Nestlé in 2013 will be close to the 2011 level. From 2014 forward, sales are expected to exceed those in 2011.

Agreement for probiotic drops and tablets in Taiwan In mid-April BioGaia signed an agreement with Unilab Group for exclusive rights to sell BioGaia's probiotic drops and tablets in Taiwan. The products will be sold under the BioGaia brand and the launch took place at the end of 2012.

Agreement with Nestle's Gerber division for the sale of drops in the USA In June, BioGaia and Gerber Products Company, a division of Nestle's S.A., signed an agreement giving Gerber exclusive sales rights for BioGaia's probiotic drops and oral rehydration solution in the USA. The products will be marketed and sold under the well known and highly regarded US Gerber brand. The probiotic drops are planned to be launched in the second quarter of 2013 and will support Gerber's Maternal and Infant Nutrition strategy to offer mothers benefits regardless of whether they choose to breastfeed or supplement with formula. Since the drops are already sold in the USA, this is part of BioGaia's ongoing programme to change distribution partners.

Agreements for oral health products In May BioGaia signed three different agreements, one with Next Force giving Next Force exclusive sales rights for BioGaia's oral health products in the Czech Republic, one with Ivodent giving Ivodent exclusive sales rights in South Africa, and one with Oral Company giving Oral Company exclusive sales rights in the Netherlands, Belgium and Luxembourg. In all countries, the products will be sold under the BioGaia brand. The launch took place in the Benelux countries and the Czech Republic at the end of 2012.

At the end of 2012, an agreement was also signed for Singapore with Pharmaforte and for Israel with Dexcel Pharma.

Agreement for the sale of tablets and drops in Pakistan In October BioGaia signed an agreement with Ferozsons Laboratories Limited, granting them exclusive rights to sell BioGaia's probiotic drops and tablets in Pakistan. The products will be sold under the BioGaia brand and the launch is planned for 2013.

Agreement with Nestlé in Mexico During the autumn, BioGaia signed an agreement with Nestlé for exclusive rights to sell BioGaia's probiotic drops in Mexico as of 2013. Since the drops are already sold in Mexico, this is part of BioGaia's ongoing programme to change distribution partners.

#### CLINICAL STUDIES

Introduction The results of 19 studies on Lactobacillus reuteri were published in 2012 (eight gastrointestinal and immune health studies in children, four gastrointestinal and immune health studies in adults and seven oral health studies. Below is a description of the most significant studies.

Results of study show that *Lactobacillus reuteri* Protectis reduces diarrhoea in children A double-blind, placebo-controlled study of 494 children showed that supplementation of *Lactobacillus reuterl* Protectis significantly reduced episodes of diarrhoea. *Lactobacillus reuterl* Protectis was particularly effective in children with lower nutritional status. Another probiotic strain from another company, which was also tested, was without effect.

The study was conducted independently from BioGaia and the results were announced in a press release by NIZO food research on 21 February 2012.

The study was published in Journal of Pediatrics.

Reduction of intestinal inflammation in premature infants A study carried out on premature infants, born with a weight below 1000 grams, showed that prophylactic supplementation of *Lactobacillus reuterl* Protectis resulted in a statistically significant reduction in necrotising enterocolitis (NEC), the most common gastrointestinal cause of death and illness in premature infants. Following the introduction of preventive supplementation of *Lactobacillus reuterl* Protectis to all premature infants in the neonatal intensive care unit where the study was performed, one case of NEC was avoided for every eight infants treated.

The study was published online in the journal BMC Pediatrics on 4 September 2012.

Lactobacillus reuteri Protectis is shown to reduce colic in infants A double-blind, placebo-controlled study of 80 colicky infants showed that the crying time was significantly reduced among the infants supplemented with drops with the probiotic Lactobacillus reuterl Protectis compared to those in the placebo group. The quality of life for the parents and families were also significantly improved in the probiotic group compared to the placebo group.

The study was done by Hania Szajewska, Professor and Chair of the Department of Paediatrics at the Medical University of Warsaw in Poland. She is one of the world's most well reputed experts on probiotics and has conducted numerous clinical trials.

The study was performed according to the highest standards of clinical trial reporting (CONSORT) and was published in The Journal of Pediatrics on 14 September 2012.

This is the third independent study with *Lactobacillus reuterl* Protectis in colicky infants, and it once again confirms the effectiveness of BioGaia's probiotic drops in reducing the symptoms of colic.

BioGaia's probiotics help premature infants In this double-blind, placebo-controlled study on 751 infants, the goal was to investigate whether probiotics can reduce the mortality rate among infants and the incidence of infections during hospitalisation. For this, 1,110 infants were needed to participate in the study. Unfortunately, the study was terminated early due to a drop in recruitment and funding restrictions from the independent funding institute. However, the study showed that feeding intolerance in the infants with a birth weight below 1500 grams was reduced by 43%.

The study was published online in Pediatrics on 15 October 2012.

Distributor/licensee	Product	Country
Avipha	Gut health tablets and drops	Taiwan
Cube Pharmaceuticals	Oral rehydration solution (ORS)	Greece
Ewopharma	Oral health tablets	Croatia, Slovenia, Serbia and Poland
Ewopharma	Gut health tablets with strawberry flavour	Romania
Fleet Laboratories	Gut health tablets with strawberry flavour	USA
Interbat	Drops	Indonesia
J Health	Drops	Hong Kong
Nestlé	Infant formula with Lactobacillus reuteri Protectis	Bangladesh, Burma, Cambodia, Caribbean, Laos, Puerto Rico, Singapore, Sri Lanka and the USA
Next Force	Oral health tablets	Czech Republic
Oral Company	Oral health tablets	Netherlands, Belgium and Luxembourg
Pharmatech	Gut health tablets and drops	Bolivia
Laboratorios Synthesis	Drops	Colombia
Sunstar	Oral health tablets	Canada

Lactobacillus reuteri Prodentis reduced pocket depth in patients with

**periodontitis** A new study on 20 patients with periodontitis was published in November. The results show that pocket depth, the most important disease indicator, was significantly reduced in the patients supplemented with the probiotic *Lactobacillus reuterl* Prodentis compared to those in the placebo group.

The study was published online in Acta Odontologica Scandinavica on 26 November 2012.

New study on type 2 diabetics BioGaia has initiated an investigative study on type 2 diabetics together with Gothia Forum for Clinical Research at Sahlgrenska University Hospital in Gothenburg in collaboration with Sahlgrenska Center for Cardiovascular and Metabolic Research.

Based on encouraging findings after supplementation with BioGaia's probiotic strain *Lactobacillus reuterl* Protectis in patients with type 2 diabetes in an earlier pilot study, this double-blind, placebo-controlled study will examine the effects of *Lactobacillus reuterl* Protectis supplementation on blood glucose control over a 12-week period. The study will both address clinical outcome parameters as well as attempting to define potential mechanistic explanations for the effects seen.

#### Financial performance in 2012

Sales Consolidated net sales reached SEK 645.2 million (315.0). This figure includes license revenue from Nestlé of SEK 356 million that is regarded as non-recurring revenue but is to a certain extent attributable to sales in 2012. In February 2012 BioGaia signed several new agreements with Nestlé including the acquisition of a perpetual license to use BioGaia's probiotic in infant formula during the remaining term of the patent. The purchase price was EUR 50.8 million, of which EUR 40.0 million (SEK 356 million) was received and recognised in the first quarter of 2012. The additional payments of EUR 10.8 million will be received over a five-year period on the achievement of predefined milestones.

The sale of the license led to a decrease in culture revenue from Nestlé during 2012. BioGaia's revenue from Nestlé in 2012 (excluding license revenue) was equal to approximately 58% of sales to Nestlé in 2011. BioGaia's assessment is that revenue from Nestlé in 2013 will be close to the 2011 level. From 2014 forward, sales are expected to exceed those in 2011. Excluding license revenue from Nestlé, net sales amounted to SEK 289.2 million (315.0), a decrease of SEK 25.8 million (-8%) compared to the previous year.

Most of the company's sales are denominated in foreign currency, primarily EUR but also USD and JPY. With unchanged exchange rates, net sales would have been SEK 5.8 million higher. Excluding foreign exchange effects, the decrease in net sales (excluding license revenue) was 6%. Exchange rate fluctuations for EUR, USD and JPY have reduced both revenue and expenses. Operating profit would have been SEK 4.7 million higher in the event of unchanged exchange rates.

#### Sales by segmen

Sales of finished consumer products rose by SEK 22.2 million (10%) to SEK 237.6 million. Excluding foreign exchange effects, the increase was 12%. Sales of finished consumer products rose in North America, Europe and Asia but declined somewhat in the rest of the world compared to the previous year. The increase in Asia is mainly due to higher sales in Japan and Indonesia. The increase in North America is explained primarily by the sale of drops and Fleet's launch of strawberry-flavoured tablets in the USA. Everidis is continuing to sell the drops until Gerber's launch, which is planned for the second quarter of 2013. In Europe, the increase is attributable to countries such as Finland, Italy and France. In the rest of the world, sales were up in South Africa but fell in Australia and South America.

Sales of component products improved by SEK 308.9 million. Excluding license revenue from Nestlé, sales fell by SEK 47.1 million (-48%) compared to the previous year. Sales of component products decreased primarily in Europe and Asia. The drop in Europe is a consequence of the agreement with Nestlé (see above).

The decrease in Asia is explained partly by a sharp decrease in sales to a dairy in South Korea during the year and partly to the fact that the figures for 2011 include income from the final settlement with Yili in China.

#### Sales by geographic market

Sales in Europe improved by SEK 324.8 million. Excluding license revenue from Nestlé, sales fell by SEK 31.2 million (-13%).

Sales in Asia were down by SEK 4.7 million (-13%).

Sales in the USA and Canada rose by SEK 10.6 million (60%).

Sales in the rest of the world fell by SEK 0.5 million (-2%).

#### The BioGaia brand

Of total finished consumer products, 45% (43) were sold under the BioGaia brand. Including so-called co-branding, the percentage was 51% (50).

**Gross profit** Gross profit amounted to SEK 557.1 million (216.3). Excluding license revenue from Nestlé, gross profit was SEK 201.1 million (216.3), which is SEK 15.2 million (-7%) lower than in the previous year.

The total gross margin (excluding license revenue) rose slightly from 69% to 70%.

Gross margin for component products fell somewhat from 62% to 59% for the full year. This is due to a lower margin on sales of culture to Nestlé.

Gross margin for finished consumer products increased somewhat due to the product mix.

Operating expenses Selling expenses totalled SEK 77.4 million (66.1), which is equal to 27% (21) of net sales (excluding license revenue). The increase of SEK 11.3 million (17%) is mainly attributable to higher expenses for personnel and marketing activities (increased participation in conferences, new websites and product samples) as well as higher costs in Japan owing partly to exchange rate fluctuations.

Administrative expenses amounted to SEK 13.4 million (13.0), which is equal to 5%(4) of net sales (excluding license revenue). The increase of SEK 0.4 million (3%) is mainly attributable to higher personnel expenses.

R&D expenses are reported at SEK 35.8 million (34.3), which is equal to 12% (11) of net sales (excluding license revenue). External expenses for clinical studies have decreased somewhat, while personnel expenses have increased.

The amortisation component of R&D expenses was SEK 0.6 million (1.2). Investments in capitalised development expenses totalled SEK 0 million (0).

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

**Operating profit** Operating profit was SEK 428.1 million (103.2), an increase of SEK 324.9 million. Excluding license revenue from Nestlé, operating profit was SEK 72.1 million, which is SEK 31.1 million (30%) lower than in the previous year.

Financial items and profit before tax Profit before tax was SEK 442.2 million (108.9), an improvement of SEK 333.3 million. Excluding license revenue from Nestlé, profit before tax was SEK 86.2 million, down by SEK 22.7 million (21%) compared to the previous year.

Net financial items include a foreign exchange gain of SEK 5.7 million (2.5) on forward exchange contracts in EUR. At 31 December 2012 the company had outstanding forward exchange contracts for EUR 10.7 million at an average exchange rate of SEK 9.01. Forward exchange contracts amounting to EUR 7.1 million will mature for payment in 2013, and the remaining EUR 3.6 million in 2014. The actual exchange gain/loss depends on the exchange rate on the maturity date of the contracts. If the EUR rate on the maturity date is lower/higher than that at 31 December 2012 (8.61), an exchange gain/loss will be recognised in the future.

**Profit after tax** Profit after tax was SEK 329.9 million (79.5), an increase of SEK 250.4 million. Excluding license revenue from Nestlé, profit after tax was SEK 63.7 million, which is a decrease of SEK 15.8 million (20%) compared to the previous year.

The tax rate for the Group was 25% (27). The Group pays tax on profits in the Swedish companies. The Swedish companies have made provisions to untaxed reserves for which deferred tax of SEK 24.5 million has been recognised. The loss in Japan is not deductible against the Swedish profits. Loss carryforwards in the Japanese subsidiary at 31 December 2012 amounted to SEK 52.5 million. The deferred tax asset for these has not been recognised, since a sustainable profit level has not yet been shown in the Japanese subsidiary.

**Earnings per share** Earnings per share amounted to SEK 18.93 (4.42). Excluding license revenue, earnings per share were SEK 3.52.

**Cash flow** The Group's cash and cash equivalents at 31 December 2012 totalled SEK 375.0 million (171.5).

Cash flow amounted to SEK 203.8 million (24.7). Cash flow includes a license payment from Nestlé of SEK 356 million, investments in TwoPac of SEK 27.5 million (15.8), tax payments of 105.7 million (35.8) and dividends of SEK 103.6 million (34.5).

**Equity** Consolidated equity amounted to SEK 456.8 million (230.4) and the equity/assets ratio was 88% (82).

In June BioGaia carried out the warrant programme that was decided 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, which provided the Parent Company with proceeds of SEK 1.3 million. Each warrant entitles the holder to subscribe for one class B share for SEK 241.90 on 1 June 2015. Volatility was estimated at 40 per cent.

If all of the subscription warrants are exercised, the company's equity will be increased by SEK 21.0 million. This represents a dilutive effect of approximately 0.5% on the share capital and 0.4 per cent on the total number of votes upon the full exercise of warrants

In order to achieve a high level of participation, the AGM decided to pay a subsidy of SEK 10 per warrant (after 1 June 2015) to the employees who have subscribed for subscription warrants but have not exercised the right to buy shares. No provisions for this obligation have yet been made, but the need will be continuously assessed. At present, the assessment is that all warrants will be exercised and that there is therefore no need for a provision.

#### Dividend

The Board of BioGaia AB proposes to the upcoming AGM an ordinary dividend of SEK 4.15 and an extraordinary dividend of SEK 5.85, for a total dividend of SEK 10.00 per share. For more information, see below under "Proposed appropriation of profits".

**Investments in property, plant and equipment** The year's investments in property, plant and equipment amounted to SEK 29.4 million (16.2), of which SEK 27.5 million (15.8) refers to TwoPac AB.

**Subsidiary in Japan** Net sales in the Japanese subsidiary are reported at SEK 15.1 million (12.6). Operating profit in the Japanese business amounted to SEK –4.6 million (-3.9).

**Subsidiary TwoPac AB** TwoPac AB is owned 50% by BioGaia and 50% by TwoPac's management. Since 1 January 2011, TwoPac is consolidated in the BioGaia Group.

Net sales in TwoPac amounted to SEK 29.3 million (26.2). Operating profit was SEK 8.8 million (7.3). The company pays tax since 2012. Profit after tax was SEK 6.2 million (6.7). The new production facility is now finished and relocation of the most important production line from the old facility was completed in November. The other production lines are scheduled for relocation during 2013.

Parent Company Net sales in the Parent Company reached SEK 634.5 million (306.2) and profit before tax and appropriations was SEK 434.9 million (102.2).

Since it is uncertain whether the receivable from BioGaia Japan will be recovered in the foreseeable future, a provision has been made for this amount. This has resulted in an impairment loss of SEK 8.5 million (10.5) that has had a negative impact on profit. In addition, an impairment loss of SEK 2.6 million was recognised on the shares in CapAble (for more information see below under "Significant risks and uncertainties; Group and Parent Company").

Profit after tax was SEK 239.3 million (72.5). Cash flow in the Parent Company totalled SEK 209.9 million (21.1).

A resolution was passed by the AGM in May to reduce the entire statutory reserve of SEK 77.8 million and transfer this amount to non-restricted reserves. The reduction was registered in August 2012.

#### Research an 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. Current areas of research include studies related to mapping of the reuteri genome and how it is linked to the bacterium's function and effects. In addition, the company is working to identify and develop new probiotic lactic acid bacteria with potential effect in a number of human applications and is conducting clinical trials on its existing and new products.

Lactobacillus reuteri is one of the world's most well researched probiotics, especially in young children. To date, 108 clinical studies using BioGaia's human strains of Lactobacillus reuteri have been performed on around 8,600 individuals of all ages. The results have been published in 72 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
- General health
- · Helicobacter pylori (the gastric ulcer bacterium).

19 studies on Lactobacillus reuteri were published in 2012 (for more information – see above under "Key events in 2012").

R&D expenses are reported at SEK 35.8 million (34.3), which is equal to 12% (11) of net sales (excluding license revenue). External expenses for clinical studies have decreased somewhat, while personnel expenses have increased.

The amortisation component of R&D expenses was SEK 0.6 million (1.2). Investments in capitalised development expenses totalled SEK 0 million (0).

For more information, see Note 13.

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 onsetion about trial design into an accepted clinical trials registry before the onsetion about 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 vision, namely to improve the health of people around the world by offering first class probiotic products. By offering alternatives that make it possible to improve heath through the use of natural organisms, without side effects, the company's hope is to reduce the use of medications and antibiotics, which also has positive effects on the environment.

In 2009 BioGaia asked the Swedish Environmental Research Institute (IVL) to calculate and compare the environmental effects of the company's different packages. The environmental aspects covered in the study were climate change, acidification, nutrification and formation of ground-level ozone. The products included in the study were BioGaia's probiotic tablets (in bottles and blister packs) and BioGaia's probiotic drops.

Because the product portfolio has developed since 2009, BioGaia will repeat the study in 2013 to see whether any changes have taken place and to include new products, such as the oral rehydration solution.

Furthermore, at the beginning of 2012 BioGaia has started an effort to measure its climate impact by calculating the company's greenhouse gas emissions related to heating, cooling, electricity, business trips, transports, etc. The measurement applies to 2012. The idea is to identify the areas where improvements can be made and follow up with a new measurement after 1-2 years. For areas where no improvement is possible, BioGaia will take climate compensation measures. The initiatives the company will support will be chosen carefully so that it is possible to closely monitor the results of the selected projects.

BioGaia conducts no operations that require permits.

#### Business risks an 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 venture The Japanese subsidiary has operated at a loss since the start in 2006. The previously chosen business model was found to be unsuccessful and in 2010 BioGaia decided to change the business model in Japan to that which is used in the other markets.

Net sales in the Japanese subsidiary during 2012 amounted to SEK 15.1 million (12.6) and operating profit to SEK -4.6 million (-3.9). On the balance sheet date, assets in the Japanese subsidiary were reported at SEK 7.0 million (8.7). BioGaia's assessment is that the subsidiary will show good profitability in the future, for which reason these was no indication of impairment of these assets on the balance sheet date

Shares 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 are reported at 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 2012 was SEK -2.6 million (-2.5). BioGaia made total conditional shareholder contributions of SEK 6 million to the subsidiary CapAble in 2009 and 2010. BioGaia AB made total group contributions of SEK 7.3 million during the period 2010-2012.

BioGaia's assessment is that CapAble will show good profitability in coming years, 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 consumers. This means that 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 40 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. In 2012 and 2013 BioGaia is carrying out a change of distributors in some 10 markets.

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.

There is also a certain risk that the studies that lie outside BioGaia's control are not performed in accordance with BioGaia's strict requirements.

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 80 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, Canada, 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, 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. In addition, there is an incentive scheme that is open to all employees in the Parent Company and the wholly owned subsidiaries.

**Product liability insurance** 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 costeffective 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 minimise the risk for negative effects on the Group's earnings. Consequently, the Group's financial investments must have a low risk profile.

The Group's assessed risk exposure and related risk management are described below.

**Currency risk** BioGaia has revenue primarily in EUR (around 75% of net sales excluding license revenue from Nestlé) but also USD, JPY and SEK and expenses primarily in SEK, EUR, JPY and USD.

In 2012 the company had a cash flow surplus of approximately EUR 55.6 (17.6) million (including the payment of EUR 40 million from Nestlé), a cash flow deficit of JPY 81.2 million (65.2) and a cash flow surplus of USD 1.7 million (-0.3).

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 2012 the company had outstanding forward exchange contracts for EUR 10.7 million at an average exchange rate of SEK 9.01, of which EUR 7.1 million will mature for payment in 2013 and EUR 3.6 million in 2014. BioGaia does not apply hedge accounting. For more information see Notes 9, 20 and 22.

A stronger SEK rate against the EUR 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 should be able to minimise the impact of earnings. The company is also trying to reallocate a portion of revenue from EUR to other currencies, primarily SEK.

Interest rate risk The Group has no loans and therefore no interest rate risks. Excess liquidity is invested mainly at bank interest rates or in fixed income securities with a high credit rating.

Credit risk 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 minimise risks.

The loan from the Parent Company to the subsidiary CapAble AB has been used to purchase equipment for manufacturing of LifeTop Cap. The company's assessment is that the loan is associated with low credit risk.

The loan from the Parent Company to the subsidiary TwoPac AB has been used mainly to build a new production facility in Eslöv, Sweden. The facility was completed and commissioned during 2012. The company's assessment is that the loan is associated with low credit risk.

**Liquidity risk** 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.

Cash flow risk In 2012 BioGaia had a positive cash flow from operating activities before changes in working capital of SEK 338.5 million (77.2). After changes in working capital, cash flow was SEK 335.6 million (72.8). Total cash flow was SEK 203.8 million (24.7). Because cash and cash equivalents at 31 December 2012 amounted to SEK 375.0 million (171.5) and cash flow was positive, no infusion of capital is necessary.

**Price risk** BioGaia buys most of its goods on the international market and has several alternative suppliers, which minimises the company's price risk

#### **Employees**

The number of employees in the Group at 31 December 2012 was 76 (64), consisting of 41 women and 35 men. The management team includes four men and four women. In 2012, 14 new employees were hired and two employees left the company.

BioGaia's incentive scheme for the employees In June BioGaia carried out the warrant programme that was decided 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, which provided the Parent Company with proceeds of SEK 1.3 million. Each warrant entitles the holder to subscribe for one class B share for SEK 241.90 on 1 June 2015. Volatility was estimated at 40%.

If all of the subscription warrants are exercised, the company's equity will be increased by SEK 21.0 million. This represents a dilutive effect of approximately 0.5% on the share capital and 0.4% on the total number of votes upon the full exercise of warrants.

In order to achieve a high level of participation, the AGM decided to pay a subsidy of SEK 10 per warrant (after 1 June 2015) to the employees who have subscribed for subscription warrants but have not exercised the right to buy shares. No provisions for this obligation have yet been made, but the need will be continuously assessed. At present, the assessment is that all warrants will be exercised and that there is therefore no need for a provision.

BioGaia has an incentive scheme that is open to all employees in the Parent Company and the wholly owned subsidiaries under which an extra bonus (equal to no more than 8% of salary) is payable depending on BioGaia's gross profit. In 2012, no provisions for bonuses were made and no bonuses were expensed.

#### Future outlook

BioGaia's goal is to create strong value growth and a good return for the share-holders. 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.

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 previous policy was to pay a shareholder dividend equal to 30% of profit after tax. In February 2013 the Board decided to change the policy so that shareholder dividends amount to 40% of profit after tax in the future.

Product launches are planned in a number of countries in the coming year. In view of the Company's strong portfolio consisting of an increased number of innovative products partly under the company's own brand, together with successful clinical trials and a growing distribution network covering a large share of the key markets, BioGaia's future outlook is bright.

# 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 time. 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 fixed salary, variable remuneration, long-term incentive schemes, pension benefits, other benefits and terms of notice/termination benefits.

**Fixed salary** Fixed 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 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 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 the other remuneration and shall be consistent with general norms in the respective geographic market.

Terms of notice and termination benefits 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.

The Board of Directors proposes that the Board be authorised 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).

#### Corporate governance

BioGaia has issued a separate corporate governance report.

#### Proposed appropriation of profits

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

Retained profit Profit for the year Together amounting to	91 859 157 239 277 552 331 136 709
The Board of Directors proposes that the profits be disposed of as follows:  To be paid as a dividend to the shareholders  To be carried forward to new account	172 709 620 <sup>*)</sup> 158 427 089
Total	331 136 709

\*) The proposed dividend consists of an ordinary dividend of SEK 4.15 per share and, in view of the company's good liquidity and strong balance sheet, an extraordinary dividend of SEK 5.85 per share, amounting to a total dividend of SEK 10.00 per share.

# Group

#### Statement of consolidated income

SEK 000s	Note	2012	2011
Net sales Cost of goods sold	2, 3	645,252 -88,179	314,992 -98,727
Gross profit	2	557,073	216,265
Selling expenses Adminstrative expenses Research and development expenses Other operating income	4 4, 5 4, 13 6	-77,361 -13,423 -35,788	-66,079 -13,014 -34,317 304
Other operating expenses	7	-2,431	-
Operating profit	8	428,070	103,159
Financial income Financial expenses	9 10	14,245 –73	5,792 –84
Net financial items		14,172	5,708
Profit before tax		442,242	108,867
Tax	11	-112,371	-29,345
PROFIT FOR THE YEAR		329,871	79,522
Other comprehensive income: Gain/losses arising on translation of the financial statements of foreign operations:		-1,059	712
Comprehensive income for the year		328,812	80,234
Profit for the year attributable to: Owners of the Parent Company Non-controlling interests	12	326,970 2,901 329,871	76,369 3,153 79,522
		023,071	10,022
Comprehensive income for the period attrib Owners of the Parent Company Non-controlling interests	utable to	325,911 2,901 328,812	77,081 3,153 80,234
Earnings per share Basic earnings per share, SEK Diluted earnings per share, SEK Number of shares, thousands Average number of shares, thousands Number of outstanding warrants, thousand. Number of outstanding warrants with a dilutive effect, thousands		18.93 18.93 17,271 17,271 87	4.42 4.42 17,271 17,271 -
Average number of shares after dilution, the	ousands	17,271	17,271

#### Cash flow statements

SEK 000s	Note	2012	2011
Operating activities			
Operating profit		428,070	103,159
A discontinuo de forma a contrata de contr			
Adjustments for non-cash items:		4 5 4 5	E 40E
Depreciation/amortisation		4,545	5,425
Capital gains/losses on the sale of non-current assets		46	1,340
Other non-cash items		300	1,340
Other hon-cash items			
		432,961	109,982
Taxes paid		-105,736	-35,768
Realised forward exchange contracts		2,818	-164
Interest received		8,563	3,269
Interest paid		-67	-80
Cash flow from operating activities			······································
before changes in working capital		338,539	77,239
Cash flow from changes in working capital:			
Inventories		445	-5,928
Current receivables		135	-13,057
Trade payables		-2,848	7,788
Current interest-free operating liabilities		<del>-</del> 714	6,750
Cash flow from operating activities		335,557	72,792
Investing activities:			
Purchase of property, plant and equipment	14	-29,400	-16,179
Sale of property, plant and equipment	14	9	_
Purchase of financial assets	15	_	2,612
Cash flow from investing activities		-29,391	-13,567
Financing activities:			
New share issue warrants		1,253	_
Dividend		-103,626	-34,542
Cash flow from financing activities		-102,373	-34,542
•			, 
CASH FLOW FOR THE YEAR		203,793	24,683
CASH AND CASH EQUIVALENTS			
AT BEGINNING OF YEAR		171,534	146,903
Exchange difference in cash and cash equiv	/alents	-353	-52
CASH AND CASH EQUIVALENTS			
AT END OF YEAR		374,974	171,534
		,	,

## Statement of financial position

SEK 000s	Note	31 Dec. 2012	2011-12-31
ASSETS			
Non-current assets:			
Intangible assets	13	_	264
Property, plant and equipment	14	49,193	24,158
Deposits		17	18
Total non-current assets		49,210	20,448
Current assets:			
Inventories	17	20,845	21,528
Trade receivables	18, 22	54,045	49,112
Tax receivable		6,476	_
Other receivables	20	7,596	7,044
Deferred expenses and accrued income	21	3,796	6,094
Short-term investments	22	80	80
Cash and cash equivalents	22	374,974	171,534
Total current assets		467,812	255,392
TOTAL ASSETS		517,022	279,832

SEK 000s	Note	31 Dec. 2012	2011-12-31
EQUITY AND LIABILITIES Equity	23		
Share capital	20	17,271	17,271
Other contributed capital		6,053	82,501
Reserves		586	1,644
Retained profit		102,423	51,979
Profit for the year attributable to			
owners of the Parent Company		326,970	76,369
Total equity attributable to			
owners of the Parent Company		453,303	229,764
Non-controlling interests	12, 15	3,491	591
Total non-controlling interests		3,491	591
Total equity		456,794	230,355
Non-current liabilities:			
Deferred tax liability		24,710	185
Total non-current liabilities		24,710	185
Current liabilities:			
Prepayments from customers	22	3,118	2,960
Trade payables	22	14,731	17,769
Current tax liability		1,599	12,102
Other liabilities	24	1,266	1,296
Accrued expenses and deferred income	25	14,804	15,165
Total current liabilities		35,518	49,292
Total liabilities		60,228	49,477
TOTAL EQUITY AND LIABILITIES		517,022	279,832
Pledged assets and contingent			

## Pledged assets and contingent liabilities in the Group

# Statement of changes in equity

Closing balance, 31 December 2012	17,271	6,053	586	429,393	453,303	3,491	456,794
Comprehensive income for the year	0	0	-1,059	326,970	325,911	2,901	328,812
Other comprehensive income Gain/losses arising on translation of the financial statements of fore	ign operations		-1,059		-1,059		-1,059
Total transactions with owners Profit for 2012	0	-76,448	0	-25,925 326,970	-102,373 326,970	0 2,901	-102,373 329,871
Closing balance, 31 December 2011 Dividend Transfer from the statutory reserve to non-restricted reserves Subscription warrants <sup>1)</sup>	17,271	<b>82,501</b> -77,701 1,253	1,644	<b>128,348</b> -103,626 77,701	<b>229,764</b> -103,626 0 1,253	591	<b>230,355</b> -103,626 0 1,253
Comprehensive income for the year Change in group structure	0	0	712	76,369	77,081	<b>3,153</b> –2,660	<b>80,234</b> –2,660
Total transactions with owners Profit for 2011 Other comprehensive income Gain/losses arising on translation of the financial statements of fore	0 ign operations	4,800	<b>0</b> 712	-39,342 76,369	<b>-34,542</b> <b>76,369</b> 712	0 3,153	<b>-34,542 79,522</b> 712
Opening balance, 1 January 2011 Reclassification of prior new share issue Dividend	17,271	<b>77,701</b> 4,800	932	<b>91,321</b> -4,800 -34,542	<b>187,225</b> 0 –34,542	98	<b>187,323</b> 0 -34,542
SEK 000s	Share capital	Other contributed capital	Translation reserve	Retained profit incl. profit for the year	Equity attributable to owners of the Parent Company	Non- controlling interests	Total equity

<sup>&</sup>lt;sup>1)</sup>The terms of the subscription warrants are described in the administration report.

# Parent Company

#### Income statements

SEK 000s	Note	2012	2011
Net sales Cost of goods sold	2, 3	634,519 -97,475	306,182 -106,868
Gross profit	2	537,044	199,314
Selling expenses	4	-57,673	-49,406
Administrative expenses	4, 5	-12,248	-11,607
Research and development expenses	4, 14	-35,868	-34,283
Other operating income	6	_	304
Other operating expenses	7	-2,430	-
Operating profit	8	428,825	104,322
Result from financial investments Impairment loss of receivable			
from group company	16	-8,574	-10,453
Impairment loss on shares in group companies Interest income and similar	s 15	-2,583	-
profit/loss items Interest expense and similar	9	17,283	8,469
profit/loss items	10	-63	-78
Net financial items		6,063	-2,062
Profit before appropriations and taxes		434,888	102,260
Provisions to tax allocation reserve	27	-109,341	_
Profit before tax		325,547	102,260
Tax	11	-86,270	-29,781
PROFIT FOR THE YEAR		239,277	72,479

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 statements

SEK 000s	Note	2012	2011
Operating activities			
Operating profit		428,825	104,322
Adjustments for non-cash items			
Depreciation/amortisation		1,510	2,096
Capital gains/losses on the sale of		0	
non-current assets Other non-cash items		8 300	- 51
Otter Hori-Casif Items		430,643	106,469
		430,043	100,403
Taxes paid		-105,690	-35,769
Realised forward exchange contracts		2,818	-164
Interest received		9,183	3,660
Interest paid		-63	-78
Cash flow from operating activities		220 004	74.440
before changes in working capital		336,891	74,118
Cash flow from changes in working capital			
Inventories		-29	-5,522
Current receivables		-5,079	-12,926
Trade payables		-2,970	6,208
Current interest-free operating liabilities		-5,434	9,554
Cash flow from operating activities		323,379	71,432
Investing activities			
Purchase of property, plant and equipment	14	1,462	-221
Sale of property, plant and equipment	14	9	
Purchase of financial assets	15	-	-50
Payment of loan to subsidiary	16	-9,670	-15,542
Cash flow from investing activities		-11,123	-15,813
Financing activities			
Subscription warrant programme		1,253	
Dividend		-103,626	-34,542
Cash flow from financing activities		-102,373	-34,542
CASH FLOW FOR THE YEAR		209,883	21,077
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR		161 065	140 040
Exchange difference in cash and		161,865	140,840
cash equivalents		-300	-52
•			
CASH AND CASH EQUIVALENTS			
AT END OF YEAR		371,448	161,865

#### Balance sheets

SEK 000s	Note	31 Dec. 2012	2011-12-31
ASSETS			
Non-current assets			
Intangible assets	13		
Capital development expenditure		-	264
Total intangible assets		-	264
Property, plant and equipment	14		
Production equipment		758	218
Office equipment and computers		1,517	1,850
Total property, plant and equipment		2,275	2,068
Financial assets			
Participations in group companies	15	21,160	21,160
Receivables from group companies	16, 29	24,513	16,513
Total financial assets		45,673	37,673
Total non-current assets		47,948	40,005
Current assets			
Inventories	17	18,694	18,665
Current receivables			
Trade receivables	18	49,455	42,872
Tax receivable	00	6,461	C 470
Other receivables  Deferred expenses and accrued income	20 21	7,385 2,934	6,479 5,547
Total current receivables	۷۱	66,235	54,898
		, , , , ,	,,,,,,
Short-term investments	22	80	80
Cash and cash equivalents		371,448	161,865
Total current assets		456,457	235,508
TOTAL ASSETS		504,405	275,513

#### Balance sheets

SEK 000s	Note	31 Dec. 2012	2011-12-3
EQUITY AND LIABILITIES			
Equity	23		
Restricted equity			
Share capital		17,271	17,27
Other restricted equity		1,253	77,700
		18,524	94,97
Non-restricted equity			
Retained profit		91,859	45,306
Profit for the year		239,277	72,479
		331,136	117,78
Total equity		349,660	212,756
Untaxed reserves			
Tax allocation reserve		109,341	-
Total untaxed reserves		109,341	-
Liabilities			
Current liabilities			
Prepayments from customers		3,118	2,960
Trade payables		11,324	14,29
Liabilities to group companies	19	16,990	19,404
Current tax liability		_	12,056
Other liabilities	24	883	779
Accrued expenses and deferred income  Total current liabilities	25	13,089 45,404	13,260
Total Garrent habilities		40,404	02,70
Total liabilities		45,404	62,75
TOTAL EQUITY AND LIABILITIES		504,405	275,513
Pledged assets and contingent			
liabilities for the Parent Company			
Floating charges	26	2,000	2,000
Contingent liabilities		None	None

## Statement of changes in equity

		Other		
		restricted	Retained profit incl.	Total
SEK 000s	Share capital	equity	profit for the year	equity
Opening balance,1 January 2011	17.271	77.700	81,661	176,632
Group contributions paid	,	77,700	-2.460	-2,460
Tax on group contributions paid			647	647
Dividend			-34,542	-34,542
Profit for 2011			72,479	72,479
Closing balance, 31 December 2011	17,271	77,700	117,785	212,756
Dividend			-103,626	-103,626
Transfer of statutory reserve to non-restricted reserves		-77,700	77,700	0
Subscription warrants <sup>1)</sup>		1,253		1,253
Profit for 2012			239,277	293,277
Closing balance, 31 December 2012	17,271	1,253	331,136	349,660

 $<sup>\</sup>ensuremath{^{1)}}$  The terms of the subscription warrants are described in the administration report.

# 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). Furthermore, the Swedish Financial Reporting Board's recommendation RFR 1, Supplementary Rules for Consolidated Financial Statements, has been applied.

The Parent Company applies 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 Companies Act limits the applicability of IFRS in the Parent Company.

Standards, interpretations and amendments applied as of 1 January 2012
Only a few minor changes and clarifications have been made in the existing standards.

The changed IFRS standards and IFRIC interpretations have not had any significant impact on the Group's financial results, financial position or disclosures

Standards and interpretations that are not yet effective and are awaiting approval from the EU have not been evaluated by BioGaia.

Basis of presentation The financial statements have been prepared in accordance with the cost method of accounting unless otherwise stated.

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 judgement in the process of applying the company's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in Note 28.

Scope of consolidation The consolidated financial statements include those companies over which the Parent Company has a controlling influence. Control is achieved where the company directly or indirectly has the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities.

The consolidated financial statements have been prepared in accordance with the acquisition method of accounting, whereby the acquisition of a subsidiary is regarded as a transaction in which the Group indirectly acquires the subsidiary's assets and assumes its liabilities and contingent liabilities. To determine the Group's cost for the investment in the subsidiary, a purchase price allocation (PPA) is conducted in connection with the acquisition. The consideration transferred for the acquisition of a subsidiary or business is measured as the aggregate of the fair values, on the date of exchange, of the assets given, equity instruments issued and liabilities incurred or assumed, and equity instruments issued by the Group in exchange for control of the acquiree. All acquisition-related costs are expensed immediately. In cases where the Group increases its equity interest sufficiently to achieve control (business

combination achieved in stages), any previously held equity interests in the acquiree are remeasured to fair value. The resulting gain or loss is recognised in the statement of comprehensive income. For acquisitions of non-controlling interests there are two alternatives for recognition of goodwill – full goodwill or partial goodwill. The choice of method is made on an acquisition-by-acquisition basis. Subsequent acquisitions once control has been achieved are regarded as transactions with owners and are recognised directly in equity.

Subsidiaries are consolidated from the date on which control is transferred to the Group and cease to be consolidated from the date on which control is transferred out of the Group. All inter-company balances and transactions, including unrealised gains or losses arising from inter-company transactions, are eliminated in full in presentation of the consolidated financial statements.

#### 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 recognised 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 recognised in operating profit, while foreign exchange gains/losses on financial receivables and liabilities are recognised in net financial items.

- 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 calculated quarterly. Exchange differences arising on translation of foreign operations are recognised 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 that form part of the net investment in a foreign operation are
  deferred to a translation reserve in other comprehensive income.

Segment reporting The Group has applied IFRS 8, Operating Segments, since 1 January 2009. The Executive Management has analysed the Group's internal reporting and determined that the Group's operations are monitored and evaluated based on the following segments:

- Finished consumer products: Sales of tablets, drops and oral health products, etc.
- Component products: Sales of cultures as an ingredient in licensee products (such as infant formula and dairy products), royalties for the use of Lactobacillus reuteri and sales of LifeTop Straw and LifeTop Cap.
- Other products: Animal Health, etc.

Revenue recognition BioGaia's net sales consist primarily of revenue from the sale of finished consumer products (tablets, drops and oral health products) to distributors but also revenue from the sale of component products for the use of Reuteri in licensee products (such as infant formula and dairy products), and to a certain extent royalties for the use of Reuteri in licensee products and revenue from the sale delivery systems such as straws and caps.

Revenue from the sale of goods is recognised 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.

Royalties are measured as a percentage of the licensee's reported sales value for consumer products containing BioGaia's products, and are recognised monthly or quarterly. License revenue received in connection with the signing of agreements is accrued in cases where it intended to cover costs until the time of launch. In other cases, the revenue is recognised immediately. Royalties from the sale of licenses (rights), such as the year's agreement with Nestlé which gives them the right to use the probiotic *Lactobacillus Reuteri* Protectis in infant formula under the remaining term of the patent, is recognised as revenue directly in cases where there are no remaining conditions to be met and the rights are transferred to the customer in connection with signing of the agreement.

Interest income is recognised in the income statement for the period in which it arises

**Leases** 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 recognised 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 law, currently at the age of 65 years. 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 the year's taxable profit. Deferred tax refers to the tax calculated partly on the basis of temporary differences and partly on taxable deficits. At every closing date, an assessment is made to determine whether to recognise deferred tax assets not previously recognised in the balance sheet. Such tax assets are recognised to the extent that it is deemed likely that sufficient taxable profits will be available in the future.

**Research and development** Costs related to research undertaken with the prospect of gaining new scientific or technical knowledge in the Group's operations are expensed as incurred.

Costs for development, where knowledge and understanding gained from research and practical experience are directed towards producing new products, processes or systems, are recognised as intangible assets in the balance sheet when they meet the criteria for capitalisation according to IAS 38, i.e. only when the technical and commercial feasibility of the product or process has been established, the Group has adequate resources to complete development and the Group intends and is able to complete the intangible asset and either use it or sell it. It should also be probable that the future economic benefits attributable to the asset will flow to the company and the cost of the asset can be reliably measured. The reported value includes all directly attributable costs, such as those for materials, purchased services and compensation to employees engaged in R&D activities. Other development costs are expensed as incurred. Individual assessment is made of all ongoing research and development projects to determine which costs for the respective project are capitalisable and to look for any indications of impairment.

The company has a number of projects that meet the criteria for capitalisation and were thus recognised in the balance sheet in previous years. These had been amortised in full at 31 December 2012. In 2012 no development projects were assessed to have reached the phase where capitalisation of development costs is appropriate according to these criteria, for which reason all of the year's development costs have been expensed in full.

**Intangible assets and property, plant and equipment** Intangible assets and property, plant and equipment are recognised at cost with a deduction for accumulated amortisation/depreciation and impairment.

The following amortisation schedules are applied:

	Group	Parent Company
Intangible assets		
Capitalised development expenditure	5-10 yrs	5–10 yrs
Licenses	5 yrs	5 yrs
Trademarks	5 yrs	5 yrs
Property, plant and equipment		
Production equipment	5–10 yrs	5 yrs
Equipment and computers	3–5 yrs	3–5 yrs
Buildings	_	_

Amortisation of intangible assets is started when a project has been completed and the product begins generating revenue.

The amortisation period varies between 5-10 years depending on the estimated useful life of the project. The only project with an amortisation schedule of more than 5 years is the Animal Health project, for which the amortisation period is matched to the term of the contract.

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. 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 recoverable amount.

Depreciation of a building is started when construction is completed. The depreciation period is 20-30 years for electricity and internal construction work, etc., and 60 years for the framework and foundation.

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

Cash and cash equivalents Cash and cash equivalents comprise cash in hand and at hank

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

The financial assets recognised in balance sheet include cash and cash equivalents, short-term investments, trade payables and loans. 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.

A financial asset or liability is recognised in the balance sheet when the company initially becomes party to the contractual provisions of the instrument. Financial liabilities are recognised 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 amortised cost less provision for impairment. Impairment losses on trade receivables are recognised in profit or loss. Trade payables are recognised when an invoice has been received.

The purchase or sale of a financial asset is recognised on the trade date, which is the date on which the company commits to purchase or sell the asset.

A financial asset is derecognised from the balance sheet when the company's rights under the agreement are realised, expire or the company has relinquished control of the asset. The same applies to a part of a financial asset. A financial liability is derecognised 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.

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.

- Subsidiaries In the Parent Company, shareholdings in subsidiaries are accounted for in accordance with the cost method of accounting
- Income taxes In the Parent Company, untaxed reserves are recognised including deferred tax liability. In the consolidated financial statements, however, untaxed reserves are divided between deferred tax liability and equity.
- Group and shareholder contributions for legal entities The Parent Company reports group and shareholder contributions in accordance with a statement from the Swedish Financial Reporting Board (RFR 2). Group contributions are reported in accordance with their financial significance. This means that Group contributions paid to minimise the Group's overall tax burden are recognised directly in retained earnings less the current tax effect. In other cases, group contributions are recognised directly in equity by the recipient and are capitalised in shares and participations by the giver, to the extent that impairment is not indicated.

#### Note 2 Segment reporting

The Executive Management, which is BioGaia's chief operating decision-maker, has analysed the Group's internal reporting and determined that the Group's operations are steered and evaluated based on the following segments:

- Finished consumer products: Sales of tablets, drops, ORS and oral health products etc.
- Component products: Sales of cultures as an ingredient in licensee products (such as infant formula and dairy products), royalties for the use of reuteri and sales of LifeTop Straw and Life Top Cap.
- Other products: Animal Health, etc.

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

#### Revenue by segment:

	Group_		Parent C	Company
	2012	2011	2012	2011
Finished consumer products	237,583	215,431	226,950	206,623
Component products	50,577	97,731	50,477	97,729
License revenue				
(component products)1)	356 004	-	356 004	-
Other products	1,088	1,830	1,088	1,830
	645,252	314,992	634,519	306,182

#### Gross profit by segment:

	2012	2011	202	2011
Finished consumer products	170,275	154,015	150,246	136,980
Component products	29,935	60,523	29,934	60,607
License revenue				
(component products)1)	356 004	-	356 004	-
Other products	859	1,727	859	1,727
	557,073	216,265	537,043	199,314

<sup>&</sup>lt;sup>1)</sup> The license revenue refers to revenue from Nestlé. The lincense revenue is included in component products but is reported on a separate line in order to achieve better comparability between years.

#### Cont'd, Note 2

#### Trade receivables by segment:

	31-Dec	31-Dec	31-Dec	31-Dec
	2012	2011	2012	2011
Finished consumer products	50,142	35,812	45,683	29,611
Component products	3,830	13,300	3,699	13,261
Other products	73	_	73	-
	54,045	49,112	49,455	42,872

In 2012, SEK 103.0 million, or 35.6% of the revenue excluding license revenue, was related to three customers, two in the Finished Consumer Products segment and one in the Component Products segment (2011: SEK 134.0 million or 42.3 per cent).

#### Net sales by geographical market:

	<u>Group</u>		Parent C	company
	2012	2011	2012	201
Europe	203,328	234,505	203,328	234,50
License revenue (Europe)2)	356 004	_	356 004	
USA and Canada	28,422	17,816	28,320	17,81
Asia	32,420	37,117	21,789	28,309
Rest of world	25,078	25,554	25,078	25,554
	645,252	314,992	634,519	306,182

2) The license revenue refers to revenue from Nestlé. The lincense 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 517,021 thousand (279,831), are located in Europe.

Of the Group's capital expediture on property, plant and equipment and intangible assets, totalling SEK 29,400 thousand (16,179), more than 90% pertained to Europe. Sales in Sweden amounted to SEK 11.4 million (14.4), or 3.9% (4.6%).

The Group's non-current assets amount to SEK 49.2 million, of which SEK 48.9 million is located in Sweden and SEK 0.3 million in other countries (the USA and Japan).

# SALES BY GEOGRAPHICAL MARKET\*) Asia USA and Canada Europe

#### Note 3 Revenue

	G	<u>Group</u>		Company
	2012	2011	2012	2011
Product revenue	280,484	302,309	269,751	293,499
Royalties	8,764	12,683	8,764	12,683
License revenue	356,004	_	356,004	-
	645.202	314.992	634.519	306.182

# Note 4 Employees and personnel expenses, remuneration to senior executives

#### Average number of employees by country:

	of whom,			of whom,
	2012	men	2011	men
Parent Company:				
Sweden	47	16	41	14
Subsidiaries:				
Sweden	15	12	13	11
Japan	6	5	5	4
USA	2	0	2	0
Total subsidiaries	23	17	20	15
Total Group	70	33	61	29

The number of employees in the Group at 31 December 2012 was 76 (64).

#### Salaries and other remuneration divided by country and between the Board/President and other employees:

	2012	2011	2012	2011
	Board	Board	Other	Othe
	and	and	employ-	employ-
	President	President	ees	ees
Parent Company:				
Sweden	3,267	2,975	23,703	20,836
Subsidiaries:				
Sweden	1,935	2,031	4,315	3,599
Japan	1,870	1,804	4,009	3,227
USA	-	-	1,144	985
Total subsidiaries	3,805	3,835	9,468	7,811
Total Group	7,072	6,810	33,171	28,647

#### Total salaries and social security expenses:

	<u>Group</u>		Parent C	ompany
	2012	2011	2012	2011
Salaries and other remuneration	40,242	35,457	26,970	23,811
Pension expenses for				
the Board and President	737	1,455	443	1,161
Pension expenses for other employees	3,400	2,965	2,898	2,561
Other social security expenses	12,074	10,490	9,682	8,386
Total	56,453	50,367	39,993	35,919

<sup>\*)</sup> Excluding license revenue from Nestlé of SEK 356 million

#### 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	0–7.5	>7.5-30	>30
within the range:	base amounts	base amounts	base amounts
Premium	6%	25%	0%

All employees aside from the President (for the President, see below) are covered by health insurance, with benefits, in addition to compensation from the Swedish Social Insurance Agency. 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 per cent of salary after a qualifying period of 3 months (depending on the level of salary).

#### 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 thereafter worked for BioGaia to a limited extent in the capacity of consultant.

At the end of 2012, BioGaia entered into a project agreement with Board member Jörgen Thorball's partly owned company XOventure. Under the agreement, and within the framework of XOventure's network, consultants will be hired to prepare preclinical documentation and product development strategy. The consulting assignment will begin in 2013.

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 7 persons who together with the President make up the executive management team. One senior executive works on a consulting basis since May 2003.

In the event of termination by the company, the President is entitled to full salary during an 18-month period of notice. For Vice Presidents, the corresponding period is 6 months. Other senior executives have a statutory notice period of at least 3 months in the event of termination by the company. For the President the company pays the cost of health insurance that provides sickness benefits equal to 75 per cent of salary after a qualifying period of 3 months. 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:

	1,200	8,685 0	1,367	296	11,567
Other senior execu (7 persons):	ıtives	6,618	924	0	7,542
President: Peter Ro	othschild	2,067	443		2,510
Board member:s Jan Annwall Stefan Elving Thomas Flinck Inger Holmström Jörgen Thorball Paula Zeilon	150 150 150 150 150 150			315	465 150 150 150 150
Board Chairman: David Dangoor:	300				300
	Director's fees	Variable Basic remun- salary eration	insurance including health insurance	Other remun-eration	Total

#### BioGaia's incentive scheme for the employees:

In June BioGaia carried out the warrant programme that was decided 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, which provided the Parent Company with proceeds of SEK 1.3 million. Each warrant entitles the holder to subscribe for one class B share for SEK 241.90 on 1 June 2015. Volatility was estimated at 40%.

If all of the subscription warrants are exercised, the company's equity will be increased by SEK 21.0 million. This represents a dilutive effect of approximately 0.5% on the share capital and 0.4% on the total number of votes upon the full exercise of warrants.

In order to achieve a high level of participation, the AGM decided to pay a subsidy of SEK 10 per warrant (after 1 June 2015) to the employees who have subscribed for subscription warrants but have not exercised the right to buy shares. No provisions for this obligation have yet been made, but will be continuously assessed. At present, the assessment is that all warrants will be exercised and that there is therefore no need for a provision.

#### Gender distribution:

	2012	2011	2012	2011
	Women	Women	Men	Men
Board members	2	2	5	5
Management including President	4	2	4	6

#### Note 5 Audit fees

	Gro	Group Parent Co		Company	
	2012	2011	2012	2011	
Grant Thornton Sweden AB:					
Audit assignments	408	431	325	346	
Audit services in addition to audit	120	120	120	120	
Audit advice	70	-	37	-	
Tax advice	50	25	30	15	
Other assignments	11	34	-	34	
Cherry, Bekaert & Holland, L.L.P.:					
Audit assignments	41	41	_	-	
Other assignments	129	100	-	-	
Nakashima Accounting Firm:					
Audit assignments	18	18	-	_	
Other assignments	-	-	-	_	

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.

#### Note 6 Other operating income

	Group		Parent Co	mpany
	2012	2011	2012	2011
Exchange gains on operating				
receivables and liabilities, net	_	304	-	304
	_	304	-	304

#### Note 7 Other operating expenses

	Gro	oup	Parent Co	mpany
	2012	2011	2012	2011
Exchange losses on operating receivables and liabilities, net	2,430	_	2,430	_
	2,430	_	2,430	_

# Note 8 Operating expenses allocated by type of cost

	_ <u>G</u>	Group		Company
	2012	2011	2012	2011
Cost of goods	88,179	98,727	97,475	106,868
Personnel expenses	56,435	50,529	39,887	35,727
Depreciation/amortisation	4,545	5,425	1,510	2,096
Other operating expenses	68,022	57,456	66,822	57,473
	217,181	212,137	205,694	202,164

Operating expenses include lease payments of SEK 191 thousand (192). Total minimum future lease payments fall due as follows: Within one year: 95
Within two to five years: 59

The Group's future payment commitments for rents amount to SEK 7.2 million, of which SEK 6.4 million refers to the Parent Company. The Group's rents fall due for payment in an amount of SEK 3.8 within one year and SEK 3.4 million within two to five years.

#### Note 9 Financial income

Gr	oup	Parent Co	ompany
2012	2011	2012	2011
8,569	3,270	11,607	5,947
5,676	2,522	5,676	2,522
14,245	5,792	17,283	8,469
	8,569 5,676	8,569     3,270       5,676     2,522	8,569     3,270     11,607       5,676     2,522     5,676

The Parent Company and the Group have entered into forward exchange contracts in EUR for a total of EUR 10.7 million (13.3) at an average exchange rate of SEK 9.01 of which EUR 7.1 million will mature in 2013 and EUR 3.6 million in 2014. The unrealised foreign exchange loss is reported as a financial income/expense.

#### Note 10 Financial expenses

	Gro	oup	Parent Co	mpany
	2012	2011	2012	2011
Other financial expenses	74	84	63	78
	7/	8/	63	79

#### Note 11 Tax on profit for the year

	G	iroup	Parent 0	Company
	2012	2011	2012	2011
Current tax	-87,846	-29,160	-85,591	-29,134
Tax on group contributions paid	_	_	-679	-647
Deferred tax	-24,525	-185	-	-
	-112,371	-29,345	-86,270	-29,781

#### Deferred tax expense/tax income:

	Group_		Parent Co	mpany
	2012	2011	2012	2011
Deferred tax income attributable to loss carryforwards capitalised				
during the year	-24,525	-185	-	_
	-24,525	-185	-	_
Change in deferred tax:	2012	2011	2012	2011
Opening balance deferred tax	185	_	_	_
Provision for deferred tax	24,525	185	-	_
Closing balance deferred tax	24,710	185	-	_

#### Reconciliation of nominal tax and actual tax expenses:

	G	Group_		Company
	2012	2011	2012	2011
Reported profit before tax	442,243	108,867	325,547	102,260
Nominal tax rate 26.3%	-116,310	-28,632	-85,619	-26,894
Tax effect of non-capitalised				
loss carryforwards	-2,436	-2,050	_	_
Tax effect of other non-deductible				
and non-taxable items	1,543	-237	-651	-2,887
Tax effect of group adjustments	_	1,574	_	_
Tax effect of temporary adjustments	s <b>4,832</b>	_	_	_
	-112,371	-29,345	-86,270	-29,781

The Group's loss carryforwards amounted to a total of SEK 52.5 million (61.9) at 31 December 2012. Loss carryforwards of SEK 0 thousand (0) are attributable to the Swedish companies.

No deferred tax has been recognised on loss carryforwards amounting to SEK 52.5 million (61.9). These carryforwards are attributable to the Japanese subsidiary and will expire as follows: SEK 2.6 million will expire in the financial year 2015, SEK 9.9 million in 2016, SEK 8.5 million in 2017, SEK 9.7 million in 2018, SEK 12.0 million in 2019, SEK 4.5 million in 2020 and SEK 5.3 million in 2021.

## Note 12 Non-controlling interests

	2012	2011	
Opening balance, 1 January	591	98	
Change in group structure	-	-2,660	
Non-controlling interests'			
share in profit/loss for the year	2,901	3,153	
Closing balance, 31 December	3,492	591	

The non-controlling interests refer to a 9.9% stake in the subsidiary CapAble AB that is held by its managing director and a 50% stake in the subsidiary TwoPac AB that is held by the management of TwoPac AB.

#### Note 13 Intangible assets

#### GROUP AND PARENT COMPANY:

	Capitalised development expenditure	Licenses and brands	Total intangible assets
Accumulated cost: Opening balance, 1 January 2011 Purchases	26,875 -	2,528	29,403
Closing balance, 31 December 20	11 26,875	2,528	29,403
Opening balance, 1 January 2012 Purchases	26,875 –	2,528 -	29,403
Closing balance, 31 December 20	12 26,875	2,528	29,403
Accumulated amortisation: Opening balance, 1 January 2011	25,702	2,528	28,230
The year's amortisation	909	_	909
Closing balance, 31 December 20	11 26,611	2,528	29,139
Opening balance, 1 January 2012 The year's amortisation	26,611 264	2,528	29,139 264
Closing balance, 31 December 20	12 26,875	2,528	29,403
Carrying amounts:			
At 1 January 2011	1,173	0	1,173
At 31 December 2011	264	0	264
At 31 December 2012	0	0	0

Capitalised expenses include internally generated and externally acquired assets.

#### Amortisation is recognised on the following lines in the income statement:

-	Group		Parent Company	
	2012	2011	2012	2011
Research and development expenses	264	909	264	909
	264	909	264	909

Amortisation begins when a project has been completed. The amortisation period varies between 5–10 years depending on the estimated useful life of the project. The year's amortisation refers to Animal Health products. All capitalised development expenses were fully amortised at 31 December 2012.

#### Total research and development expenditure:

	Group		Parent C	<u>ompany</u>
	2012	2011	2012	2011
Total R&D expenditure	35,185	33,035	35,267	33,058
The year's capitalisation of				
development expenses	_	_	_	_
Uncapitalised R&D expenditure	35,185	33,035	35,267	33,058
Amortisation/depreciation				
recognised in R&D expenses	603	1,282	601	1,225
R&D expenses with an				•••••••••••••••••••••••••••••••••••••••
effect on income	35,788	34,317	35,868	34,283

#### Note 14 Property, plant and equipment

#### GROUP:

				Office	Total
				equip-	property,
		Prod-	Work	ment	plant
	Land	uction	in	and	and
	and	equip-	pro-	com-	equip-
	buildings	ment	gress	puters	ment
Opening balance,					
1 January 2011	_	4,541	_	11,503	16,044
Opening balance,					
1 January 2011 in TwoPa	c AB –	13,461	3,141	746	17,348
Purchases	506	926	14,272	482	16,186
Sales and disposals	-	-2,241	-77	-264	-2,582
Reclassifications	-	2,046	-2,046	-	0
Impairment losses	-	-	-774	-	-774
Translation difference	-	_	-	50	50
Closing balance,					······································
31 December 2011	506	18,733	14,516	12,517	46,272
Onanina balansa					
Opening balance,	500	40.700	44.540	10.517	40.070
1 January 2012	506	18,733	14,516	12,517	46,272
Purchases	315	1,879	25,407	1,771	29,372
Sales and disposals	-	-2,421	05 770	-30	-2,451
Reclassifications	34,165	1,614	-35,779	-	_
Translation difference	_		_	-86	-86
Closing balance,		40.00=		44.470	
31 December 2012	34,986	19,805	4,144	14,172	73,107
		.0,000	.,	,	,
Accumulated amortication	n.	10,000	1,111	,	. 0, . 0 .
Accumulated amortisation	on:	.0,000	,,	14,112	
Opening balance,	on:		,,,,,	·	
Opening balance, 1 January 2011	on: –	2,983	-	8,845	11,828
Opening balance, 1 January 2011 Opening balance,	-	2,983	-	8,845	11,828
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa	-	2,983 7,128	- -	8,845 613	11,828 7,741
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa Depreciation	– c AB – –	2,983 7,128 2,398	- -	8,845 613 1,352	11,828 7,741 3,750
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa Depreciation Sales and disposals	-	2,983 7,128	- -	8,845 613 1,352 –259	11,828 7,741 3,750 –1,242
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa Depreciation Sales and disposals Translation difference	– c AB – –	2,983 7,128 2,398	- -	8,845 613 1,352	11,828 7,741 3,750
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa Depreciation Sales and disposals Translation difference Closing balance,	- c AB - - -	2,983 7,128 2,398 –983	- - - -	8,845 613 1,352 –259 36	11,828 7,741 3,750 -1,242 36
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa Depreciation Sales and disposals Translation difference	– c AB – –	2,983 7,128 2,398	- -	8,845 613 1,352 –259	11,828 7,741 3,750 –1,242
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011	- c AB - - - -	2,983 7,128 2,398 –983	- - - -	8,845 613 1,352 –259 36	11,828 7,741 3,750 -1,242 36
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation	- c AB - - - -	2,983 7,128 2,398 –983	- - - -	8,845 613 1,352 –259 36	11,828 7,741 3,750 -1,242 36
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance,	- c AB - - - -	2,983 7,128 2,398 -983 - 11,526	- - - -	8,845 613 1,352 -259 36 10,587	11,828 7,741 3,750 -1,242 36 <b>22,113</b>
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPa Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance, 1 January 2012	- c AB	2,983 7,128 2,398 -983 - 11,526	- - - -	8,845 613 1,352 -259 36 10,587	11,828 7,741 3,750 -1,242 36 <b>22,113</b>
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPal Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance, 1 January 2012 Depreciation	- c AB	2,983 7,128 2,398 -983 - 11,526 11,526 2,647	- - - -	8,845 613 1,352 -259 36 <b>10,587</b> 1,470	11,828 7,741 3,750 -1,242 36 <b>22,113</b> 4,282
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPal Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance, 1 January 2012 Depreciation Sales and disposals	- c AB	2,983 7,128 2,398 -983 - 11,526	- - - -	8,845 613 1,352 -259 36 <b>10,587</b> 1,470 -21	11,828 7,741 3,750 -1,242 36 22,113 4,282 -2,405
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPal Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance, 1 January 2012 Depreciation Sales and disposals Translation difference	- c AB	2,983 7,128 2,398 -983 - 11,526 11,526 2,647	- - - -	8,845 613 1,352 -259 36 <b>10,587</b> 1,470	11,828 7,741 3,750 -1,242 36 <b>22,113</b> 4,282
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPal Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance, 1 January 2012 Depreciation Sales and disposals	- c AB	2,983 7,128 2,398 -983 - 11,526 11,526 2,647	- - - -	8,845 613 1,352 -259 36 <b>10,587</b> 1,470 -21	11,828 7,741 3,750 -1,242 36 22,113 4,282 -2,405
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPal Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance, 1 January 2012 Depreciation Sales and disposals Translation difference Closing balance,	- c AB	2,983 7,128 2,398 -983 - 11,526 11,526 2,647 -2,384	0	8,845 613 1,352 -259 36 <b>10,587</b> 10,587 1,470 -21 -77	11,828 7,741 3,750 -1,242 36 22,113 4,282 -2,405 -77
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPal Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance, 1 January 2012 Depreciation Sales and disposals Translation difference Closing balance, 31 December 2012  Carrying amounts	C AB 0 0 on:	2,983 7,128 2,398 -983 -983 -11,526 11,526 2,647 -2,384 - 11,789	0	8,845 613 1,352 -259 36 <b>10,587</b> 10,587 1,470 -21 -77	11,828 7,741 3,750 -1,242 36 22,113 4,282 -2,405 -77
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPal Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance, 1 January 2012 Depreciation Sales and disposals Translation difference Closing balance, 31 December 2012  Carrying amounts At 1 January 2011	- C AB	2,983 7,128 2,398 -983 -983 -11,526 11,526 2,647 -2,384 - 11,789	- - - - - - - - - 0	8,845 613 1,352 -259 36 <b>10,587</b> 10,587 1,470 -21 -77 <b>11,959</b>	11,828 7,741 3,750 -1,242 36 22,113 4,282 -2,405 -77 23,913
Opening balance, 1 January 2011 Opening balance, 1 January 2011 in TwoPal Depreciation Sales and disposals Translation difference Closing balance, 31 December 2011  Accumulated depreciation Opening balance, 1 January 2012 Depreciation Sales and disposals Translation difference Closing balance, 31 December 2012  Carrying amounts	C AB 0 0 on:	2,983 7,128 2,398 -983 -983 -11,526 11,526 2,647 -2,384 - 11,789	0	8,845 613 1,352 -259 36 10,587 10,587 1,470 -21 -77	11,828 7,741 3,750 -1,242 36 22,113 4,282 -2,405 -77 23,913

#### Cont'd. Note 14

PARENT COMPANY:		Office	Total
		equipment	property,
	Production	and	plant and
	equipment	computers	equipment
Accumulated cost:			
Opening balance, 1 January 2011	2,315	10,032	12,347
Purchases	_	220	220
Sales and disposals	_	-70	-70
Closing balance, 31 December 20	11 2,315	10,182	12,497
Opening balance, 1 January 2012	2,315	10,182	12,497
Purchases	704	758	1,462
Sales and disposals	_	-30	-30
Closing balance, 31 December 20	12 3,019	10,910	13,929
Accumulated depreciation:			
Opening balance, 1 January 2011	2,012	7,301	9,313
Depreciation	85	1,101	1,186
Sales and disposals	_	-70	-70
Closing balance, 31 December 20	11 2,097	8,332	10,429
Opening balance, 1 January 2012	2,097	8,332	10,429
Depreciation	164	1,082	1,246
Sales and disposals	_	-21	-21
Closing balance, 31 December 20	12 2,261	9,393	11,654
Carrying amounts			
At 1 January 2011	303	2,731	3,034
At 31 December 2011	218	1,850	2,068
At 31 December 2012	758	1,517	2,275

Depreciation is recognised on the following lines in the income statement:

	Group		Parent Company	
	2012	2011	2012	2011
Cost of goods sold	1,774	2,249	-	_
Selling expenses	1,758	1,341	734	693
Administrative expenses	412	553	175	178
Research and	339	373	337	316
development expenses	339	3/3	331	310
	4,282	14,516	1,246	1,187

#### Note 15 Financial assets

#### PARENT COMPANY

Participations in group companies	2012	2011
At beginning of year	21,160	10,469
Conditional shareholder contribution to CapAble AB	2,583	-
Impairment loss of shares in CapAble AB	-2,583	-
Reclassification of TwoPac AB from		
associated company to group company	_	10,641
Purchase of Infant Baby AB	_	50
Book value at end of year	21,160	21,160

#### 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 ,00	100	0
TriPac AB /556153-2200/Stockholm	10,000	100	3,568
CapAble AB /556768-3601/Stockholm	9,010	90.1	6,901
BioGaia Japan Inc. /-/Hiroshima, Japan	180	100	0
TwoPac AB /556591-9767/Eslöv	5,000	50	10,641
Infant Baby AB /556873-8586/Stockholm	50,000	100	50
			21 160

The assets and liabilities of the American subsidiary BioGaia Biologics Inc. have been translated at the closing day rate of exchange, SEK 6.50 (6.88). All items in the income statement have been translated at the average exchange rate during the year, SEK 6.77 (6.48). The assets and liabilities of the Japanese subsidiary BioGaia Japan Inc. have been translated at an exchange rate of SEK 0.076 (0.089). All items in the income statement have been translated at an exchange rate of SEK 0.085 (0.082). The resulting translation differences have been recognised in consolidated comprehensive income.

CapAble AB was formed in the autumn of 2008. BioGaia owns 90.1 per cent of the company. CapAble's President, Staffan Pålsson, owns 9.9 per cent of the company. The non-controlling interests' share in equity of CapAble amounts to SEK -271 thousand.

TwoPac AB was formed in 2002 and is owned 50% by BioGaia and 50 per cent by the management of TwoPac. The non-controlling interests' share in equity of TwoPac amounts to SEK 3,763 thousand.

Of total purchases made by the Parent Company, 15.4% (13.9) was attributable to group companies. Of total sales made by the Parent Company, 0.7 per cent (1.2) was attributable to group companies.

# Note 16 Non-current receivables from subsidiaries and associated company

#### Non-current receivables from subsidiaries:

	2012	2011
	Parent Company	Parent Company
At beginning of year	16,513	1,022
Payment of Ioan to BioGaia Japan Inc.	1,670	4,451
Payment of Ioan to TwoPac AB	8,000	11,091
Reclassification of loan to associated compan	y –	4,400
Sale of products to BioGaia Japan Inc.	4,518	3,759
Interest income from BioGaia Japan Inc.	2,386	2,243
Provisions for receivables 1)	-8,574	-10,453
	24,513	16,513

<sup>&</sup>lt;sup>1)</sup> Because it is uncertain whether the receivable from the subsidiary in Japan will be repaid within the foreseeable future, a provision has been made for this amount.

#### Non-current recievables from subsidiaries at December 31:

	2012	2011
	Parent Company Pa	arent Company
CapAble AB	1,022	1,022
TwoPac AB	23,491	15,491
Closing balance at end of year	24,513	16,513

#### Note 17 Inventories

	<u>Group</u>		Parent Company	
	2012	2011	2012	2011
Raw materials and consumables	1,904	2,297	_	96
Finished goods and goods for resale	18,941	19,231	18,693	18,569
	20,845	21,528	18,693	18,665

The company's provisions for obsolescence amounted to SEK 937 thousand (469) at 31 December 2012. An individual assessment of the obsolescence reserve has been carried out. The entire inventory value is recorded at cost with a deduction for obsolescence.

#### Note 18 Trade receivables

The Group and the Parent Company have recorded a loss of SEK 0 thousand (0) on the write-down of trade receivables in 2012.

Provisions for bad debt losses amounted to SEK 268 thousand (244) at 31 December 2012.

At 31 December 2012, trade receivables of SEK 7,643 thousand (1,751) were overdue without any assessed grounds for impairment.

Of the overdue receivables, SEK 7,512 thousand had been recovered as of the closing date.

#### An age analysis of overdue trade receivables is shown below:

	Group		Parent Company	
	2012	2011	2012	2011
Less than 3 months	7,512	1,727	7,512	1,714
3-6 months	131	24	-	_
	7,643	1,751	7,512	1,714

#### The reported amounts for the Group's trade receivables by currency are:

	G	Group		ompany
	2012	2011	2012	2011
SEK	6,356	3,349	6,347	3,338
EUR	39,578	35,479	39,578	35,464
USD	3,617	3,327	3,495	3,314
DKK	_	756	_	756
NOK	35	_	35	_
JPY	4,459	6,201	-	-
	54.045	49.112	49.455	42.872

#### Note 19 Related party transactions

**Group** Annwall & Rothschild Investment AB holds 740,668 class A shares and 1,259,332 class B shares, corresponding to 11.6 per cent of the share capital and 36.2 per cent 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 transaction that took place during 2012 is a dividend of SEK 6.00 per share. No other transactions have taken place between BioGaia and Annwall & Rothschild Investment AB. For further information, see Note 4, Employees and personnel expenses.

At the end of 2012, BioGaia entered into a project agreement with Board member Jörgen Thorball's partly owned company XOventure. Under the agreement, and within the framework of XOventure's network, consultants will be hired to prepare preclinical documentation and product development strategy. The consulting assignment will begin in 2013.

Parent Company The Parent Company owns 50 per cent of TwoPac AB, which is reported as a group company since 1 January 2011. The Parent Company owns 100 per cent of the shares in BioGaia Biologics Inc, USA, BioGaia Japan Inc, Tripac AB and Infant Baby AB. The Parent Company owns 90.1 per cent of the shares in CapAble AB.

#### The following transactions have taken place with TwoPac AB:

	i ai ciii C	<u>Juliparty</u>
	2012	2011
Interest income	643	487
Loan paid	-8,000	-11,091
Purchase of goods	-29,314	-26,179

Goods are purchased at cost plus profit margin.

#### The following transactions have taken place with BioGaia Japan Inc.

	<u>raient company</u>	
	2012	2011
Interest income	2,386	2,244
Loan paid	-1,670	-4,451
Sale of goods	4,518	3,759

Due to uncertainty as to whether the receivable from BioGaia Japan will be recovered within the foreseeable future, a provision has been made for this amount.

#### The following transactions have taken place with BioGaia Biologics Inc.:

	Parent C	<u>ompany                                    </u>	
	2012	2011	
Purchase of services	-2,442	-2,384	

#### The following transactions have taken place with CapAble AB:

	Parent Company	
	2012	2011
Interest income	38	43
Sales of services	137	165
Group contribution paid	-2,583	-2,459
Tax on group contribution paid	679	647

#### The following transactions have taken place with Tripac AB:

	Parent C	<u>,ompany</u>
	2011	2010
Group contribution paid	_	-1
Tax on group contribution paid	_	_

Parent Company

#### The closing balance was as follows:

Non-current receivables, related parties	31 Dec 2012	31 Dec 2011
Non-current receivables, TwoPac AB Non-current receivables, CapAble AB	23,491 1.022	15,491 1.022
Non-current receivables, Capable Ab	24,513	15,513
Current liabilities, related parties		
Current liabilities, BioGaia Biologics Inc.	-700	-805
Current liabilities, BioGaia Japan	-4,241	-4,241
Current liabilities, CapAble AB	-5,592	-6,720
Current liabilities, Tripac AB	-4,648	-4,648
Current liabilities, TwoPac AB	-1,809	-2,990
	-16,990	-19,404

#### Note 20 Other receivables

	<u>Group</u>		Parent Co	ompany
	2012	2011	2012	2011
VAT refund	3,595	2,883	3,467	2,797
Tax asset	129	358	81	253
Foreign exchange contracts	3,296	2,873	3,296	2,873
Other receivables	577	930	541	556
	7,597	7,044	7,385	6,479

Forward contracts have been measured at fair value, taking into account the applicable interest rates and exchange rates on the balance sheet date.

# Note 21 Deferred expenses and accrued income

	<u>Group</u>		Parent Co	ompany
	2012	2011	2012	2011
Accrued income	2,063	3,633	2,063	3,620
Prepaid rents	1,066	880	808	789
Other deferred expenses	667	1,581	63	1,138
	3,796	6,094	2,934	5,547

#### Note 22 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 assets at fair value through profit or loss consist of cash and cash equivalents and short-term investments. The financial assets are recognised in the balance sheet and are valued at the closing day rate of exchange.

	Fair value		Carrying	amount
	31 Dec	31 Dec	31 Dec	31 Dec
Assets (SEK 000s)	2012	2011	2012	2011
Cash and cash				
equivalents in SEK	365,744	156,561	365,744	156,561
Cash and cash				
equivalents in EUR	4,978	12,319	4,978	12,319
Cash and cash				
equivalents in USD	3,998	2,358	3,998	2,358
Cash and cash				
equivalents in JPY	173	260	173	260
Cash and cash				
equivalents in DKK	81	36	81	36
Short-term investments	25	80	80	80
Total assets	374,999	171,614	375,054	171,614

Short-term investments refer to listed securities. The shares are recognised at historical cost less accumulated impairment. The intention is to sell the shares when an appropriate occasion arises. Fair value corresponds to the quoted market price on the balance sheet date.

The company has taken forward currency hedges EUR. The forward currency hedges have been recognised at their fair value at 31 December 2012. This value is included in other receivables – see Note 20.

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

**Loans and receivables** The Group's trade receivables amount to SEK 54,045 thousand (49,112). Fair value corresponds to the carrying amount.

**Other financial liabilities** TThe Group's other financial liabilities consist of trade payables and prepayments from customers.

_	Fair value		Carrying	Carrying amount	
	31 Dec	31 Dec	31 Dec	31 Dec	
	2012	2011	2012	2011	
Trade payables	14,731	17,769	14,731	17,769	
Prepayments from customers	3,118	2,960	3,118	2,960	
Total other financial liabilities	17,849	20,729	17,849	20,729	

#### Note 23 Equity

The share capital in BioGaia AB consists of 740,668 class A shares, carrying 10 votes each, and 16,530,294 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.

A resolution was passed by the AGM in May to reduce the entire statutory reserve of SEK 77.8 million and transfer this amount to non-restricted reserves. The reduction was registered in August 2012.

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

Retained profit consists of other equity. The Parent Company's dividend for 2012 was SEK 103.6 million, equal to SEK 6.00 per share. For 2013 the Board and President propose that the company pay an ordinary dividend of SEK 4.15 per share and an extraordinary dividend of SEK 5.85 per share, amounting to a total dividend of SEK 10.00 per share. This is equal to total dividends of SEK 172.7 million.

Non-controlling interests account for 9.9 per cent of equity in the subsidiary CapAble and 50 per cent of equity in the subsidiary TwoPac 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 2011, total consolidated equity amounted to SEK 456.8 million (230.3) and equity attributable to owners of the Parent Company amounted to SEK 453.3 million (229.8).

**BioGaia's dividend policy** has previously been to pay a shareholder dividend equal to 30% of profit after tax. The Board has now decided to change the policy so that shareholder dividends in the coming years amount to 40% of profit after tax.

#### Key ratios

	2012	2011	
Number of shares at 31 Dec., thousands	17,271	17,271	
Average number of shares, thousands	17,271	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	17,271	17,271	
Earnings per share, SEK	18.93	4,42	
Earnings per share after dilution, SEK	18.93	4,42	
Equity per share, SEK	26.25	13,30	
Equity per share after dilution, SEK	26.25	13,30	
Return on equity, %	96	37	
Share price on closing day, SEK	175.00	163.00	
Dividend per share SFK	10.00 <sup>1)</sup>	6.00	

1) Dividend proposed but not yet approved. The Board and President propose that the company pay an ordinary dividend of SEK 4.15 per share and an extraordinary dividend of SEK 5.85 per share, equal to a total dividend of SEK 10.00 per share.

#### Note 24 Other liabilities

	Group		Parent Company	
	2012	2011	2012	2011
Employee withholding tax	1,036	880	883	779
Other current liabilities	1,829	416	-	-
	2,865	1,296	883	779

# Note 25 Accrued expenses and deferred income

	<u>Group</u>		Parent C	ompany
	2012	2011	2012	2011
Accrued holiday pay	5,190	3,985	4,169	3,364
Accrued social security expenses	1,077	859	810	709
Other accrued expenses	8,537	10,321	8,110	9,190
	14,804	15,165	13,089	13,263

# Note 26 Pledged assets and contingent liabilities

	<u>Group</u>		Parent Company		
Pledged assets	2012	2011	2012	2011	
Floating charges Blocked account for new	2,000	2,000	2,000	2,000	
facility in TwoPac AB	_	3,874	_	_	
Contingent liabilities	None	None	None	None	

#### Note 27 Tax allocation reserve

	Parent C	Company
	31-dec	31-dec
	2012	2011
Tax allocation reserve	109,341	_
Deferred tax in tax allocation reserve	24,055	_

# Note 28 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 minimise the risk for negative effects on the Group's earnings. Consequently, the Group's financial investments must have a low risk profile. The Group's assessed risk exposure and related risk management are described below:

Currency risk BioGaia has revenue primarily in EUR (around 75 per cent of net sales excluding the license revenue fron Nestlé) but also in SEK, USD and JPY, and expenses primarily in SEK, EUR, JPY and USD. In 2012 the company had a cash flow surplus of approximately EUR 55.6 million (17.6), including the payment of EUR 40 million from Nestlé a cash flow deficit of JPY -81.2 million (-65.2) and a cash flow deficit of USD 1.7 million (0.3). 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 per cent of projected cash flow 12 months forward and approximately 10-40 per cent of projected cash flow 13-24 months forward in order to spread the risk for exchange rate fluctuations. At 31 December 2012 the company had outstanding forward exchange contracts for EUR 10.7 million at an average exchange rate of SEK 9.01, of which EUR 7.1 million will mature for payment in 2013 and EUR 3.6 million in 2014. For more information see Notes 10 and 21. A stronger SEK rate against the EUR 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 should be able to minimise the impact on earnings. BioGaia is also trying to reallocate a portion of its revenue from EUR to other currencies, primarily SEK.

Interest rate risk The Group has no loans and therefore no interest rate risks. Excess liquidity is held in bank or invested in fixed income securities with a high credit rating, which the company regards as a risk-free investment.

Credit risk 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 minimise risks.

The loan from the Parent Company to the subsidiary CapAble AB has been used to purchase equipment for manufacturing of LifeTop Cap. The company's assessment is that the loan entails low credit risk.

The loan from the Parent Company to the subsidiary TwoPac AB has been used mainly to build a new production facility in Eslöv, Sweden. The facility was completed and commissioned during 2012. The company's assessment is that the loan entails low credit risk.

**Liquidity risk** The company's cash and cash equivalents shall be invested only in bank accounts, commercial paper or other fixed income securities with very limited risk. This means that no investements may be made in shares, equity funds, options, etc.

Cash flow risk In 2012 BioGaia had a positive cash flow from operating activities before changes in working capital of SEK 338.5 million (77.2). After changes in working capital, cash flow was SEK 335.6 million (72.8). Total cash flow for the year was SEK 203.8 million (24.7). Because cash and cash equivalents at 31 December 2012 amounted to SEK 375.0 million (171.5) and cash flow is positive, no infusion of capital is necessary.

**Price risk** BioGaia buys most of its goods on the international market and has several alternative suppliers, which minimises the company's price risk.

# Note 29 Critical accounting estimates and assumptions

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

BioGaia's Japanese venture The Japanese subsidiary has operated at a loss since the start in 2006. The previously chosen business model was found to be unsuccessful and in 2010 BioGaia decided to change the business model in Japan to that which is used in the other markets. On the balance sheet date, assets in the Japanese subsidiary were reported at SEK 7.0 million (8.7). BioGaia's assessment is that the subsidiary will show good profitability in the future, for which reason there was no indication of impairment of these assets on the balance sheet date.

Shares in group companies CapAble, which is 90.1 per cent owned by BioGaia AB, was started in November 2008 to manufacture and sell the patented LifeTop Cap. The shares in the subsidiary CapAble are reported at a total of SEK 6.9 million in the Parent Company. CapAble has operated at a loss since the start in 2008. Loss before tax for 2012 was SEK -2.6 (-2.5) million. BioGaia made total conditional shareholder contributions of SEK 6 million to CapAble in 2009 and 2010. BioGaia AB made total group contributions of SEK 7.3 million during the period 2010-2012. BioGaia's assessment is that CapAble will show good profitability in the coming years, for which reason there was no indication of impairment on the balance sheet date.

Recognition of license revenue In February 2012 BioGaia signed several new agreements with Nestlé including the acquisition of a perpetual license to use BioGaia's probiotic in infant formula during the remaining term of the patent. The purchase price was EUR 50.8 million, of which EUR 40.0 million (SEK 356 million) was received and recognised in the first quarter of 2012, in accordance with generally accepted accounting principles.

The additional payments of EUR 10.8 million will be received during 2014-2017 on the achievement of predefined milestones.

The company assesses the probability of achieving these milestones as high, but is of the opinion that there is still too much uncertainty to recognise this revenue in accordance with generally accepted accounting principles.

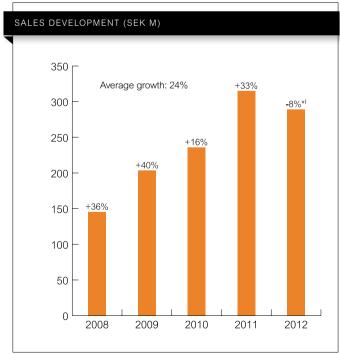
The Board of Directors and the President hereby give their assurance that the consolidated financial statements and annual report have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and generally accepted auditing practices, and give a true and 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, 19 February 2013

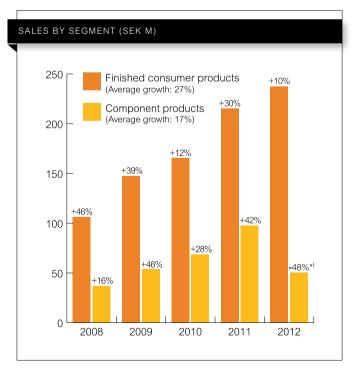
David Dangoor Chairman	Peter Rothschild President
Jan Annwall	Stefan Elving
Thomas Flinck	Inger Holmström
Jörgen Thorball	Paula Zeilon

My audit report was submitted on 19 February 2013 Grant Thornton Sweden AB

Lena Möllerström Nording
Authorised Public Accountant



<sup>\*)</sup> Excluding license revenue from Nestlé of SEK 356 million

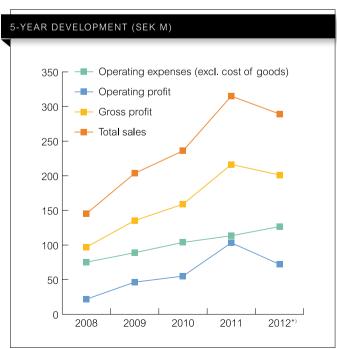


# Five-year summary

Key ratios	2012	20121)	2011	2010	2009	2008
Net sales, SEK M	645.2	289.2	315.0	236.0	203.5	145.2
Net sales, finished consumer products, SEK M	237.6	237.6	215.4	165.6	147.7	106.3
Net sales, component products, SEK M	406.6	50.6	97.7	68.6	53.8	36.9
Operating profit, SEK M	428.1	72.1	103.2	56.3	47.7	25.8
Profit before tax, SEK M	442.2	86.2	108.9	69.7	53.1	24.0
Profit after tax, SEK M	329.9	63.7	79.5	47.2	36.0	36.1
Profit after tax attributable to owners of the Parent Company, SEK M	327.0	60.8	76.4	47.3	36.3	36.1
Growth, %	105	-8	33	16	40	36
Operating margin, %	66	25	33	24	23	18
Profit margin, %	69	30	35	30	26	17
Current ratio, times	13.2	5.1	5.2	5.1	8.2	5.1
Equity/assets ratio, %	88	824)	82	82	90	86
Capital employed, SEK M	481.5	195.74)	230.5	187.3	161.1	132.4
Return on capital employed, %	124	404)	52	40	36	25
Return on equity, %	96	29 <sup>4)</sup>	37	27	25	32
Average number of employees	70	70	61	45	43	39
Data per share						
Number of shares at 31 Dec., thousands 2)	17,271	17,271	17,271	17,271	17,208	17,208
Average number of shares, thousands	17,271	17,271	17,271	17,230	17,208	17,208
Number of outstanding warrants, thousands	87	87	_	_	129	129
Number of outstanding warrants with a dilutive effect, thousands	-	_	_	_	129	-
Number of outstanding shares including outstanding warrants						
with a dilutive effect, thousands	17,271	17,271	17,271	17,271	17,337	17,208
Basic earnings per share, SEK	18.93	3.52	4.42	2.74	2.11	2.10
Diluted earnings per share, SEK	18.93	3.52	4.42	2.74	2.09	2.10
Equity per share, SEK	26.25	10.834)	13.30	10.84	9.37	7.69
Equity per share after dilution, SEK	26.25	10.834)	13.30	10.84	9.30	7.69
Share price on the balance sheet date, SEK	175.00	175.00	163.00	96.00	80.00	33.10
Dividend per share, SEK	10.00 <sup>3)</sup>	10.00 <sup>3)</sup>	6.00	2.00	1.50	0.40

<sup>&</sup>lt;sup>1)</sup> Key ratio excluding license revenue from Nestlé. For more information, see administration report.

<sup>&</sup>lt;sup>4)</sup> Adjusted compared to the year-end report for 2012.



#### \*) Excluding licence revenue from Nestlé of SEK 356 Million

#### Definitions

**Basic earnings per share** Profit after tax attributable to owners of the Parent Company divided by the number of shares.

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.

# Audit report

To the general meeting 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 for the year 2012. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 38-60.

Responsibilities of the Board of Directors and the President for the annual accounts and consolidated accounts The Board of Directors and the President 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 President 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 President, 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 opinion.

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 2012 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 2012 and of their financial performance and cash flows in accordance with International 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 statement of consolidated income and financial position for the Group.

# Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have examined the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the President of BioGaia AB for the year 2012.

Responsibilities of the Board of Directors and the President 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 President 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 and the Articles of Association.

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 President is liable to the company. We also examined whether any member of the Board of Directors or the President 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 opinion.

**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 President be discharged from liability for the financial year.

Stockholm, 19 February 2013 Grant Thornton Sweden AB

Lena Möllerström Nording

Authorised Public Accountant

<sup>&</sup>lt;sup>2)</sup> The share capital consists of 740,668 class A shares and 16,530,294 class B shares. The quota value is SEK 1 per share.

<sup>&</sup>lt;sup>3)</sup> Dividend proposed but not yet approved.

# Corporate governance report 2012

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.

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 11.6 per cent of the share capital and 36.2 per cent of the votes in the company. Other individual shareholders hold less than 10 per cent of the share capital and votes each.

2012 AGM BioGaia's AGM was held on 8 May 2012 and was attended by shareholders representing 51.5 per cent 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 and all of the Board members elected by the year's AGM, as well as the company's elected auditor.

2013 AGM The 2013 AGM will be held at 1:00 p.m. on Friday, 26 April 2013, at Lundqvist & Lindqvist 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 shall be published in Svenska Dagbladet no earlier than six weeks and no later than four weeks prior to the AGM.

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

The 2012 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 2012. 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 their 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 AGM 2013. 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. The same applies of a member of the Nominating Committee leaves the Committee for some other reason.

In accordance with the AGM's resolution, the Nominating Committee was appointed and consists of Per-Erik Andersson, representing Annwall & Rothschild Investment AB, the company's largest shareholder, Allan Ladow, representing Sebastian Jahreskog, who via direct and indirect ownership is the second largest shareholder, and Board Chairman David Dangoor, the third largest shareholder. All three members of the Nominating Committee are independent in relation to the company and its management.

The Nominating Committee will prepare recommendations for the following matters to be put before the 2013 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) fees for members of the Board
- e) fees for the auditors

f) appointment of the Nominating Committee ahead of the 2014 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.

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 2012 the Board consisted of seven 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 six remaining members are independent in relation to both the company and its management. A presentation of the Board is provided on pages 66-67.

BioGaia's independent legal counsel has been appointed to serve as Secretary at Board meetings. The President is not a member of the Board but is coopted 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 division of responsibilities between the Board and the President and the structure of Board activities during the year. Furthermore, the Board has adopted instructions for the President, authorisation instructions including instructions for liquidity management and a policy for foreign exchange management. The rules of procedure, President's instructions and authorisation instructions are reviewed at least once a year.

The Board decides on matters related to the Group's overall strategy, organisation and management. The Board approves both interim reports and the annual report before these are published. The Board held eight minuted meetings and one strategy seminar in 2012. All members attended the Board meetings during the year, including the strategy seminar. At these meetings the Board has discussed budgetary matters, business plans, financial accounts, investments, financial reports and major agreements. At the strategy seminar, the Board dealt mainly with issues concerning R&D, product development, patent strategy, regulatory and quality issues and related matters.

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

Board fees The 2012 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 eight individuals who are presented on pages 66-67. 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 authorisation

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 2010 AGM elected Grant Thornton Sweden AB as the company's auditor until the end of the 2014 AGM, Grant Thornton has appointed Lena Möllerström Nording as Auditor in Charge. By decision of the AGM, auditing fees are paid according to the way's of operation.

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 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.

In addition, 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 5 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. Instead, 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 2012 financial year

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.

Financial reporting The Board is responsible for ensuring that the company's organisation 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 authorisation 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 organisation and its operation in which 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

BioGaia's values BioGaia also has a set of shared values and the company's employees are well aware of these (see below).

BioGaia's vision is to improve the health of people around the world by offering first class probiotic solutions.

BioGaia and BioGaia's employees

- are fast, innovative and respectful
- build strong relationships with their customers
- strive for high quality and deliver on time
- have ethical principles and are open and honest
- take personal responsibility for and are dedicated to the company's success

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 the identification of significant risks for misstatements and deficiencies in the financial reporting. To limit these risks, suitable processes and controls are built into the company's operations. 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. Authorisation 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 2012 the company's employees met for two days in May.

Monitoring The Executive Management performs a yearly evaluation of the effectiveness of internal control. Every year, the company's elected auditing firm, Grant Thornton Sweden AB, also audits of 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, 19 February 2013

Board of Ddirectors 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 2012 (on pages 62-63) 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, 19 February 2013 Grant Thornton Sweden AB

Lena Möllerström Nording Authorised 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 2012 BioGaia shares were traded for a total of around SEK 1,077 million (872), corresponding to approximately 6.0 million shares (6.3).

The number of shareholders at 31 December 2012 was 7,384 (6,752).

The total registered share capital of BioGaia AB consists of 740,668 class A shares and 16,530,294 class B shares.

Share price development In 2012 the share price increased from SEK 163.00 to SEK 175.00. The highest closing price during the year was SEK 227.50 and the lowest was SEK 144.75. Market capitalisation at 31 December 2012 was approximately SEK 3,022 million (2,815).

**Dividend policy** BioGaia's previous policy was to pay a shareholder dividend equal to 30% of profit after tax. In February 2013 the Board decided to change the policy so that shareholder dividends amount to 40% of profit after tax in the future.

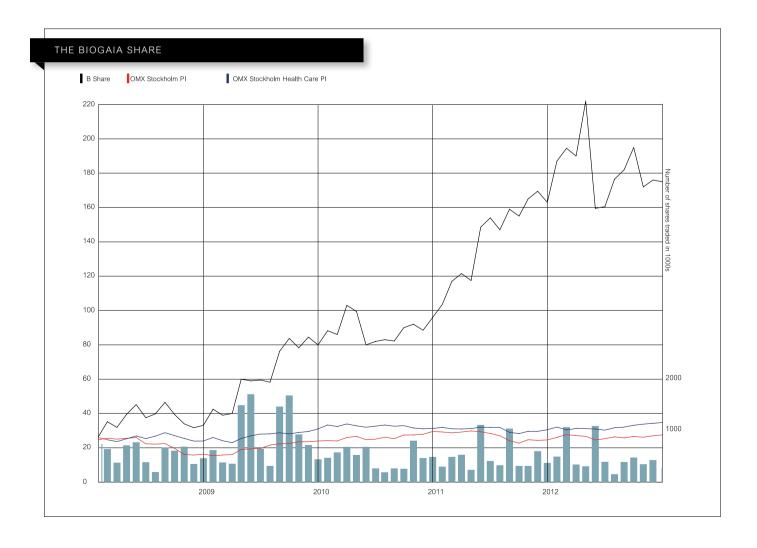
**Incentive scheme** In June BioGaia carried out the warrant programme that was decided by the Annual General Meeting on 8 May 2012. A total of 87,000 warrants were subscribed for, of which the management subscribed for 41,000. The

warrants were issued at a market price of SEK 14.27 each following valuation according to the Black & Scholes formula, which provided the Parent Company with proceeds of SEK 1.3 million. Each warrant entitles the holder to subscribe for one class B share for SEK 241.90 on 1 June 2015. Volatility was estimated at 40%.

If all of the subscription warrants are exercised, the company's equity will be increased by SEK 21.0 million. This represents a dilutive effect of approximately 0.5% on the share capital and 0.4% on the total number of votes upon the full exercise of warrants.

#### Distribution of ownership

Distribution of ownership				
	Total number of shareholder			
Number of shares	31 December 2011	31 December 2012		
1–500	5,245	5,933		
501-1,000	781	733		
1,001–5,000	525	502		
5,001–10,000	72	80		
10,001–15,000	21	24		
15,001–20,000	13	23		
20,001-	95	89		
Total number of shareholders:	6,752	7,384		



#### Largest shareholders in BioGaia at 31 December 2012 (source: Euroclear 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	1,259	2,000	8,666	11.6	36.2
Sebastian Jahreskog	7-71	1.144	1.144	1.144	6.6	4.8
David Dangoor (incl. company)		569	569	569	3.3	2.4
Futuris		530	530	530	3.1	2.2
Handelsbankens fondbolag		510	510	510	3.0	2.1
Pictet & CIE, W8IMY		506	506	506	2.9	2.1
Swedbank Robur fonder		416	416	416	2.4	1.7
Handelsbanken Fonder AB		415	415	415	2.4	1.7
Skandinaviska Enskilda Banken S.A., NQI		407	407	407	2.4	1.7
AMF-Försäkring och fonder		387	387	387	2.2	1.6
Caroline Hamilton		302	302	302	1.7	1.3
Försäkringsaktiebolaget Avanza Pension		288	288	288	1.7	1.2
Banque Carnegie Luxembourg SA		279	279	279	1.6	1.2
Hanvad Invest Aktiebolag		268	268	268	1.6	1.1
Six Sis AG		264	264	264	1.5	1.1
SSB CL Omnibus AC		256	256	256	1.5	1.1
Livförsäkringsaktiebolaget Skandia		249	249	249	1.4	1.0
Bk Julius Baer & Co Sweden Main AC		234	234	234	1.4	1.0
Fidelity Nordic Fund		229	229	229	1.3	1.0
JPM Chase NA		208	208	208	1.2	0.9
Subfund Ruffer European FD		200	200	200	1.2	0.8
Lars Thunberg		197	197	197	1.1	0.8
Sten Irwe		178	178	178	1.0	0.7
Credit Agricole Suisse SA		163	163	163	0.9	0.7
UBS AG Clients Account		154	154	154	0.9	0.6
Other shareholders		6 918	6 918	6 918	40.1	28.9
Total	741	16,530	17,271	23,937	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	no. or onaroo	oapitai, ozrt	150,000	71 0110100	30,000	5.00	
1991	New share issue	12,857	64,285	214,285		42,857	5.00	
1993	New share issue	12,554	62,770	277,055		55,411	5.00	, ,
1995	New share issue	2,303	11,515	288,570		57,714	5.00	, ,
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 <sup>*</sup>
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 November	425,000	425,000	17,107,562	740,668	16,366,894	1.00	11,505,294*
2004	New share issueIndustrifonden	100,000	100,000	17,207,562	740,668	16,466,894	1.00	100,000
2010	New share issue warrant progra	amme 63,400	63,400	17,270,962	740,668	16,530,294	1.00	4,862,780

<sup>\*</sup> Excluding underwriting costs



#### PETER ROTHSCHILD

Born in 1950. M.B.A. President, founder and principal shareholder. Board assignments in Looft Industries AB and Moberg Derma AB. Holds 370,334 class A shares and 629,666 class B shares via Annwall & Rothschild Investment AB and 10,000

#### 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 9,000 class B shares and
3,000 warrants.

#### ANN WENNERSTRÖM

Born in 1961. Registered nurse, education in marketing, PR and Public Affairs. Marketing Director. Employed by the company since 2012. Holds 6,000 warrants.

#### STAFFAN STRÖMBERG

Born in 1967. Ph.D. Eng. Vice President Development & Regulatory Affairs. Employed by the company since 2012. Holds 6,000 warrants.

#### **EAMONN CONNOLLY**

Born in 1957. Ph.D.
Senior Vice President Research.
Employed by the company since 2000, in current position since 2002.
Holds 0 shares.

#### JESSICA EIDEMO

Born in 1974. M.Sc. Biology. Sales Director. Employed by the company since 2012. Holds 6,000 warrants.

#### KRISTINA SILVERIO UR

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

#### URBAN STRINDLÖV

Born in 1964. Mechanical Engineer. Executive Vice President Partner Alliances and Product Development. Employed by the company since 2004, in current position since 2010. Holds 10,000 warrants.

#### **Board of Directors**

#### DAVID DANGOOR

Born in 1949. Chairman of the Board. 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 Prends Inc.

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

#### INGER HOLMSTRÖM

Born in 1948. Elected to the Board in 2007. M.A. in language and linguistics and a degree in journalism. Communication and Relationships Director in Paf. Former Corporate Communications Director at Coop Norden, Posten and Vattenfall.Other board assignments: Star Management AB. Holds 500 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 629,666 class B shares via Annwall & Rothschild Investment AB.

#### JÖRGEN THORBALL

Born in 1962. Elected to the Board in 2008. Physician. Managing Partner in XOventure GmbH. Former international senior positions for example at Novozymes, BioGaia, Aventis and Pharmacia. Other board assignments: ViroGates A/S, YourGlobalEye Aps and Immudex A/S. Holds 0 shares.

#### PAULA ZEILON

Born in 1962. Elected to the Board in 2003. M.Sc.Eng. Partner in Conlega affärskonsultbolag. President of Life Science Foresight Institute. Former Marketing Director of Amersham Biosciences AB. Holds 1,000 shares.

#### STEFAN ELVING

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

#### THOMAS FLINCK

Born in 1948. Elected to the Board in 1996. M.B.A. Managing Director and partner in Centrecourt AB. Other board assignments: Centrecourt AB, Briggen Tre Kronor AB, Hemverket AB and Inner Sweden Holding AB.





The annual report will be distributed to all shareholders.

The year-end report, annual report and quarterly reports are also available in English.

All financial information is published on www.biogaia.com and can be ordered from BioGaia's head office.

The 2013 AGM will be held at 1:00 pm on Friday 26 April 2013 at Lundqvist & Lindquist

Klara Strand, Klarabergsviadukten 90 in Stockholm.

#### Headoffice BioGaia AB

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