“BioGaia’s probiotic reduced colic in infants and improved quality of life for the family”
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.

**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. Powerfull 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 10 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 rights to use *Lactobacillus reuteri* Protectis in infant nutrition products during the remaining term of the patent, which resulted in license revenue of SEK 306 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.
- Ferozam for the sale of drops and digestive health tablets in Pakistan.

**NEW AGREEMENTS FOR LACTOBACILLUS REUTERI PRODENTIS WITH**

- Next Force in the Czech Republic.
- Iovdent in South Africa.
- Oral Company in the Benelux countries.
- Pharmafora in Singapore.
- Deodex 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.

**KEY RATIOS**

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<td>Net sales, SEK M</td>
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<td>82</td>
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<tr>
<td>Average number of employees</td>
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<td>61</td>
<td>45</td>
<td>43</td>
<td>39</td>
</tr>
</tbody>
</table>

**TOP EVENTS 2012**

- The fermentation facility Multiferm 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.
- 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 (51 per cent-owned) in Espoo is formed together with a couple of entrepreneurs to develop a concept for straws containing *Lactobacillus reuteri*.
- BioGaia extends and deepens its collaboration with Nestlé. TwoPac’s new production facility is completed.

**HIGHLIGHTS OF 2012**

- **1990** Peter Rothchild 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** ICA acquires the BRA trademark and concept.
- **1996** Introduction of Lactoforte.
- **1997** The fermentation facility MultiFerm 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** 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 (51 per cent-owned) in Espoo is formed together with a couple of entrepreneurs to develop a concept for straws containing *Lactobacillus reuteri*.
- **2006** The first year that the company makes a profit.
- **2008** CapAble is founded and is responsible for development of caps containing *Lactobacillus reuteri*.
- **2009** 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 51 per cent-owned subsidiary TwoPac builds a new production facility in Espoo to meet demand for increased volumes.
- **2012** BioGaia acquires the BRA trademark and concept.

**WEB DESIGN**

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Every 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 2006 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 €10.8 million in February and will pay an additional €356 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 closer to the launch dates. Two of them have already been announced, namely the agreement with Gerber, Nestlé’s subsidiary in the US, and that with Nestlé Mexico for the sale of BioGaia’s probiotic drops in these countries. The goal is to quickly build up our sales to Nestlé at least on par with the level in 2012.

**THE NEW EFSRA 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 we do not stand or fall with the results of individual trials. We work across a number of different indication areas and are thus not dependent on success in every one of these.

It is difficult to say whether, and if so, how we have been affected by the financial crisis in Europe, although sales are in fact growing in a number of markets. Since this involves markets where we sell 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.

**IN THE PAST YEAR, TWO PAC,** our 50 per cent-owned manufacturing company in Eslov, 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.

**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.

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**IT IS DIFFICULT TO SAY** whether, and if so, how we have been affected by the financial crisis in Europe, although sales are in fact growing in Italy and Spain. It is not unreasonable to assume that a better economic situation in Europe would have positive consequences 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.

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**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 2013 we will focus on the BRIC countries and the US market. We are also continuing to build our brand. Sales of products under 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.

Peter Rothchild, Founder and President, BioGaia
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.

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Digestive 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 25 per cent of all infants in the West. Colic is defined as recurrent 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.

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.

BIOGAIA ANNUAL REPORT 2012
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.

The 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 Protectis 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.

BioGaia a world-leader with unique products

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.

In 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”.

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.
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.

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

2. **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.

4. **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 it is 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.

A 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 recently been 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 glycocide hydrodase 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 our 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. Recent performed treatments show that enemas containing the faeces of healthy individuals, known as “stool transplants”, can be successful. These can be performed treatments show that enemas containing the faeces of healthy individuals, known as “stool transplants”, can 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 microbiome seems to somehow confuse 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.

**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 Sammon Connolly and his colleagues function as the pivotal link and engine.

**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** 13th International Symposium of Probiotics and Prebiotics in Pediatrics 2012
- **STOCKHOLM, SWEDEN** ESPGHAN 2012
- **MOSCOW, RUSSIA** Global Congress for Consensus in Pediatrics & Child Health 2012
- **VIENNA, AUSTRIA** Europero 7 The European Federation of Periodontology
- **SARAWAK, MALAYSIA** 14th Asia Pacific Congress of Pediatrics (APCP)
- **HELSINGI, FINLAND** PIER / 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).

The majority of clinical studies carried out with BioGaia’s products are randomised, double-blind and placebo-controlled, and are thus fairly 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 microbiota 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 microbiota 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 ratti 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 microbiota 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.

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). Necrotising enterocolitis 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 5–10 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, 7.5 per cent with birth weight 2000 grams was reduced by 43 per cent. 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 microbiota.

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 intoler- ance in the infants with a birth weight below 1500 grams was reduced by 43 per cent.

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.

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, 492 apparently healthy children between the ages of one and six years were randomly assigned to four groups, of which one received supplements of Lactobacillus ratti 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.
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.

“Later studies on colic seemed too good to be true. It is always useful to conduct a study that confirms those 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 first 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.”

Earlier studies on colic

2007

For a period of 28 days, 85 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 53 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.

2010

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.

26% of all infants in the West.

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

**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.


**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.

**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.**
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.

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 10 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.

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 Activia (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.
**Market maturity:** Probiotics like yoghurt well-known among the public.
**Products:** BioGaia Profectis 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.

A stomach in balance is a happy stomach.
**Trio with strong growth**

There are many common denominators between the three neighbouring countries of Croatia, Serbia and Slovenia, for example that Linex is one of the main competitors. The product has been sold in the region for a long time – 36 years in Slovenia – where it is even registered as a type of pharmaceutical. Another thing they have in common is that BioGaia has been successful in establishing both the drops and the tablets. One explanation for this success is that Ewopharma focuses strongly on personal visits and cooperation with doctors and pharmacists. The number of sales staff in relation to the population is high compared to many other countries where BioGaia’s products are sold. In 2012 BioGaia ProDentis was launched in all three countries.

**Croatia**

**Partner:** Ewopharma.

**Population:** 4.4 million.

**Births per year:** 44,000.

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

**Products:** ProTects 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, Sandox with Linex and 35c with ProfiLife and Neormia. 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 20 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:** ProTects 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 33 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 children and infants, amongst 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:** ProTects 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 2.5 billion tablets are sold for each child born. As in the other countries, Ewopharma focuses on the market for probiotics for oral health is immature and will take time to build up.

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 terms of both volume and patient dialogue is another success factor.

“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 antibiotic-associated 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 year.”

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 health tablets.”
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 ProFectics 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.

Singapore

**Partners:** Age D’Or and Nestlé.  
**Population:** 5.2 million.  
**Births per year:** 242,300.  
**Market maturity:** Probiotics well known among doctors and the public.  

**Singapore is a small country with a high standard of living.** The Singaporeans 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 maintain a healthy bacteria culture. BioGaia has a market share of around 19 percent in the small and prosperous country of Singapore, which is a low level of knowledge among the public but enormous opportunities.

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.  

**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 Rilus 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.

Canada

**Partners:** Ferring and Sunstar.  
**Population:** 34.5 million.  
**Births per year:** 4.4 million.  
**Market maturity:** Probiotics relatively well known among both paediatricians and general practitioners, with regional differences.  

**Healthcare professionals in Canada** have limited 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 competition, but the low level of knowledge about probiotics among both consumers and healthcare professionals. The competing products include Simethicone, flora-Lax, Fleet Laboratories (tablets with strawberry flavour), Gerber (drops), Sunstar (oral health tablets) and Gerber (infant formula).  

Cardinal Health 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 store chain’s 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 Everside 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.

**USA**

**Partners:** Everside (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.  

**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 store chain’s 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.

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**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.

**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 ProTects 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 ProTects drops (2012).

**BIOGAI’A’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 Recalcati 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 ProTects 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 made 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 ProTects 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.

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*Nicolas 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 diseases.”

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 infections 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.”
Fruitful collaboration with Nestlé

The researchers and product developers at Nestlé had an infant formula with probiotics in its product range, 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 Nestle'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 Nestle'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.

BioGaia 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 40% 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 disease.

In 2012 BioGaia took part in several highly regarded international scientific conferences for dental professionals, including EuroPeri and ASDER.

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

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.
**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 2012, partly to ensure ongoing development in the company 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 reassessed 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 alarmingly more and more bacteria develop antimicrobial resistance. By strengthening the human immune defense, we can decrease the use of antibiotics.

Since 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 these 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 wrong. 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 60,000 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 ruteri Protectis.

**THIS IS HOW PETER ROTHSCHILD WOULD LIKE to turn things around. To modernize 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 defense 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**

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**BioGaia’s Annual Report 2012**

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Despite having sales in 80 countries, BioGaia has only 76 employees. The explanation lies in the business model, which is based on strong collaboration primarily with three external networks. There are a number of core areas represented in the company, which uses a flat and effective organisation.

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 primarily with three external networks. There are a number of core areas represented 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 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.

LOW SICKNESS ABSENCE Sickness absence in the company is low, and in 2012 the employees had an average of three sick days (aside from one long-term sickness absence).

NEW EMPLOYEES 14 people were hired in 2012 and 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 years.

HIGH LEVEL OF EXPERTISE The level of expertise is 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’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.
Employee voices

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

“We support our partners in their marketing to doctors and other healthcare professionals among other things by providing them with marketing material and training and by participating in international conferences.”

EVA NELSON, COMMUNICATIONS MANAGER, STOCKHOLM
Now it's full speed ahead! Partners have created the conditions for new success.

**Biogaia's revenue from Nestlé in 2012 (excluding license revenue) was approximately 8% of the value of sales to Nestlé during 2011. Biogaia's assignment 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 Nestlé Gerber division for the sale of drops in the USA** In June, Biogaia and Gerber Products Company, a division of Nestlé 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 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 Nestle Force giving Nestle 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 Pharmahutle and for Israel with Dassal 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 giving Nestle Mexico 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. They include studies in children, four gastrointestinal and immune health studies in adults and seven oral health studies.

**Below is a description of the most significant.**

Results of study show that Lactobacillus reuteri Protectis reduces diarrhea in children A double-blind, placebo-controlled study of 494 children showed that supplementation of Lactobacillus reuteri Proteirotectis significantly reduced episodes of diarrhea. Lactobacillus reuteri 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 1,000 grams, showed that probiotic supplementation of Lactobacillus reuteri Proteirotectis 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 reuteri Proteirotectis to all premature infants in one 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 BMJ Pediatrics* on 4 September 2012.

**Lactobacillus reuteri Protectis is shown to reduce colic in infants** A double-blind, placebo-controlled study of 90 colicky infants showed that the crying time was significantly reduced among the infants supplemented with the probiotic Lactobacillus reuteri Protectis compared to those in the placebo group. The quality of life for the parents and families was also significantly improved in the probiotic group compared to the placebo group.

The study was performed by Maria 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 reuteri Proteirotectis in colicky infants, and it once again confirms the effectiveness of Biogaia's probiotic products in reducing the symptoms of colic.

Biogaia's probiotics help premature infants in this difficult 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 tolerance in the infants with a birth weight below 1,500 grams was reduced by 43%.

The study was published online in *Pediatrics* on 15 October 2012.
Lactobacillus reuteri Probiotics reduced pocket depth in patients with periodontitis

A new study on 20 patients with periodontitis was published in November. The results show that a probiotic lactic acid bacteria with potential effect in a number of human applications was used.

The BioGaia brand

Of total finished consumer products, 49% (45) were sold under the BioGaia brand, including: 49% (45) for sales in Sweden, 8% (7) for sales in Japan and 5% (5) for sales in South Africa.

Gross profit

Gross profit amounted to SEK 507.1 million (261.1), or 32% of sales. Excluding proforma revenue, gross profit was SEK 201.1 million (263.3), which is 5% lower than in the previous year.

Equity

Consolidated equity amounted to SEK 458.6 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 in February 2012. The exercise price of the warrants was SEK 6.80 per warrant, which is 15% higher than the shares listed on Nasdaq Stockholm.

The Japanese subsidiary has operated at a loss since 2009. The Japanese venture is fundamentally a research and development business, and the results are affected by exchange rates.

The Group’s cash and cash equivalents at 31 December 2012 amounted to SEK 457.4 million (432.3) after the payment from Nestlé of SEK 356 million, investments in TwoPac of SEK 27.5 million and bond issues of SEK 63.7 million.
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 the balance in the translation reserve was SEK 39.0 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.

Share in group companies

Capable, which is 0.1% owned by Biogia 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 the year was SEK 2,601,673 (2,338,814). Biogia made a total conditional contribution of SEK 6 million to the subsidiary Capable in 2009 and 2010. Biogia has no controlling interest of SEK 7.3 million during the period 2010-2012. Biogia’s assessment is that Capable will show good profitability in coming years, for which reason the value of the subsidiary is reported on the balance sheet date.

Biogia’s partners

Biogia 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 Biogia partners invest the resources necessary for marketing and sales. In order to influence this to a greater extent on its own, Biogia launched its own brand in 2006. Today a number of Biogia’s partners will sell products wholly or partly under the Biogia brand and Biogia-branded products are currently sold in more than 40 countries. Biogia 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 Biogia is carrying out a change of distributors in some 10 markets.

Research and development

Biogia 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 fail before it is marketed. There is also a certain risk that the studies that lie outside Biogia’s control will not be conducted in line with Biogia’s expectations.

Intellectual property

Biogia’s business activities are based on a large number of intellectual properties relating to the development of several series of strains and internal domains. The company works continuously to strengthen its intellectual property rights by protecting the use of the company’s products. The various patents have in recent years covered the most used strains in Biogia’s products up until 2012.

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. Biogia continuously monitors the market.

Regulatory status

Biogia’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 in certain markets in which Biogia operates, in 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 effect 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 all applicable products. The assurance is valid worldwide with various claims about preventive health effects, for example that a lower intake of cholesterol reduces the risk of 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 Biogia’s products the assurance to healthcare professionals (doctors, midwives, etc.) who then recommend the products to their patients is less urgent in terms of new research needs, due to the products’ practical effects. As a result, the EFSA rules are not applicable to the majority of Biogia’s products. Furthermore, because the products are primarily non-prescription products, in most countries there is no need to make general health claims in the marketing materials. In the case of the company was marketing a yoghurt or beverage directly to consumers.

If it becomes necessary to use another type of marketing for future products, Biogia will apply for approval of its health claims from the EFSA. Together with partners Biogia is assessing the opportunities to register its products under the existing regulations for Special Medical Purposes, natural remedies, etc. For the future, cash flow in working capital was SEK 336.5 million (728.8). Total cash flow for the period was SEK 119.0 million (-18.0). In December 2012 amounted to SEK 370.5 million (171.1) and cash flow was positive in the period.

Price risk

Biogia buys most of its goods on the international market and has several alternative suppliers, which minimise the company’s price risk.

Employees

The number of employees in the Group at 31 December 2012 was 76 (64), consisting of 41 (35) in BioGaia and 35 (29) in the BioGaia-branded team. Biogia’s assessment is that these insurance amounts are relevant and adequate for the company’s operations.

Financial risk management

The overall objective of the Group’s finance function is to secure cost-effective financing for the Group’s operations and group companies and to provide secure cash management with a marked basis for return or 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

Biogia has revenue primarily in EUR (around 75% of net sales excluding license revenue from Nestle) but also USD, JPY and SEK and expenses primarily in SEK, EUR and USD.

In 2012 the company had a cash flow surplus of approximately EUR 556.1 (17.6) million (including the payment of EUR 40 million from Nestle), a cash flow deficit of EUR 84.4 million (10.6) million and a provision.

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 decided to issue Eurobonds in December 2012 for a total of EUR 57.3 million (7.3) million and a provision.

The Board of Directors’ proposal to the AGM and other terms of employment for senior executives

The Board of Directors proposes that the AGM approve the following guidelines for variable remuneration in the form of long-term incentive schemes or pension benefits, other benefits and terms of termination of employment.

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-related incentive scheme should be proposed to the AGM. Other types of long-term incentive schemes can be proposed to 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 other remuneration and shall be consistent with general norms in the respective geographical market.

Notes

The most recently adopted guidelines correspond to those that are proposed to the AGM (see above). For more information about remuneration to senior executives, see Note 4.

The Board of Directors proposes to the AGM regaring remuneratio and other terms of employment for senior executives

The Board of Directors proposes that the AGM approve the following guidelines for variable remuneration and other terms of employment for senior executives.

These principles apply to employment contracts entered into after the decision of the AGM, which means that new contracts would be subject to the principles from the time they are signed. 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 fairly and internally balanced terms that are market-based in the company’s various segments. The total remuneration package for the affected individuals should contain a well-balanced mix of variable remuneration, variable remuneration in the form of long-term incentive schemes, pension benefits, other benefits and terms of termination of employment.

The Board of Directors proposes that the AGM approve the following terms of employment for senior executives.

Proposed approprition of profits

The following funds in the Parent Company are at the disposal of the Annual General Meeting (AGM):
### Statement of consolidated income

<table>
<thead>
<tr>
<th>SEK 000s</th>
<th>Note</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>2, 3</td>
<td>645,252</td>
<td>314,992</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td></td>
<td>–86,179</td>
<td>–96,727</td>
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<tr>
<td>Gross profit</td>
<td>2</td>
<td>557,073</td>
<td>216,265</td>
</tr>
<tr>
<td>Selling expenses</td>
<td>4</td>
<td>–71,361</td>
<td>–66,079</td>
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<tr>
<td>Administrative expenses</td>
<td>4</td>
<td>–15,423</td>
<td>–13,014</td>
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<tr>
<td>Research and development expenses</td>
<td>4, 13</td>
<td>–35,788</td>
<td>–34,317</td>
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<tr>
<td>Other operating income</td>
<td>6</td>
<td>300</td>
<td>58</td>
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<tr>
<td>Other operating expenses</td>
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<td>432,961</td>
<td>109,392</td>
</tr>
<tr>
<td>Operating profit</td>
<td>8</td>
<td>428,070</td>
<td>103,159</td>
</tr>
<tr>
<td>Financial income</td>
<td>9</td>
<td>14,245</td>
<td>5,789</td>
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<tr>
<td>Financial expenses</td>
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<td>73</td>
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<tr>
<td>Net financial items</td>
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<tr>
<td>Profit before tax</td>
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<td>108,867</td>
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<tr>
<td>Tax</td>
<td>11</td>
<td>–112,371</td>
<td>–29,345</td>
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<tr>
<td>PROFIT FOR THE YEAR</td>
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<td>329,871</td>
<td>79,522</td>
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</table>

### Cash flow statements

<table>
<thead>
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<th>SEK 000s</th>
<th>Note</th>
<th>2012</th>
<th>2011</th>
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<tr>
<td>Operating activities</td>
<td></td>
<td>428,070</td>
<td>103,159</td>
</tr>
<tr>
<td>Adjustments for non-cash items:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation/amortisation</td>
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<td>4,545</td>
<td>5,425</td>
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<tr>
<td>Capital gains/losses on the sale of non-current assets</td>
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<td>46</td>
<td>1,340</td>
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<tr>
<td>Other non-cash items</td>
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<td>300</td>
<td>58</td>
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<tr>
<td>Taxes paid</td>
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<td>–105,736</td>
<td>–36,768</td>
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<td>Reallocated forward exchange contracts</td>
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<td>2,818</td>
<td>–164</td>
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<tr>
<td>Interest received</td>
<td></td>
<td>8,563</td>
<td>3,269</td>
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<tr>
<td>Interest paid</td>
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<td>–87</td>
<td>–80</td>
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<tr>
<td>Cash flow from operating activities before changes in working capital</td>
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<td>338,539</td>
<td>77,239</td>
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<tr>
<td>Cash flow from changes in working capital:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inventories</td>
<td></td>
<td>445</td>
<td>–5,928</td>
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<tr>
<td>Current receivables</td>
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<td>135</td>
<td>–13,057</td>
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<tr>
<td>Trade payables</td>
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<td>7,788</td>
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<tr>
<td>Current interest-free operating liabilities</td>
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<td>–714</td>
<td>6,750</td>
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<tr>
<td>Cash flow from operating activities</td>
<td></td>
<td>335,557</td>
<td>72,792</td>
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<tr>
<td>Investing activities:</td>
<td></td>
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<tr>
<td>Purchase of property, plant and equipment</td>
<td></td>
<td>–29,400</td>
<td>–16,179</td>
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<tr>
<td>Sale of property, plant and equipment</td>
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<tr>
<td>Purchase of financial assets</td>
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<tr>
<td>Cash flow from investing activities</td>
<td></td>
<td>–29,391</td>
<td>–13,567</td>
</tr>
<tr>
<td>Financing activities:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>New share issue warrants</td>
<td></td>
<td>1,253</td>
<td>–</td>
</tr>
<tr>
<td>Dividend</td>
<td></td>
<td>–103,826</td>
<td>–34,542</td>
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<tr>
<td>Cash flow from financing activities</td>
<td></td>
<td>–102,573</td>
<td>–34,542</td>
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<tr>
<td>CASH FLOW FOR THE YEAR</td>
<td></td>
<td>203,793</td>
<td>24,683</td>
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</table>

### Statement of financial position

<table>
<thead>
<tr>
<th>SEK 000s</th>
<th>Note</th>
<th>31 Dec. 2012</th>
<th>2011-12-31</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSETS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intangible assets</td>
<td>13</td>
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<tr>
<td>Property, plant and equipment</td>
<td>14</td>
<td>49,193</td>
<td>24,158</td>
</tr>
<tr>
<td>Deposits</td>
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<tr>
<td>Total non-current assets</td>
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<td>Current assets:</td>
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<tr>
<td>Inventories</td>
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<td>20,845</td>
<td>21,528</td>
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<td>Trade receivables</td>
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<td>54,045</td>
<td>49,112</td>
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<tr>
<td>Tax receivable</td>
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<tr>
<td>Other receivables</td>
<td>20</td>
<td>7,596</td>
<td>7,044</td>
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<tr>
<td>Deferred expenses and accrued income</td>
<td>21</td>
<td>3,796</td>
<td>6,034</td>
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<tr>
<td>Short-term investments</td>
<td>22</td>
<td>80</td>
<td>80</td>
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<tr>
<td>Cash and cash equivalents</td>
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<td>374,974</td>
<td>171,534</td>
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<tr>
<td>Total current assets</td>
<td></td>
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<td>255,392</td>
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<tr>
<td>TOTAL ASSETS</td>
<td></td>
<td>517,022</td>
<td>279,832</td>
</tr>
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<table>
<thead>
<tr>
<th>EQUITY AND LIABILITIES</th>
<th></th>
<th>31 Dec. 2012</th>
<th>2011-12-31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share capital</td>
<td></td>
<td>17,271</td>
<td>17,371</td>
</tr>
<tr>
<td>Other contributed capital</td>
<td></td>
<td>6,053</td>
<td>82,501</td>
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<tr>
<td>Reserves</td>
<td></td>
<td>586</td>
<td>1,864</td>
</tr>
<tr>
<td>Retained profit</td>
<td></td>
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<td>51,979</td>
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<tr>
<td>Total equity attributable to owners of the Parent Company</td>
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<td>326,970</td>
<td>76,369</td>
</tr>
<tr>
<td>Total equity attributable to owners of the Parent Company</td>
<td></td>
<td>453,303</td>
<td>229,764</td>
</tr>
<tr>
<td>Non-controlling interests</td>
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<td>12, 15</td>
<td>3,491</td>
</tr>
<tr>
<td>Total non-controlling interests</td>
<td></td>
<td>3,491</td>
<td>591</td>
</tr>
<tr>
<td>Total equity</td>
<td></td>
<td>465,794</td>
<td>230,355</td>
</tr>
<tr>
<td>Non-current liabilities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deferred tax liability</td>
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<td>24,710</td>
<td>185</td>
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<tr>
<td>Total non-current liabilities</td>
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<td>185</td>
</tr>
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<td>Current liabilities:</td>
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<tr>
<td>Prepayments from customers</td>
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<td>2,960</td>
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<td>Trade payables</td>
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<td>14,731</td>
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<tr>
<td>Current tax liability</td>
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<td>1,599</td>
<td>12,102</td>
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<tr>
<td>Other liabilities</td>
<td>24</td>
<td>1,266</td>
<td>1,296</td>
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<tr>
<td>Accrued expenses and deferred income</td>
<td>25</td>
<td>14,804</td>
<td>15,165</td>
</tr>
<tr>
<td>Total current liabilities</td>
<td></td>
<td>35,518</td>
<td>49,292</td>
</tr>
<tr>
<td>Total liabilities</td>
<td></td>
<td>60,228</td>
<td>49,477</td>
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<tr>
<td>TOTAL EQUITY AND LIABILITIES</td>
<td></td>
<td>517,022</td>
<td>279,832</td>
</tr>
<tr>
<td>Pledged assets and contingent liabilities in the Group</td>
<td></td>
<td>26</td>
<td></td>
</tr>
</tbody>
</table>

### Statement of changes in equity

<table>
<thead>
<tr>
<th>SEK 000s</th>
<th>Note</th>
<th>Share capital</th>
<th>Other contributed capital</th>
<th>Translation reserve</th>
<th>Retained profit incl. profit for the year</th>
<th>Equity attributable to owners of the Parent Company</th>
<th>Non-controlling interest</th>
<th>Total equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening balance, 1 January 2011</td>
<td></td>
<td>17,271</td>
<td>77,701</td>
<td>932</td>
<td>91,321</td>
<td>187,225</td>
<td>98</td>
<td>187,323</td>
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<td>Reclassification of prior new share issue</td>
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<td>4,900</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Dividend</td>
<td></td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–34,542</td>
<td>–34,542</td>
<td>–34,542</td>
<td>–34,542</td>
</tr>
<tr>
<td>Total transactions with owners</td>
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<td>–34,542</td>
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<td>–34,542</td>
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<tr>
<td>Profit for 2011</td>
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<td>76,369</td>
<td>3,153</td>
<td>79,522</td>
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<td></td>
<td></td>
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<tr>
<td>Other comprehensive income</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gains/losses arising on translation of the financial statements of foreign operations</td>
<td>712</td>
<td>712</td>
<td>712</td>
<td>712</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Comprehensive income for the year</td>
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<td>49,292</td>
<td>–2,660</td>
<td>–2,660</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Change in group structure</td>
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<td>6,053</td>
<td>12,102</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Closing balance, 31 December 2011</td>
<td></td>
<td>17,271</td>
<td>82,501</td>
<td>1,644</td>
<td>128,348</td>
<td>239,764</td>
<td>591</td>
<td>230,355</td>
</tr>
<tr>
<td>Dividend</td>
<td></td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–34,542</td>
<td>–34,542</td>
<td>–34,542</td>
<td>–34,542</td>
</tr>
<tr>
<td>Transfer from the statutory reserve to non-restricted reserves</td>
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<td>–77,701</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Subscription warrants</td>
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<td>1,253</td>
<td>1,253</td>
<td>1,253</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total transactions with owners</td>
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<td>–25,925</td>
<td>–102,373</td>
<td>0</td>
<td>–102,373</td>
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</tr>
<tr>
<td>Profit for 2012</td>
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<td>326,970</td>
<td>326,970</td>
<td>2,901</td>
<td>329,871</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other comprehensive income</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gains/losses arising on translation of the financial statements of foreign operations</td>
<td></td>
<td>–1,059</td>
<td>–1,059</td>
<td>–1,059</td>
<td>–1,059</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comprehensive income for the year</td>
<td></td>
<td>326,970</td>
<td>325,911</td>
<td>2,901</td>
<td>328,812</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Closing balance, 31 December 2012</td>
<td></td>
<td>17,271</td>
<td>6,053</td>
<td>586</td>
<td>429,393</td>
<td>453,303</td>
<td>3,491</td>
<td>456,794</td>
</tr>
</tbody>
</table>

1) The terms of the subscription warrants are described in the administration report.
### Profit/loss items

Interest expense and similar

### Statement of comprehensive income.

which means that comprehensive income for the year corresponds to profit

### Balance sheets

#### ASSETS

- Non-current assets
  - Intangible assets
    - 13
  - Capital development expenditure
    - 324
  - Total intangible assets
    - 264
  - Property, plant and equipment
    - 14
    - Production equipment
      - 758
    - 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
    - 49,873
    - 37,673
  - Total non-current assets
    - 47,349
    - 40,005

#### EQUITY AND LIABILITIES

- Equity
  - Profit for the year
    - 72,479
  - Total equity
    - 331,136
    - 117,785

#### Liabilities

- Current liabilities
  - Floating charges
    - 26
  - Pledged assets and contingent liabilities
    - 26
    - 2,000
    - 2,000

- Non-current liabilities
  - Liabilities to group companies
    - 19
    - 16,090
    - 19,404
  - Current tax liability
    - -12,056
  - Other liabilities
    - 24
    - 883
    - 779

#### Total liabilities

- 45,404
- 62,757

#### TOTAL EQUITY AND LIABILITIES

- 504,405
- 275,513

### Statement of changes in equity

#### SHARE CAPITAL AND OTHER LIABILITIES

- Opening balance, 1 January 2011
  - 17,271
  - 77,700
  - 91,981
  - 176,832
- Group contributions paid
  - -2,480
  - -2,480
- Tax on group contributions paid
  - 647
  - 647
  - 3,045
- Dividend
  - 72,479
  - 72,479
- Profit for 2011
  - 3,660
  - 3,660

- Closing balance, 31 December 2011
  - 17,271
  - 77,700
  - 117,785
  - 212,756
- Dividend
  - -34,542
  - -34,542
- Transfer of statutory reserve to non-restricted reserves
  - 77,700
  - 77,700
  - 1,253
  - 1,253
- Subscription warrants
  - 2,097
  - 2,097

- Opening balance, 1 January 2012
  - 17,271
  - 77,700
  - 91,981
  - 176,832
- Group contributions paid
  - -2,480
  - -2,480
- Tax on group contributions paid
  - 647
  - 647
  - 3,045
- Dividend
  - 72,479
  - 72,479
- Profit for 2012
  - 3,660
  - 3,660

- Closing balance, 31 December 2012
  - 17,271
  - 77,700
  - 117,785
  - 212,756
- Dividend
  - -34,542
  - -34,542
- Transfer of statutory reserve to non-restricted reserves
  - 77,700
  - 77,700
  - 1,253
  - 1,253
- Subscription warrants
  - 2,097
  - 2,097

#### Retained profit incl. profit for the year

- 331,136
- 349,600
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 cash flow.

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, the purchase price allocation (PPA) is conducted in connection with the signing of agreements. Transaction cost incurred in connection with the signing of agreements are accrued in cases where it intended to cover costs until the time of launch. In other cases, the revenue is recognised immediately. Royalties for the use of the ‘Lactobacillus Reuteri’ trademark (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.

Revenue recognition
Biogäa’s net sales consist primarily of revenue from the sale of finished consumer products (tablets, drops and oral health products) to customers, but also revenue from the sale of component products for the use of Reuten in licenses products (such as infant formulas and dairy products), royalties from the use of Lactobacillus reuteri in infant formulas and dairy products, and sales of Lactobacillus reuteri in infant formulas and dairy products.

Royalties are measured as a percentage of the licensor’s reported sales value for consumer products containing Biogäa’s products, and are recognised monthly as the income is generated. In connection with the signing of agreements of revenues are accrued in cases where they intend to cover costs until the time of launch. In other cases, the revenue is recognised immediately.

The preparation of financial statements in conformity 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.

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 shall 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 none of all the development costs have been expensed in full.

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Note 6 Other operating income
Note 7 Other operating expenses
Note 8 Operating expenses allocated by type of cost
Note 9 Financial income
Note 10 Financial expenses
Note 11 Tax on profit for the year
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Note 28 Policy for financial risk management
Note 27 Tax allocation reserve
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Note 25 Accrued expenses and deferred income
Note 24 Other liabilities
Note 23 Equity
Note 22 Financial assets and liabilities
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Note 20 Receivables
Note 19 Related party transactions
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Note 10 Financial expenses
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Note 7 Other operating income
Note 6 Other operating expenses
Note 5 Audit fees
Note 4 Employees and personnel expenses, remuneration to senior executives
Note 3 Revenue
Note 2 Segment reporting
Note 1 Accounting policies

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.
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:

### Intangible assets

<table>
<thead>
<tr>
<th>Capitalised development expenditure</th>
<th>5–10 yrs</th>
<th>5–10 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licenses</td>
<td>5 yrs</td>
<td>5 yrs</td>
</tr>
<tr>
<td>Trademarks</td>
<td>5 yrs</td>
<td>5 yrs</td>
</tr>
</tbody>
</table>

### Property, plant and equipment

<table>
<thead>
<tr>
<th>Production equipment</th>
<th>5–10 yrs</th>
<th>5 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment and computers</td>
<td>3–5 yrs</td>
<td>3–5 yrs</td>
</tr>
<tr>
<td>Buildings</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

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 less 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 include cash and cash equivalents comprising cash in hand and at bank.

### Financial assets and liabilities

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

Financial assets and liabilities are initially measured at cost, corresponding to the fair value, including provisions for obsolescence. Cost is measured according to weighted average prices. Financial assets and liabilities are initially measured at cost, corresponding to the fair value, including provisions for obsolescence. Cost is measured according to weighted average prices.

Trade receivables are recognised when an invoice has been received.

Trade payable is discussed in notes related to current financial liabilities.

Financial assets are 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 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.
- Financial assets or liabilities at amortised cost, which includes trade receivables, trade payables, held-to-maturity investments, loans and financial assets and liabilities measured at fair value through profit or loss.

### 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, unrealised reserves are recognised including deferred tax liability. In the consolidated financial statements, however, unrealised reserves are divided between deferred tax liability and equity.
- Group and shareholder contributions for legal entities In the Parent Company, 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 how 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 licence-protected products (such as infant formula and dairy products), noodles for the use of neuter and sales of Lifesoft Shot 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:

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Finished consumer products</td>
<td>203,328</td>
</tr>
<tr>
<td>Component products</td>
<td>204,324</td>
</tr>
<tr>
<td>License revenue (Europe)</td>
<td>–</td>
</tr>
<tr>
<td>Asia</td>
<td>–</td>
</tr>
<tr>
<td>Rest of world</td>
<td>–</td>
</tr>
<tr>
<td>Net sales</td>
<td>454,045</td>
</tr>
</tbody>
</table>

In 2012, SEK 10.3 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 13.4 million or 42.3% of the revenue).

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

Average number of employees by country:

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Europe</td>
<td>634,519</td>
</tr>
<tr>
<td>Asia</td>
<td>306,182</td>
</tr>
<tr>
<td>Japan</td>
<td>199,314</td>
</tr>
<tr>
<td>Other</td>
<td>73</td>
</tr>
</tbody>
</table>

### Total salaries and social security expenses

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Europe</td>
<td>356,004</td>
</tr>
<tr>
<td>Asia</td>
<td>49,112</td>
</tr>
<tr>
<td>Rest of world</td>
<td>25,078</td>
</tr>
<tr>
<td>Total</td>
<td>456,004</td>
</tr>
</tbody>
</table>

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 13.4 million or 42.3% of the revenue).

### Note 3 Revenue

Average number of employees by country:

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Europe</td>
<td>356,004</td>
</tr>
<tr>
<td>Asia</td>
<td>49,112</td>
</tr>
<tr>
<td>Rest of world</td>
<td>25,078</td>
</tr>
<tr>
<td>Total</td>
<td>456,004</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Europe</td>
<td>356,004</td>
</tr>
<tr>
<td>Asia</td>
<td>49,112</td>
</tr>
<tr>
<td>Rest of world</td>
<td>25,078</td>
</tr>
<tr>
<td>Total</td>
<td>456,004</td>
</tr>
</tbody>
</table>

Total salaries and social security expenses:

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Europe</td>
<td>356,004</td>
</tr>
<tr>
<td>Asia</td>
<td>49,112</td>
</tr>
<tr>
<td>Rest of world</td>
<td>25,078</td>
</tr>
<tr>
<td>Total</td>
<td>456,004</td>
</tr>
</tbody>
</table>

### Note 3 Revenue

Average number of employees by country:

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>Europe</td>
<td>356,004</td>
</tr>
<tr>
<td>Asia</td>
<td>49,112</td>
</tr>
<tr>
<td>Rest of world</td>
<td>25,078</td>
</tr>
<tr>
<td>Total</td>
<td>456,004</td>
</tr>
</tbody>
</table>
Note 5 Audit fees

<table>
<thead>
<tr>
<th>Year</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit firms</td>
<td>Grant Thornton Sweden AB</td>
<td>Deloitte</td>
<td>Deloitte</td>
<td>Deloitte</td>
</tr>
<tr>
<td>Audit assignments</td>
<td>406</td>
<td>431</td>
<td>325</td>
<td>346</td>
</tr>
<tr>
<td>Audit services in addition to audit</td>
<td>129</td>
<td>120</td>
<td>120</td>
<td>120</td>
</tr>
<tr>
<td>Tax advice</td>
<td>11</td>
<td>30</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Other assignments</td>
<td>1</td>
<td>34</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Cherry, Beisek &amp; Hvånd, L.L.P.</td>
<td>41</td>
<td>41</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Other assignments</td>
<td>129</td>
<td>105</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Nakamichi Accounting Firm</td>
<td>18</td>
<td>18</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Other assignments</td>
<td>18</td>
<td>18</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

Note 6 Other operating income

<table>
<thead>
<tr>
<th>Year</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exchange gains on operating receivables and liabilities, net</td>
<td>–</td>
<td>304</td>
<td>304</td>
</tr>
<tr>
<td>Other financial expenses</td>
<td>74</td>
<td>84</td>
<td>63</td>
</tr>
</tbody>
</table>
Note 13 Intangible assets

GROUP AND PARENT COMPANY:

<table>
<thead>
<tr>
<th>Capitalised development expenditure</th>
<th>Licenses and brands</th>
<th>Total intangible assets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accumulated cost:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opening balance, 1 January 2011</td>
<td>26,875</td>
<td>2,528</td>
</tr>
<tr>
<td>Purchases</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Closing balance, 31 December 2011</td>
<td>26,875</td>
<td>2,528</td>
</tr>
<tr>
<td>Opening balance, 1 January 2012</td>
<td>26,875</td>
<td>2,528</td>
</tr>
<tr>
<td>Purchases</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Closing balance, 31 December 2012</td>
<td>26,875</td>
<td>2,528</td>
</tr>
<tr>
<td>Accumulated amortisation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opening balance, 1 January 2011</td>
<td>25,702</td>
<td>2,528</td>
</tr>
<tr>
<td>The year’s amortisation</td>
<td>909</td>
<td>–</td>
</tr>
<tr>
<td>Closing balance, 31 December 2011</td>
<td>26,511</td>
<td>2,528</td>
</tr>
<tr>
<td>Opening balance, 1 January 2012</td>
<td>26,611</td>
<td>2,528</td>
</tr>
<tr>
<td>The year’s amortisation</td>
<td>264</td>
<td>–</td>
</tr>
<tr>
<td>Closing balance, 31 December 2012</td>
<td>26,347</td>
<td>2,528</td>
</tr>
</tbody>
</table>

Carrying amounts:
At 1 January 2011  1,173  0  1,173
At 31 December 2011 0 0 0

Capitalised expenses include internally generated and externally acquired assets.

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

<table>
<thead>
<tr>
<th>Research and development expenses</th>
<th>2012</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accumulated cost</td>
<td>264</td>
<td>264</td>
<td>264</td>
</tr>
<tr>
<td>Accumulated amortisation</td>
<td>264</td>
<td>264</td>
<td>264</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>35,185</td>
<td>33,055</td>
</tr>
<tr>
<td>35,267</td>
<td>33,055</td>
</tr>
<tr>
<td>35,305</td>
<td>33,055</td>
</tr>
</tbody>
</table>

Total R&D expenditure:

<table>
<thead>
<tr>
<th>The year’s capitalisation of development expenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
</tr>
<tr>
<td>35,185</td>
</tr>
<tr>
<td>35,267</td>
</tr>
<tr>
<td>35,305</td>
</tr>
</tbody>
</table>

Amortisation/depreciation recognised in R&D expenses:

<table>
<thead>
<tr>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>603</td>
<td>601</td>
</tr>
<tr>
<td>1,125</td>
<td></td>
</tr>
</tbody>
</table>

R&D expenses with an effect on income:

53,788  34,317  35,868  34,283

Note 14 Property, plant and equipment

GROUP:

<table>
<thead>
<tr>
<th>Land and equipment</th>
<th>Buildings</th>
<th>Production equipment</th>
<th>Total property, plant and equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accumulated cost:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opening balance, 1 January 2011</td>
<td>–</td>
<td>4,541</td>
<td>11,503</td>
</tr>
<tr>
<td>Purchases</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Closing balance, 31 December 2011</td>
<td>506</td>
<td>18,733</td>
<td>14,516</td>
</tr>
<tr>
<td>Opening balance, 1 January 2012</td>
<td>506</td>
<td>18,733</td>
<td>14,516</td>
</tr>
<tr>
<td>Purchases</td>
<td>315</td>
<td>1,879</td>
<td>25,407</td>
</tr>
<tr>
<td>Closing balance, 31 December 2012</td>
<td>34,165</td>
<td>1,614</td>
<td>35,783</td>
</tr>
</tbody>
</table>

Carrying amounts:
At 1 January 2011  1,173  0  1,173
At 31 December 2011 0 0 0

Accumulated amortisation on the following lines in the income statement:

<table>
<thead>
<tr>
<th>Depreciation</th>
<th>2011</th>
<th>2012</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 January 2011 in TwoPac AB</td>
<td>7128</td>
<td>–</td>
<td>613</td>
<td>7,741</td>
</tr>
<tr>
<td>Purchases</td>
<td>2,396</td>
<td>3,052</td>
<td>1,246</td>
<td></td>
</tr>
<tr>
<td>Sales and disposals</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>Reclassification</td>
<td>3,052</td>
<td>1,246</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>Translation difference</td>
<td>–</td>
<td>36</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Closing balance, 31 December 2012</td>
<td>34,821</td>
<td>8,016</td>
<td>4,144</td>
<td>2,212</td>
</tr>
</tbody>
</table>

Participations in group companies:

<table>
<thead>
<tr>
<th>Note 14</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>Parent Company</td>
</tr>
<tr>
<td>35,267</td>
<td>33,055</td>
</tr>
</tbody>
</table>

Note 15 Financial assets

PARENT COMPANY:

<table>
<thead>
<tr>
<th>Participation in group companies</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditional shareholder contribution to CapAble AB</td>
<td>2,583</td>
<td>–</td>
</tr>
<tr>
<td>Impairment loss of shares in CapAble AB</td>
<td>–2,583</td>
<td>–</td>
</tr>
<tr>
<td>Reclassification of TwoPac AB from associated company to group company</td>
<td>–10,841</td>
<td>–</td>
</tr>
</tbody>
</table>

Book value at end of year:

21,160 21,160

Note 16 Non-current receivables from subsidiaries and associated company

Non-current receivables from subsidiaries:

<table>
<thead>
<tr>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>16,515</td>
<td>1,022</td>
</tr>
<tr>
<td>4,574</td>
<td>5,493</td>
</tr>
</tbody>
</table>

Specified in the Parent Company’s equity holdings in group companies:

<table>
<thead>
<tr>
<th>Subsidiaries</th>
<th>Holdings</th>
<th>Bock value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biogia Biologics Inc. /–/Raleigh, NC, USA</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>CapAble AB /556591-9767/Eslöv</td>
<td>50</td>
<td>50</td>
</tr>
</tbody>
</table>

Note 17 Non-current receivables from subsidiaries at December 31:

<table>
<thead>
<tr>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>24,513</td>
<td>16,513</td>
</tr>
</tbody>
</table>

Note 18 Non-current liabilities of group companies:

<table>
<thead>
<tr>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>16,515</td>
<td>1,022</td>
</tr>
<tr>
<td>4,574</td>
<td>5,493</td>
</tr>
</tbody>
</table>

Biogia Biologics Inc. /–/Raleigh, NC, USA
CapAble AB /556591-9767/Eslöv
TwoPac AB /556591-9767/Eslöv
Biogia Japan Inc. /–/Shinagawa-ku, Tokyo

The assets and liabilities of the American subsidiary BioGaia Biologics Inc. have been translated at the closing day rate of exchange, SEK 6.50 (6.89). All items in the income statement have been translated at the average exchange rate during the year, SEK 6.77 (6.49). 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 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% by the management of TwoPac. The non-controlling interests’ share in equity of TwoPac amounts to SEK 5,763 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 17 Inventories

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:

<table>
<thead>
<tr>
<th>Description</th>
<th>Parent Company</th>
<th>2012/11</th>
<th>2011/12</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAT refund</td>
<td></td>
<td>3,595</td>
<td>2,883</td>
</tr>
<tr>
<td>Tax asset</td>
<td></td>
<td>129</td>
<td>358</td>
</tr>
<tr>
<td>Foreign exchange contracts</td>
<td></td>
<td>3,296</td>
<td>2,673</td>
</tr>
<tr>
<td>Other receivables</td>
<td></td>
<td>577</td>
<td>930</td>
</tr>
<tr>
<td>Interest income</td>
<td></td>
<td>643</td>
<td>467</td>
</tr>
<tr>
<td>Loan paid</td>
<td></td>
<td>-8,000</td>
<td>-11,091</td>
</tr>
<tr>
<td>Purchase of goods</td>
<td></td>
<td>-20,314</td>
<td>-26,179</td>
</tr>
</tbody>
</table>

Note 18 Trade receivables

The Group and the Parent Company have recorded a loss of SEK 937 thousand (469) at 31 December 2012. An individual assessment of the doubtful receivables has been carried out. The entire inventory value is recorded at cost with a deduction for doubtful receivables.

The Group’s gross overdue receivables at 31 December 2012, by currency, are:

<table>
<thead>
<tr>
<th>Description</th>
<th>Parent Company</th>
<th>2012/11</th>
<th>2011/12</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEK</td>
<td></td>
<td>2,135</td>
<td>2,512</td>
</tr>
<tr>
<td>EUR</td>
<td></td>
<td>34,719</td>
<td>27,579</td>
</tr>
<tr>
<td>DKK</td>
<td></td>
<td>3,511</td>
<td>3,085</td>
</tr>
<tr>
<td>USD</td>
<td></td>
<td>6,257</td>
<td>3,689</td>
</tr>
<tr>
<td>JPY</td>
<td></td>
<td>44,395</td>
<td>42,213</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>41,470</td>
<td>33,496</td>
</tr>
</tbody>
</table>

Note 19 Related party transactions

Group Anrell & Rothschild Investment AB holds 740,668 class A shares and 1,259,332 class B shares, comprising 11.6 per cent of the share capital and 36.2 per cent of the votes. Anrell & Rothschild Investment AB is owned by Peter Rothschild, President of BioGaia AB, and Jan Anrell, 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 Anrell & 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 Jörn Throblin’s partly owned company XO Venture. Under the agreement, and within the framework of XO Venture’s network, consultants will be hired to prepare preclinical documentation and product development strategy. The consulting assignment will begin in 2013.

Note 20 Other receivables

The following transactions have taken place with BioGaia Japan Inc:

<table>
<thead>
<tr>
<th>Description</th>
<th>Parent Company</th>
<th>2012/11</th>
<th>2011/12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interest income</td>
<td></td>
<td>2,160</td>
<td>2,494</td>
</tr>
<tr>
<td>Loan paid</td>
<td></td>
<td>-8,036</td>
<td>-11,091</td>
</tr>
<tr>
<td>Purchase of goods</td>
<td></td>
<td>-20,314</td>
<td>-26,179</td>
</tr>
</tbody>
</table>

Note 21 Deferred expenses and accrued income

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:

Group 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.

<table>
<thead>
<tr>
<th>Description</th>
<th>Fair value</th>
<th>Carrying amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>365,744</td>
<td>365,744</td>
</tr>
<tr>
<td>Cash and cash equivalents in EUR</td>
<td>4,978</td>
<td>4,978</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>3,998</td>
<td>3,998</td>
</tr>
<tr>
<td>Cash and cash equivalents in JPY</td>
<td>173</td>
<td>173</td>
</tr>
<tr>
<td>Short-term investments</td>
<td>374,999</td>
<td>375,054</td>
</tr>
<tr>
<td>Total assets</td>
<td>717,161</td>
<td>717,161</td>
</tr>
</tbody>
</table>

Note 22 Financial assets and liabilities

The Group has no held-to-maturity investments. Loans and receivables is the Group’s trade receivables amount to SEK 54,045 thousand (49,112). Fair value corresponds to the carrying amount.

Note 23 Equity

BIOGAIA ANNUAL REPORT 2012

1) Dividend proposed but not yet approved. The Board and Parent propose that the company pay an ordinary dividend of SEK 4.5 per share and an extraordinary dividend of SEK 5.85 per share, equal to a total dividend of SEK 10.35 per share.
Note 24 Other liabilities

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
</tbody>
</table>

Note 25 Accrued expenses and deferred income

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
</tbody>
</table>

Note 26 Pledged assets and contingent liabilities

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>2012</td>
<td>2011</td>
</tr>
</tbody>
</table>

Note 27 Tax allocation reserve

<table>
<thead>
<tr>
<th>Parent Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>31-Dec</td>
</tr>
<tr>
<td>2011</td>
</tr>
</tbody>
</table>

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.

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 (6.7). 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 percent 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 3.6 (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 licence 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 336 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.
### Definitions

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

**Capital employed**
Balance sheet total less interest-free liabilities.

---

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales, SEK M</td>
<td>645.2</td>
<td>289.2</td>
<td>315.0</td>
<td>236.0</td>
<td>203.5</td>
<td>145.2</td>
</tr>
<tr>
<td>Net sales, finished consumer products, SEK M</td>
<td>237.8</td>
<td>25.0</td>
<td>251.4</td>
<td>165.6</td>
<td>147.7</td>
<td>106.3</td>
</tr>
<tr>
<td>Net sales, component products, SEK M</td>
<td>406.6</td>
<td>50.6</td>
<td>97.7</td>
<td>68.6</td>
<td>53.6</td>
<td>36.9</td>
</tr>
<tr>
<td>Operating profit, SEK M</td>
<td>438.9</td>
<td>72.1</td>
<td>103.2</td>
<td>56.3</td>
<td>47.7</td>
<td>25.8</td>
</tr>
<tr>
<td>Profits before tax, SEK M</td>
<td>442.2</td>
<td>86.2</td>
<td>108.9</td>
<td>69.7</td>
<td>53.1</td>
<td>24.0</td>
</tr>
<tr>
<td>Profit after tax, SEK M</td>
<td>329.0</td>
<td>65.7</td>
<td>79.5</td>
<td>47.2</td>
<td>36.0</td>
<td>36.1</td>
</tr>
<tr>
<td>Net sales, SEK M</td>
<td>237.8</td>
<td>25.0</td>
<td>251.4</td>
<td>165.6</td>
<td>147.7</td>
<td>106.3</td>
</tr>
<tr>
<td>Operating margin, %</td>
<td>69.3</td>
<td>30.9</td>
<td>30.5</td>
<td>24.8</td>
<td>28.6</td>
<td>21.8</td>
</tr>
<tr>
<td>Diluted earnings per share, SEK</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Basic earnings per share, SEK</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Number of outstanding warrants with a dilutive effect, thousands</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Average number of shares, thousands</td>
<td>17,271</td>
<td>17,271</td>
<td>17,271</td>
<td>17,271</td>
<td>17,271</td>
<td>17,271</td>
</tr>
<tr>
<td>Diluted earnings per share, SEK</td>
<td>4.42</td>
<td>2.74</td>
<td>2.11</td>
<td>2.10</td>
<td>2.10</td>
<td>2.10</td>
</tr>
<tr>
<td>Diluted earnings per share, SEK</td>
<td>4.42 M</td>
<td>2.74 M</td>
<td>2.11 M</td>
<td>2.10 M</td>
<td>2.10 M</td>
<td>2.10 M</td>
</tr>
<tr>
<td>Current ratio</td>
<td>132.5</td>
<td>51.1</td>
<td>5.2</td>
<td>5.1</td>
<td>8.2</td>
<td>5.1</td>
</tr>
<tr>
<td>Equity/assets ratio</td>
<td>88%</td>
<td>82%</td>
<td>82%</td>
<td>82%</td>
<td>82%</td>
<td>82%</td>
</tr>
<tr>
<td>Capital employed, SEK M</td>
<td>481.5</td>
<td>195.7</td>
<td>230.5</td>
<td>187.3</td>
<td>161.1</td>
<td>132.4</td>
</tr>
<tr>
<td>Return on equity</td>
<td>96%</td>
<td>92%</td>
<td>80%</td>
<td>76%</td>
<td>67%</td>
<td>66%</td>
</tr>
<tr>
<td>Return on equity</td>
<td>17%</td>
<td>16%</td>
<td>15%</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
</tr>
</tbody>
</table>
| Shareholders’ equity attributable to the owners of the Parent Company as of 31 December 2012 and of its 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. 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 opinion.
**Corporate governance in BioGaia**

BioGaia is a Swedish public limited company which is listed on the Swedish Stock Exchange. The company’s corporate governance is exercised through the General Meeting of the company shareholders, the Board of Directors and the President in accordance with the Swedish Companies Act, the Articles of Association and the other regulations applicable in Sweden.

**Articles of Association**

BioGaia’s Articles of Association, the company’s by-laws, are approved by the shareholders and are listed on the company’s website.

**Shareholders**

The company has one class of share and an unlimited number of shares. The company’s shareholders are entitled to participate in the company’s annual general meeting (AGM) and vote. Each share carries one vote. Each shareholder is entitled to vote in proportion to the number of shares owned.

**Board of Directors**

The Board of Directors consists of at least five and at most eight members. The Board of Directors is responsible for overseeing the entire company, managing its business and assets, and taking major decisions.

**Chairman of the Board**

The Chairman of the Board is appointed by the Board of Directors at the commencement of the company’s regular annual meeting. The Chairman, together with other members of the Board, is responsible for overseeing the company’s business and assets, and taking major decisions.

**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 responsible for managing the company’s day-to-day operations, ensuring that the company’s strategic plans are implemented and achieving the results and targets set.

**Remuneration Committee**

The Remuneration Committee is appointed by the Board of Directors at the commencement of the company’s regular annual meeting. The Committee is responsible for establishing the terms and conditions of remuneration for the Board of Directors and members of Executive Management.

**Audit Committee**

The Audit Committee is appointed by the Board of Directors at the commencement of the company’s regular annual meeting. The Committee is responsible for examining the company’s financial reports and ensuring that the company’s financial reports are prepared in accordance with generally accepted accounting principles.

**Corporate Governance**

BioGaia’s corporate governance is designed to ensure that the company is managed in accordance with its strategic goals and in the best interests of its shareholders. The company’s corporate governance is exercised through the General Meeting of the company shareholders, the Board of Directors and the President in accordance with the Swedish Companies Act, the Articles of Association and the other regulations applicable in Sweden.
were subscribed for, of which the management subscribed for 41,000. The decision was made by the Annual General Meeting on 8 May 2012. A total of 87,000 warrants were exercised during June 2012, which was in line with the warrant programme that was announced in the previous year.

Dividend policy
BioGaia’s previous policy was to pay a shareholder dividend equal to 30% of profit after tax. In late 2011, the board decided to change the policy so that shareholder dividends amount to 40% of profit after tax in the future.

Share price development
In 2012 the share price increased from SEK 163.00 to SEK 227.50 compared to SEK 144.75 at the beginning of the year and SEK 175.00 at the end of the year. 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 SEK 175,000,000 and the number of shareholders was 7,384.

Number of shares and ownership distribution
The total registered share capital of BioGaia AB consists of 740,668 class A shares and 16,530,294 class B shares. The number of shareholders was 7,384 (6,752) at 31 December 2012. The changes in share capital since the Company’s formation are shown in the following table:

Changes in share capital since the Company’s formation

<table>
<thead>
<tr>
<th>Year</th>
<th>Transaction</th>
<th>Increase in share capital, SEK</th>
<th>No. of shares</th>
<th>Total no. of A shares</th>
<th>Total no. of B shares</th>
<th>Quote value, SEK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>Company founded</td>
<td>1990,000</td>
<td>54,000</td>
<td>54,000</td>
<td>54,000</td>
<td>54,000</td>
</tr>
<tr>
<td>1991</td>
<td>New share issue</td>
<td>61,176</td>
<td>61,176</td>
<td>61,176</td>
<td>61,176</td>
<td>61,176</td>
</tr>
<tr>
<td>1993</td>
<td>New share issue</td>
<td>61,355</td>
<td>61,355</td>
<td>61,355</td>
<td>61,355</td>
<td>61,355</td>
</tr>
<tr>
<td>1994</td>
<td>New share issue</td>
<td>2,303</td>
<td>2,303</td>
<td>2,303</td>
<td>2,303</td>
<td>2,303</td>
</tr>
<tr>
<td>1995</td>
<td>Bonus issue</td>
<td>60,541,986</td>
<td>60,541,986</td>
<td>60,541,986</td>
<td>60,541,986</td>
<td>60,541,986</td>
</tr>
<tr>
<td>1996</td>
<td>New share issue</td>
<td>16,300,000</td>
<td>16,300,000</td>
<td>16,300,000</td>
<td>16,300,000</td>
<td>16,300,000</td>
</tr>
<tr>
<td>1997</td>
<td>New share issue</td>
<td>2,608,696</td>
<td>2,608,696</td>
<td>2,608,696</td>
<td>2,608,696</td>
<td>2,608,696</td>
</tr>
<tr>
<td>1998</td>
<td>New share issue</td>
<td>6,200,000</td>
<td>6,200,000</td>
<td>6,200,000</td>
<td>6,200,000</td>
<td>6,200,000</td>
</tr>
<tr>
<td>1999</td>
<td>New share issue</td>
<td>10,000,000</td>
<td>10,000,000</td>
<td>10,000,000</td>
<td>10,000,000</td>
<td>10,000,000</td>
</tr>
<tr>
<td>2000</td>
<td>New share issue</td>
<td>2,681,512</td>
<td>2,681,512</td>
<td>2,681,512</td>
<td>2,681,512</td>
<td>2,681,512</td>
</tr>
<tr>
<td>2001</td>
<td>New share issue</td>
<td>1,000,000</td>
<td>1,000,000</td>
<td>1,000,000</td>
<td>1,000,000</td>
<td>1,000,000</td>
</tr>
<tr>
<td>2002</td>
<td>New share issue</td>
<td>50,000</td>
<td>50,000</td>
<td>50,000</td>
<td>50,000</td>
<td>50,000</td>
</tr>
</tbody>
</table>

Largest shareholders in BioGaia at 31 December 2012 (source: Euroclear Sweden AB)

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Shares, 000’s</th>
<th>Voting %</th>
<th>% of total number of votes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AMF-Försäkring och fonder</td>
<td>15,320,000</td>
<td>20.0</td>
<td>20.0</td>
</tr>
<tr>
<td>2</td>
<td>Banque Carnegie Luxembourg S.A., NQI</td>
<td>13,490,000</td>
<td>18.0</td>
<td>18.0</td>
</tr>
<tr>
<td>3</td>
<td>Handelsbanken Fonder AB</td>
<td>10,950,000</td>
<td>14.0</td>
<td>14.0</td>
</tr>
<tr>
<td>4</td>
<td>Pictet &amp; CIE, W8IMY</td>
<td>10,825,000</td>
<td>14.0</td>
<td>14.0</td>
</tr>
<tr>
<td>5</td>
<td>Handelsbanken Fonder AB</td>
<td>5,760,000</td>
<td>7.0</td>
<td>7.0</td>
</tr>
</tbody>
</table>

The BioGaia share

Figures in brackets refer to the preceding year.

Change in ownership

<table>
<thead>
<tr>
<th>Number of shares</th>
<th>Total number of shareholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-500</td>
<td>5,275,000</td>
</tr>
<tr>
<td>501–1,000</td>
<td>781,000</td>
</tr>
<tr>
<td>1,001–5,000</td>
<td>525,000</td>
</tr>
<tr>
<td>5,001–10,000</td>
<td>72,000</td>
</tr>
<tr>
<td>10,001–15,000</td>
<td>21,000</td>
</tr>
<tr>
<td>15,001–20,000</td>
<td>13,000</td>
</tr>
<tr>
<td>20,001–25,000</td>
<td>95,000</td>
</tr>
</tbody>
</table>

Total number of shareholders: 6,752 (7,384)
Executive Management

PETER ROTHSCCHILD

MARGARETA HAGMAN
Born in 1946. 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

STAFFAN STRÖMBERG
Born in 1948. 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

DAVID DANGOOR

INGE HOLMSTRÖM

JAN ANNWALL
Born in 1950. Elected to the Board in 1990. M.B.A. Former Executive Vice President and CFO of Biogas AB. Founder and principal shareholder in Biogas AB. Holds 370,334 class A shares and 629,666 class B shares via Annwall & Rothschild Investment AB.

JÖRGEN THORBALL

PAULA ZEILON

STEFAN ELVING
Born in 1941. Elected to the Board in 2001. Former Marketing Director and Executive Vice President of ICA Handlanas AB. Other board assignments: Arcus AB and Cerva AB. Holds 0 shares.

THOMAS FUNCK
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.