

## BioGaia AB Interim report 1 January – 30 September 2012 (15 pages)

(Figures in brackets refer to the same period of last year)

### 1 January – 30 September 2012

- Net sales reached SEK 572.8 million (232.6). This figure includes licence revenue of SEK 356.0 million from Nestlé that is regarded as non-recurring revenue but is to a certain extent attributable to sales in 2012. Excluding license revenue from Nestlé, net sales amounted to SEK 216.8 million (232.6), a decrease of SEK 15.8 million (-7%). (Excluding foreign exchange effects, the decrease was 6%).
- Net sales of finished consumer products amounted to SEK 172.0 million (158.0), an increase of SEK 14.0 million (9%). Excluding foreign exchange effects, net sales rose by 10%.
- Net sales of component products totalled SEK 399.8 million (73.2). Excluding license revenue from Nestlé, net sales of component products reached SEK 43.8 million (73.2), a decrease of SEK 29.4 million (-40%) which is a result of the earlier agreement with Nestlé (see above).
- Operating profit was SEK 414.9 million (79.4), an improvement of SEK 335.5 million. Excluding license revenue from Nestlé, operating profit was SEK 58.9 million (79.4), down by SEK 20.5 million (-26%). (Excluding foreign exchange effects, the decrease was 22%).
- Profit after tax was SEK 314.1 million (57.8). Excluding license revenue, profit after tax was SEK 51.7 million (57.8), a decrease of SEK 6.1 million (-11%).
- Earnings per share totalled SEK 18.07 (3.24). Excluding license revenue, earnings per share amounted to SEK 2.88.
- The period's total cash flow was SEK 233,3 million (14,2). Cash flow includes payments from Nestlé amounting to SEK 356.0 million, investments in TwoPac of SEK 21.7 million (10,8), tax payments of SEK 73.5 million (30,1) and dividends of SEK 103.6 million (34,5). Cash and cash equivalents at 30 September 2012 totalled SEK 404.1 million (161,4).

### Third quarter 2012

- Net sales reached SEK 62.8 million (73.1), a decrease of SEK 10.3 million (-14%). Excluding foreign exchange effects, net sales fell by 9%.
- Net sales of finished consumer products amounted to SEK 50.2 million (46.5), an improvement of SEK 3.7 million (8%). Excluding foreign exchange effects, net sales rose by 14%.
- Net sales of component products totalled SEK 12.5 million (25.9), down by SEK 13.4 million (-52%) which is a result from the earlier agreement with Nestlé (see above). (Excluding foreign exchange effects, net sales fell by 48%).
- Operating profit was SEK 13.5 million (22.1), a decrease of SEK 8.6 million (39%). Excluding foreign exchange effects, operating profit declined by 26%.
- Profit after tax was SEK 14.2 million (15.6), down by SEK 1.4 million (9%).

### Key events in the third quarter of 2012

- Publication of study showing that *Lactobacillus reuteri* Protectis prevented necrotizing enterocolitis (NEC) in premature infants.
- Publication of a further study showing that *Lactobacillus reuteri* Protectis reduced colic in infants.

### Key events after the end of the third quarter of 2012

- Agreement for the sale of tablets and drops in Pakistan.
- Publication of study showing that *Lactobacillus reuteri* Protectis is safe and effective in premature infants.

“As in earlier years, the third quarter was characterised by lower activity among our distributors and suppliers due to the customary summer holiday. Despite the ongoing change of distributors in several countries, which effect the sales negatively short term, sales of finished consumer products increase” says Peter Rothschild, president BioGaia AB.

“All in all, we are now better equipped than ever before to continue our expansion through more effective marketing and sales and via the launch of new products in existing markets and our existing products in new markets”, concludes Peter Rothschild.

You are welcome to take part in a teleconference on the interim report that will be held today at 9:30 a.m. by President Peter Rothschild. To participate in the conference, please see <http://www.biogaia.com/investor-relations> for further instructions.

BioGaia has published this information in accordance with the Swedish Securities Market Act. The information was issued for publication on 23 October 2012, 8:00 a.m. CET.

## BioGaia AB (publ.)

### INTERIM REPORT, 1 JANUARY – 30 SEPTEMBER 2012

*Figures in brackets refer to the same period of last year.*

The Board of Directors and the President of BioGaia AB (publ) hereby present the interim report for the period from 1 January to September 2012. A brief description of the company's operations is provided on page 15.

#### PRESIDENT'S COMMENTS

As in earlier years, the third quarter was characterised by lower activity among our distributors and suppliers due to the customary summer holiday. Despite the ongoing change of distributors in several countries, which effect the sales negatively short term, sales of finished consumer products increase.

In the past few months, several studies showing positive results for the use of *Lactobacillus reuteri* Protectis have been published. Two of these applies to treatment of premature infants and another once again confirms the significant results of Protectis on infants with colic. The studies on premature infants are vital, since this is an area where safety is of crucial importance. The outcomes are very encouraging and we will continue working in this area to find the most optimal solution in all respects. With regard to results on infants with colic, you might think that we already have sufficient data to convince healthcare professionals that our products work and can be recommended as a safe and effective treatment. However, the third and latest study is of major importance since it was conducted by a physician who is regarded as one of the world's most well reputed experts on probiotic and because the study was performed according to the highest standards of clinical trial reporting (CONSORT). We now have a very strong position in this indication area, which will greatly aid our efforts to get paediatricians to recognise and also recommend other BioGaia products.

The change of distributors in a number of countries is continuing, but the negative effects of this have been offset by strong sales in a number of countries. Our sales to Fleet Pharmaceuticals in the USA have given this market a real boost and North America as whole is becoming an increasingly important market for us. Excluding foreign exchange effects, sales of finished consumer products rose by 14% during the quarter and by 13% for the rolling 12-month period. This is lower than the average for the past few years when sales growth for these products has been around 30%. The change of distributors is naturally intended to ensure sustained strong growth in the future.

Sales in Japan were somewhat lower in the third quarter, but this has not changed our assessment that sales in Japan will continue to show healthy growth.

Our focus on oral health products is now starting to pay off in the form of sales growth and product launches in the Netherlands and Belgium.

Following the agreements signed with Nestlé in February, sales have decreased by around 50% according to plan and we are now working together intensively to create new opportunities that are expected to generate substantial sales to Nestlé in a longer perspective. This is a comprehensive process, but touches on areas with major potential.

Personnel expenses have risen somewhat more than usual, since we have among other things hired a new

Sales Director, a new Marketing Director and a new director for our quality/regulatory affairs department during the year. All of these individuals come from the pharmaceutical industry and are contributing considerable new expertise in areas that are critical for us.

All in all, we are now better equipped than ever before to continue our expansion through more effective marketing and sales and via the launch of new products in existing markets and our existing products in new markets.

#### FINANCIAL PERFORMANCE FOR THE PERIOD FROM 1 JANUARY TO 30 SEPTEMBER 2012

##### **Sales**

Consolidated net sales reached SEK 572.8 million (232.6). This figure includes license revenue from Nestlé of SEK 356 million that is regarded as non-recurring revenue but is to a certain extent attributable to sales in 2012. In February 2012 BioGaia signed several new agreements with Nestlé including the acquisition of a perpetual license to use BioGaia's probiotic in infant formula during the remaining term of the patent. The purchase price was EUR 50.8 million, of which EUR 40.0 million (SEK 356 million) was received and recognised in the first quarter of 2012. The sale of the license will lead to a decrease in culture revenue from Nestlé during 2012, which will also result in lower sales of component products. BioGaia's assessment is that revenue (excluding license revenue) from Nestlé will be equal to approximately 50% of the value of sales during 2011, and will increase in 2013 to close to the 2011 level. From 2014 forward, sales are expected to exceed those in 2011.

Excluding license revenue from Nestlé, net sales amounted to SEK 216.8 million (232.6), a decrease of SEK 15.8 million (7%) compared to the same period of last year.

A large share of the company's sales are denominated in foreign currency, primarily EUR but also USD and JPY. With unchanged exchange rates, net sales would have been SEK 2.4 million higher. Excluding foreign exchange effects, the decrease in net sales (excluding license revenue) was 6%.

Exchange rate fluctuations for EUR, USD and JPY have reduced both revenue and expenses. Operating profit would have been SEK 2.9 million higher in the event of unchanged exchange rates.

For the past 12-month period, sales (excluding license revenue from Nestlé) were up by 1% compared to the same period of last year.

##### Sales per segment

Sales of finished consumer products rose by SEK 14 million (9%) to SEK 172.0 million. Excluding foreign exchange effects, the increase was 10%. For the past 12-month period, sales of finished consumer products grew by 13% compared to the same period of last year.

Sales of finished consumer products rose in North America, Europe and Asia but declined in the rest of the world compared to the same period of last year. The increase in Asia is mainly due to higher sales in Japan and Indonesia. The increase in North America is explained primarily by Fleet's launch of strawberry-flavoured tablets in the USA. In Europe, the increase is attributable to countries such as Spain, Italy and France. In the rest of the world, sales were down in Australia but rose in South Africa.

Sales of component products improved by SEK 326.6 million. Excluding license revenue from Nestlé, sales fell by 29.4 million (40%) compared to the same period of last year. Sales of component products declined in Europe and Asia. The drop in Europe is a consequence of the agreement with Nestlé (see above). The decrease in Asia is explained by the fact that the figures for the previous year include income from the agreement with Yili in China. For the past 12-month period, sales of component products were down by 25% (excluding license revenue from Nestlé).

#### Sales per geographical market

Sales in Europe improved by SEK 333.8 million. Excluding license revenue from Nestlé, sales fell by SEK 22.2 million (13%). For the past 12-month period, sales in Europe were down by 6% (excluding license revenue).

Sales in Asia decreased by SEK 3.3 million (11%). For the past 12-month period, sales in Asia decreased by 1%.

Sales in the USA and Canada rose by SEK 11.4 million (123%) compared to the same period of last year. For the past 12-month period, sales in the USA and Canada improved by 154%.

Sales in the rest of the world fell by SEK 1.6 million (8%) compared to the same period of last year. For the past 12-month period, sales in the rest of the world increased by 3%.

#### BioGaia Brand

Of total finished consumer products, 44% (42) were sold under the BioGaia brand. Including so-called co-branding, the percentage was 51% (51).

#### **Gross profit**

Gross profit amounted to SEK 509.0 million (159.0). Excluding license revenue from Nestlé, gross profit was SEK 153.0 million (159.0), which is SEK 6.0 million (4%) lower than in the same period of last year.

Gross margin (excluding license revenue) rose from 68% to 71%. This is both due to increased sales in Japan, where the margins are higher, and decreased sales to Nestlé, where the margin is lower.

#### **Operating expenses**

Selling expenses totalled SEK 55.9 million (47.8), which is equal to 26% (21) of net sales (excluding license revenue). The increase of SEK 8.1 million (17%) is mainly attributable to higher personnel expenses and marketing activities (increased participation in conferences, new websites and product samples) as well as higher costs in Japan owing partly to exchange rate fluctuations. For the past 12-month period, selling expenses rose by 16%.

Administrative expenses amounted to SEK 9.7 million (8.8), which is equal to 4% (4) of net sales (excluding license revenue). The increase of SEK 0.9 million (10%) is mainly attributable to higher personnel expenses. Administrative expenses for the past 12-month period rose by 17%, mainly due to higher personnel expenses.

R&D expenses are reported at SEK 25.2 million (24.4), which is equal to 12% (11) of net sales (excluding license revenue). External expenses for clinical studies have decreased, while personnel and patent expenses have increased.

The amortisation component of R&D expenses was SEK 0.5 million (1.0). Investments in capitalised development

expenses totalled SEK 0 million (0). For the past 12-month period, R&D expenses grew by 11%.

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

#### **Operating profit**

Operating profit was SEK 414.9 million (79.4), an increase of SEK 335.5 million. Excluding license revenue from Nestlé, operating profit was SEK 58.9 million, which is SEK 20.5 million (26%) lower than in the same period of last year.

#### **Financial items and profit before tax**

Profit before tax was SEK 428.7 million (79.2), an improvement of SEK 349.5 million. Excluding license revenue from Nestlé, profit before tax was SEK 72.7 million, a decrease of SEK 6.5 million (8%) compared to the same period of last year.

Net financial items include a foreign exchange gain/loss of SEK 7.3 million (-2.2) on forward exchange contracts in EUR. At 30 September 2012 the company had outstanding forward exchange contracts for EUR 10.8 million at an average exchange rate of SEK 9.09. Forward exchange contracts amounting to EUR 2.1 million will mature for payment in 2012, EUR 6.4 million in 2013 and the remaining EUR 2.3 million in 2014. The actual exchange gain/loss depends on the exchange rate on the maturity date of the contracts. If the EUR rate on the maturity date is lower/higher than that at 30 September 2012 (8.44), an exchange gain/loss will be recognised in the future.

#### **Profit after tax**

Profit after tax was SEK 314.1 million (57.8), an increase of SEK 256.3 million. Excluding license revenue from Nestlé, profit after tax was SEK 51.7 million, which is a decrease of SEK 6.1 million (11%) compared to the same period of last year.

The tax rate for the Group (excluding license revenue) was 29% (27). The Group pays tax on profits in the Swedish companies. The loss in Japan is not deductible against the Swedish profits. Loss carryforwards in the Japanese subsidiary at 30 September 2012 amounted to SEK 67.9 million. The deferred tax asset for these has not been recognised, since a sustainable profit level has not yet been shown in the Japanese subsidiary. Since the loss in Japan has increased compared to the corresponding period of last year, the tax rate has risen.

#### **Earnings per share**

Earnings per share amounted to SEK 18.07 (3.24). Excluding non-recurring revenue, earnings per share were SEK 2.88.

#### **Cash flow**

The Group's cash and cash equivalents at 30 September 2012 totalled SEK 404.1 million (161.4).

Cash flow amounted to SEK 233.3 million (14.2). Cash flow includes a non-recurring payment from Nestlé amounting to SEK 356 million, investments in TwoPac of SEK 21.7 million (10.8), tax payments of SEK 73.5 million (30.1) and dividends of SEK 103.6 million (34.5).

#### **Equity**

Consolidated equity amounted to SEK 441.7 million (208.6) and the equity/assets ratio was 84% (83).

In June BioGaia carried out the warrant programme that was resolved on by the Annual General Meeting on 8 May 2012. A total of 88,500 warrants were subscribed for, of which the management subscribed for 41,000. The warrants were issued at a market price of SEK 14.27 each following valuation according to the Black & Scholes formula, which provided the Parent Company with proceeds of SEK 1.3 million. Each warrant entitles the holder to subscribe for one class B share for SEK 241.90 on 1 June 2015. Volatility was estimated at 40%.

If all of the subscription warrants are exercised, the company's equity will be increased by SEK 21.4 million. This represents a dilutive effect of approximately 0.5% on the share capital and 0.4% on the total number of votes upon the full exercise of warrants.

In order to achieve a high level of participation, the AGM resolved to pay a subsidy of SEK 10 per warrant (after 1 June 2015) to the employees who have subscribed for subscription warrants but have not exercised the right to buy shares. No provisions for this obligation have yet been made, but will be continuously assessed.

#### **Investments in property, plant and equipment**

The period's investments in property, plant and equipment amounted to SEK 23.5 million (11.0), of which SEK 21.7 million (10.8) refers to TwoPac.

#### **Subsidiary in Japan**

Net sales in the Japanese subsidiary are reported at SEK 10.4 million (9.2). Operating profit amounted to SEK -4.7 million (-3.3).

#### **Subsidiary TwoPac AB**

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

Net sales in TwoPac amounted to SEK 20.6 million (17.2). Operating profit was SEK 6.3 million (4.3). The company pays tax since 2012. Profit after tax was SEK 4.3 million (4.0). The new production facility is now finished and the transfer of production lines has been started, with expected completion in the first quarter of next year.

#### **Parent Company**

Net sales in the Parent Company reached SEK 564.7 million (225.6) and profit before tax was SEK 426.1 million (75.6). Profit after tax was SEK 313.0 million (39.7). Cash flow in the Parent Company totalled SEK 235.6 million (8.4).

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

### **FINANCIAL PERFORMANCE IN THE THIRD QUARTER OF 2012**

#### **Third quarter sales**

Net sales for the third quarter reached SEK 62.8 million (73.1), a decrease of SEK 10.3 million (14%) compared to the same period of last year. The decrease is attributable to component products and is explained above under sales for the period from 1 January to 30 September 2012. Excluding foreign exchange effects (see above), sales were down by 9%.

Sales of finished consumer products amounted to SEK 50.2 million (46.5), an increase of SEK 3.7 million (8%). Excluding foreign exchange effects, sales of finished consumer products rose by 14%. Compared to the second quarter, sales of finished consumer products declined by SEK 16.9 million. Third quarter sales are typically the lowest of the year due to the customary summer holiday in Europe, which results in a lower level of activity among BioGaia's customers and suppliers.

Sales of component products totalled SEK 12.5 million (25.9), a decrease of SEK 13.4 million that is explained above under sales for the period from 1 January to 30 September 2012.

Growth in sales varies between quarters. For a more accurate picture, a rolling 12-month income statement is presented on page 8.

#### **Gross profit for the third quarter**

Gross profit was SEK 43.3 million (47.8), down by SEK 4.5 million compared to the same period of last year.

#### **Other operating expenses for the third quarter**

Selling expenses for the third quarter were SEK 1.9 million (12%) higher than the same period of last year, which is due to increased personnel expenses and marketing activities.

Administrative expenses rose by SEK 0.3 million (10%) compared to the same period of last year.

R&D expenses fell by SEK 0.5 million (7%) compared to the same period of last year. External expenses for clinical studies have decreased, while personnel and patent expenses have increased.

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

Compared to the previous quarter, selling, administrative and R&D expenses decreased as a result of lower activity during the quarter due to the customary summer holiday in Sweden and the rest of Europe.

#### **Operating profit for the third quarter**

Operating profit for the third quarter was SEK 13.5 million (22.1), which is SEK 8.6 million lower than in the same period of last year.

#### **Profit before tax for the third quarter**

Profit before tax for the third quarter was SEK 20.1 million (21.4), a decrease of SEK 1.3 million compared to the same period of last year. Net financial items include a foreign exchange gain of SEK 4.3 million on forward exchange contracts in EUR (for more information – see above). The corresponding period of 2011 included a foreign exchange loss of SEK 1.5 million.

#### **Profit after tax for the third quarter**

Profit after tax was SEK 14.2 million (15.6), down by SEK 1.4 million compared to the same period of last year.

#### **Cash flow for the third quarter**

Cash flow for the third quarter was SEK -9.9 million (34.4).

During the period, the Group paid tax of SEK 32.2 million (5.6).



## KEY EVENTS IN THE THIRD QUARTER OF 2012

### Launches in the third quarter of 2012

Distributor/licensee	Product	Country
Nestlé	Infant formula with <i>Lactobacillus reuteri</i> Protectis	Puerto Rico
Oral Company	Oral health tablets	Netherlands and Belgium

### BioGaia's probiotics prevented necrotizing enterocolitis (NEC) in premature infants

A study carried out on premature infants, born with a weight below 1000 grams, showed that prophylactic supplementation of *Lactobacillus reuteri* Protectis resulted in a statistically significant reduction in necrotizing enterocolitis (NEC), the most common gastrointestinal cause of death and illness in premature infants.

Following the introduction of preventive supplementation of *Lactobacillus reuteri* Protectis to all premature infants in the neonatal intensive care unit where the study was performed, one case of NEC was avoided for every eight infants treated.

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

### *Lactobacillus reuteri* Protectis shown to reduce colic in infants

A double-blind, placebo-controlled study of 80 colicky infants showed that the crying time was significantly reduced among the infants supplemented by drops with the probiotic *Lactobacillus reuteri* Protectis compared to those in the placebo group. The quality of life for the parents and families were also significantly improved in the probiotic group compared to the placebo group. The study was done by Hania Szajewska, Professor and Chair of the Department of Paediatrics at the Medical University of Warsaw in Poland. She is one of the world's most well reputed experts on probiotics and has conducted numerous clinical trials.

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

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

## KEY EVENTS AFTER THE END OF THE THIRD QUARTER

### Agreement for the sale of tablets and drops in Pakistan

In October BioGaia signed an agreement with Ferozsons Laboratories Limited, giving 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.

### BioGaia's probiotics safe and effective in premature infants

Results from the largest probiotic study to date in premature infants showed that necrotizing enterocolitis (NEC), the most common gastrointestinal cause of death and illness in premature infants, decreased by 40% in the infants supplemented by *Lactobacillus reuteri* Protectis compared to the placebo. Furthermore, in the infants below 1500 grams, *Lactobacillus reuteri* Protectis reduced episodes of feeding intolerance by 43%.

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

## KEY EVENTS EARLIER IN 2012

### Launches in the first half of 2012

Distributor/licensee	Product	Country
Cube Pharmaceuticals	Oral rehydration solution (ORS)	Greece
Ewopharma	Oral health lozenges	Croatia, Slovenia, Serbia and Poland
Ewopharma	Digestive health tablets with strawberry flavour	Romania
Fleet Laboratories	Digestive health tablets with strawberry flavour	USA
Interbat	Drops	Indonesia
Nestlé	Infant formula with <i>Lactobacillus reuteri</i> Protectis	Bangladesh, Burma, Cambodia, the Caribbean, Laos, Singapore, Sri Lanka and the USA
Recalcine	Digestive health tablets and drops	Bolivia
Sunstar	Oral health lozenges	Canada

### BioGaia extends collaboration with Nestlé

Since 2008, BioGaia and Nestlé have collaborated in the field of infant nutrition products. After the signing of several new agreements in mid-February 2012, the parties have further extended this collaboration.

The agreements include the entry by Nestlé into a perpetual licence to use BioGaia's patented *Lactobacillus reuteri* in infant nutrition products for EUR 50.8 million. The initial payment of EUR 40 million (SEK 356 million) was made and recognised in the first quarter of 2012. Additional payments of EUR 10.8 million will be paid and recognised over a five-year period on the achievement of certain milestones.

The agreements are of significant strategic value for BioGaia, since they not only involve an extended collaboration with Nestlé but also provide greater financial freedom for BioGaia to further invest in its own brand, develop its own new products, conduct research on new indications and increase the distribution of BioGaia-branded products. The additional finances also give the Board scope to propose a generous dividend policy.

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

Furthermore, Nestlé and BioGaia are working on several other projects, including the development of innovative products in the infant nutrition and other nutrition categories and the distribution of BioGaia-branded products in new markets. These further developments will be announced at an appropriate time closer to launch. The first agreement, which was announced in

June, is the agreement with Gerber for the sale of BioGaia's probiotic baby drops on the US market (see below).

As a result of the up-front payments for the acquisition of the licence, BioGaia estimates that revenue from Nestlé during 2012, excluding the up-front payment, will be equal to around 50% of the value of sales during 2011, and will increase in 2013 to close to the 2011 level. From 2014 forward, sales are expected to exceed those in 2011.

#### **Results of study show that *Lactobacillus reuteri* Protectis reduces diarrhoea in children**

A double-blind, placebo-controlled study of 494 children showed that supplementation of *Lactobacillus reuteri* Protectis significantly reduced episodes of diarrhoea. *Lactobacillus reuteri* Protectis was particularly effective in children with lower nutritional status. Another probiotic strain, 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.

#### **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 is planned for 2012.

#### **New study on type 2 diabetics**

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

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

#### **Agreements for oral health products in the Czech Republic, the Benelux countries and South Africa**

In May BioGaia signed three different agreements, one with Next Force giving Next Force exclusive sales rights for BioGaia's oral health products in the Czech Republic, one with Ivodent giving Ivodent exclusive sales rights in South Africa, and one with Oral Company giving Oral Company exclusive sales rights in the Netherlands, Belgium and Luxembourg. In all countries, the products will be sold under the BioGaia brand and the launch is planned to take place during 2012.

#### **Agreement with Nestlé's 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 launch in the beginning of 2013 and will support Gerber's Maternal and Infant Nutrition strategy to offer mothers benefits regardless of whether they choose to breastfeed or supplement with formula.

This is the first contract with Nestlé since BioGaia's sale to Nestlé of perpetual license rights to use BioGaia's patented *Lactobacillus reuteri* Protectis in infant formula, as announced in February 2012 (see above), at which time the two companies entered into a number of development and option agreements. The agreement with Gerber is a major step forward for BioGaia in the large United States paediatric market.

#### **EMPLOYEES**

The number of employees in the Group (TwoPac included) at 30 September 2012 was 74 (63).

#### **Incentive scheme for the employees**

In June BioGaia carried out the subscription warrant programme for all employees in the BioGaia Group that was resolved on by the AGM on 8 May 2012. For more information, see above under "Equity" on page 3.

#### **SIGNIFICANT RISKS AND UNCERTAINTIES; GROUP AND PARENT COMPANY**

The business model previously used in Japan was found to be ineffective and the company has changed to the business model that is being used successfully in other markets. The Japanese subsidiary's sales have now picked up and are expected to increase continuously.

On the balance sheet date, assets in the Japanese subsidiary were reported at SEK 7.6 million in the Group. BioGaia's assessment is that there is no indication of impairment of these assets. In the Parent Company, all receivables and participations in the Japanese subsidiary have been written down to zero.

The shares in the subsidiary CapAble amount to a total of SEK 6.9 million in the Parent Company. So far CapAble has reported a loss. CapAble, which is 90.1% owned by BioGaia AB, was started in November 2008 to manufacture and sell the patented LifeTop Cap. BioGaia made total conditional shareholder contributions of SEK 6 million to CapAble in 2009 and 2010. BioGaia's assessment is that CapAble will show profitability in coming years, for which reason there was no indication of impairment on the balance sheet date.

For further information see the administration report and Notes 28 and 29 of the annual report for 2011.

## **ACCOUNTING POLICIES**

The consolidated financial statements are presented in compliance with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and the interpretations published by the IFRS Interpretations Committee (IFRIC) that have been endorsed by the European Commission for application in the EU.

This interim report has been prepared for the Group in accordance with IAS 34, Interim Financial Reporting, and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Unless otherwise stated below, the Group and Parent Company have applied the same accounting and valuation standards as in the latest annual report.

### ***New accounting standards***

The applied accounting policies correspond to those described in the annual report for 2011, aside from a number of minor amendments to existing standards and new interpretations that are effective as of 1 January 2012. These are not assessed to have any significant impact on the Group's or the Parent Company's profit, financial position or disclosures.

## **FUTURE OUTLOOK**

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

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

BioGaia's dividend policy is to pay a shareholder dividend equal to 30% of profit after tax.

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

**STATEMENTS OF COMPREHENSIVE INCOME**

(Amounts in SEK 000's)

	Jan-Sept 2012	Jan-Sept 2011	July-Sept 2012	July-Sept 2011	Jan-Sept 2011	Oct 2011- Sept 2012	Oct 2010- Sept 2011
Net sales	216 845	232 596	62 814	73 107	314 992	299 241	295 353
Licence revenue	356 004	-	-	-	-	356 004	-
Cost of goods sold	-63 871	-73 567	-19 500	-25 286	-98 727	-89 031	-92 977
<i>Gross profit</i>	<b>508 978</b>	<i>159 029</i>	<b>43 314</b>	<i>47 821</i>	<i>216 265</i>	<b>566 214</b>	<i>202 376</i>
Selling expenses	-55 895	-47 791	-17 423	-15 532	-66 079	-74 183	-64 177
Administrative expense	-9 736	-8 849	-2 901	-2 635	-13 014	-13 901	-11 857
Research and development expenses	-25 227	-24 444	-6 959	-7 498	-34 317	-35 100	-31 759
Other operating expenses	-3 189	1 456	-2 575	-49	304	-4 341	910
Share in profit/loss of associated company	-	-	-	-	-	-	100
<i>Operating profit</i>	<b>414 931</b>	<i>79 401</i>	<b>13 456</b>	<i>22 107</i>	<i>103 159</i>	<b>438 689</b>	<i>95 593</i>
Financial income <sup>1)</sup>	13 807	2 149	6 696	845	5 792	19 699	4 606
Financial expenses <sup>2)</sup>	-48	-2 311	-9	-1 542	-84	-70	-2 326
<i>Profit before tax</i>	<b>428 690</b>	<i>79 239</i>	<b>20 143</b>	<i>21 410</i>	<i>108 867</i>	<b>458 318</b>	<i>97 873</i>
Tax expense	-114 626	-21 476	-5 985	-5 826	-29 345	-122 495	-27 223
<b>PROFIT FOR THE PERIOD</b>	<b>314 064</b>	57 763	<b>14 158</b>	15 584	79 522	<b>335 823</b>	70 650
<b>Other comprehensive income</b>							
Gain/losses arising on translation of the financial statements of foreign operations	-372	680	-532	995	712	-340	797
<b>Comprehensive income for the period</b>	<b>313 692</b>	58 443	<b>13 626</b>	16 579	80 234	<b>335 483</b>	71 447
<b>Profit for the period attributable to:</b>							
Owners of the Parent Company	312 115	55 956	13 849	14 846	76 369	332 528	68 779
Non-controlling interests	1 949	1 807	309	738	3 153	3 295	1 871
	<b>314 064</b>	57 763	<b>14 158</b>	15 584	79 522	<b>335 823</b>	70 650
<b>Comprehensive income for the period attributable to:</b>							
Owners of the Parent Company	311 743	56 636	13 317	15 841	77 081	332 188	69 576
Non-controlling interests	1 949	1 807	309	738	3 153	3 295	1 871
	<b>313 692</b>	58 443	<b>13 626</b>	16 579	80 234	<b>335 483</b>	71 447
<b>Earnings per share</b>							
Basic earnings per share, SEK	18,07	3,24	0,80	0,86	4,42		
Diluted earnings per share, SEK	18,07	3,24	0,80	0,86	4,42		
Number of shares, thousands	17 271	17 271	17 271	17 271	17 271		
Average number of shares, thousands	17 271	17 271	17 271	17 271	17 271		
Number of outstanding warrants, thousands	89	-	89	-	-		
Number of outstanding warrants with a dilutive effect, thousands	-	-	-	-	-		
Number of shares after dilution, thousands	17 271	17 271	17 271	17 271	17 271		
1) Financial income consists of:							
Interest income	6 519	2 149	2 429	845	3 270		
Exchange gains on forward exchange contracts	7 288	-	4 267	-	2 522		
	<b>13 807</b>	2 149	<b>6 696</b>	845	5 792		
2) Financial expenses consists of:							
Exchange losses on forward exchange contracts	-	-2 249	-	-1 535	-		
Other financial expenses	-48	-62	-9	-7	-84		
	<b>-48</b>	-2 311	<b>-9</b>	-1 542	-84		



**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

	30 Sept	31 Dec	30 Sept
(Amounts in SEK 000s)	2012	2011	2011
<b>ASSETS</b>			
Intangible assets	-	264	453
Property, plant and equipment	43,874	24,158	19,941
Other non-current receivables	17	18	18
<i>Total non-current assets</i>	<b>43,891</b>	<b>24,440</b>	<b>20,412</b>
Current assets excl. cash and cash equivalents	78,038	83,858	70,400
Cash and cash equivalents	404,065	171,534	161,434
<i>Total current assets</i>	<b>482,103</b>	<b>255,392</b>	<b>231,834</b>
<b>TOTAL ASSETS</b>	<b>525,994</b>	<b>279,832</b>	<b>252,246</b>
<b>EQUITY AND LIABILITIES</b>			
Equity attributable to owners of the Parent Company	439,156	229,764	209,320
Non-controlling interests	2,539	591	-756
Total equity	441,695	230,355	208,564
Provision for deferred tax	185	185	-
Interest-free current liabilities	84,114	49,292	43,682
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>525,994</b>	<b>279,832</b>	<b>252,246</b>
<b>Pledged assets</b>	<b>2,000</b>	<b>5,874</b>	<b>5,814</b>

**CONSOLIDATED CASH FLOW STATEMENTS**

	Jan-Sept	Jan-Sept	July-Sept	July-Sept	Jan-Dec
(Amounts in SEK 000s)	2012	2011	2012	2011	2011
<i>Operating activities</i>					
Operating profit	414,931	79,401	13,456	22,107	103,159
Depreciation/amortisation	4,024	5,677	1,383	1,211	5,425
Other non-cash items	623	-90	547	-19	1,398
	419,578	84,988	15,386	23,299	109,982
Gains/losses on realised forward exchange contracts	1,965	-20	1,298	-330	-164
Paid tax	-73,515	-30,121	-32,221	-5,649	-35,768
Interest received and paid	6,471	2,226	2,420	977	3,189
Cash flow from operating activities before changes in working capital	354,499	57,073	-13,117	18,297	77,239
Changes in working capital	4,578	129	8,805	20,516	-4,447
<i>Cash flow from operating activities</i>	<b>359,077</b>	<b>57,202</b>	<b>-4,312</b>	<b>38,813</b>	<b>72,792</b>
<i>Cash flow from investing activities</i>	<b>-23,475</b>	<b>-8,447</b>	<b>-5,670</b>	<b>-4,396</b>	<b>-13,567</b>
<i>Cash flow from financing activities</i>	<b>-102,352</b>	<b>-34,542</b>	<b>97</b>	<b>-</b>	<b>-34,542</b>
Cash flow for the period	233,250	14,213	-9,885	34,417	24,683
Cash and cash equivalents at beginning of period	171,534	146,903	414,499	126,646	146,903
Exchange difference in cash and cash equivalents	-719	318	-549	371	-52
Cash and cash equivalents at end of period	404,065	161,434	404,065	161,434	171,534

### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

(Amounts in SEK 000s)	Jan-Sept 2012	Jan-Sept 2011	Jan-Dec 2011
At beginning of period	230,355	187,323	187,323
Dividends	-103,626	-34,542	-34,542
Subscription warrants	1,274	-	-
Change in group structure	-	-2,660	-2,660
Comprehensive income for the period	313,692	58,443	80,234
<b>At end of period</b>	<b>441,695</b>	208,564	230,355

### REPORTING BY SEGMENT – GROUP

(Amounts in SEK 000s)

<b>Revenue by segment</b>	Jan-Sept 2012	Jan-Sept 2011	July-Sept 2012	July-Sept 2011	Jan-Dec 2011	Oct 2011- Sept 2012	Oct 2010- Sept 2011
Finished consumer products	172,002	157,956	50,181	46,496	215,431	229,477	202,576
Component products	43,803	73,186	12,461	25,874	97,731	68,348	90,925
License revenue (component products) 1)	356,004	-	-	-	-	356,004	-
Other products	1,040	1,454	172	737	1,830	1,416	1,852
	<b>572,849</b>	232,596	<b>62,814</b>	73,107	314,992	<b>655,245</b>	295,353

<b>Gross profit by segment</b>	Jan-Sept 2012	Jan-Sept 2011	July-Sept 2012	July-Sept 2011	Jan-Dec 2011	Oct,2011- Sept,2012	Oct,2010- Sept,2011
Finished consumer products	123,476	111,090	35,621	33,377	154,015	166,401	140,935
Component products	28,643	46,558	7,540	13,768	60,523	42,608	59,670
License revenue (component products) 1)	356,004	-	-	-	-	356,004	-
Other products	855	1,381	153	676	1,727	1,201	1,771
	<b>508,978</b>	159,029	<b>43,314</b>	47,821	216,265	<b>566,214</b>	202,376

1) License revenue refers to revenue from Nestlé (see above in text). The license revenue is included in component products but is reported on a separate line in order to achieve better comparability between years.

### Revenue by geographical market

	Jan-Sept 2012	Jan-Sept 2011	July-Sept 2012	July-Sept 2011	Jan-Dec 2011	Oct 2011- Sept 2012	Oct 2010- Sept 2011
Net sales							
Europe	151,568	173,777	44,411	51,473	234,505	212,296	226,553
License revenue (Europe) 1)	356,004	-	-	-	-	356,004	-
USA and Canada	20,675	9,288	3,967	4,922	17,816	29,203	11,503
Asia	26,167	29,526	7,787	9,104	37,117	33,758	33,935
Rest of world	18,435	20,005	6,649	7,608	25,554	23,984	233,362
	<b>572,849</b>	232,596	<b>62,814</b>	73,107	314,992	655,245	295,353

<b><u>PARENT COMPANY INCOME STATEMENTS</u></b>	<b>Jan-Sept</b>	Jan-Sept	Jan-Dec
(Amounts in SEK 000s)	<b>2012</b>	<b>2011</b>	<b>2011</b>
Net sales	<b>208,741</b>	225,590	306,182
License revenue	<b>356,004</b>	-	-
Cost of goods sold	<b>-69,754</b>	<b>-78,171</b>	<b>-106,868</b>
<i>Gross profit</i>	<b>494,991</b>	147,419	199,314
Selling expenses	<b>-41,627</b>	-35,464	-49,406
Administrative expenses	<b>-9,055</b>	-7,749	-11,607
Research and development expenses	<b>-25,200</b>	-24,425	-34,283
Other operating income	-	-	304
Other operating expenses	<b>-3,189</b>	<b>1,456</b>	<b>-</b>
<i>Operating profit</i>	<b>415,920</b>	81,237	104,322
Impairment loss on receivable from subsidiary	<b>-5,348</b>	-7,461	-10,453
Net financial items	<b>15,534</b>	<b>1,851</b>	<b>8,391</b>
Profit before tax	<b>426,106</b>	75,627	102,260
Tax expense	<b>-113,083</b>	<b>-21,476</b>	<b>-29,781</b>
<b>PROFIT FOR THE PERIOD</b>	<b>313,023</b>	54,151	72,479

<b><u>PARENT COMPANY BALANCE SHEETS</u></b>	<b>30 Sept</b>	31 Dec	30 Sept
	<b>2012</b>	<b>2011</b>	<b>2011</b>
<b><u>ASSETS</u></b>			
Intangible assets	-	264	453
Property, plant and equipment	<b>2,505</b>	2,068	2,313
Shares in group companies	<b>21,160</b>	21,160	21,110
Non-current receivables from subsidiaries	<b>24,513</b>	<b>16,513</b>	<b>16,513</b>
<i>Total non-current assets</i>	<b>48,178</b>	40,005	40,389
Current assets excl. cash and cash equivalents	<b>71,170</b>	73,643	61,831
Cash and cash equivalents	<b>396,792</b>	<b>161,865</b>	<b>149,354</b>
<i>Total current assets</i>	<b>467,962</b>	235,508	211,185
<b>TOTAL ASSETS</b>	<b>516,140</b>	275,513	251,574
<b><u>EQUITY AND LIABILITIES</u></b>			
Equity	<b>423,427</b>	212,756	196,421
Interest-free current liabilities	<b>92,713</b>	<b>62,757</b>	<b>55,333</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>516,140</b>	275,513	251,754
<b>Pledged assets</b>	<b>2,000</b>	2,000	2,000

<b><u>PARENT COMPANY CASH FLOW STATEMENTS</u></b>	<b>Jan-Sept</b>	Jan-Sept	Jan-Dec
	<b>2012</b>	<b>2011</b>	<b>2011</b>
<u>Operating activities</u>			
Operating profit	415,920	81,237	104,322
Depreciation/amortisation	1,177	1,627	2,096
Other non-cash items	623	-93	51
Gain/losses on realised foreign exchange contracts	1,965	-20	-164
Paid tax	-73,482	-30,121	-35,769
Interest received and paid	6,939	2,224	3,582
Cash flow from operating activities before changes in working capital	353,142	54,854	74,118
Changes in working capital	-4,218	2,953	-2,686
<i>Cash flow from operating activities</i>	<b>348,924</b>	57,807	71,432
<i>Cash flow from investing activities</i>	<b>-10,999</b>	-14,844	-15,813
<i>Cash flow from financing activities</i>	<b>-102,352</b>	-34,542	-34,542
Cash flow for the period	235,573	8,421	21,077
Cash and cash equivalents at beginning of period	161,865	140,840	140,840
Exchange difference in cash and cash equivalents	-646	93	-52
Cash and cash equivalents at end of period	396,792	149,354	161,865

**PARENT COMPANY STATEMENTS OF CHANGES IN EQUITY**

(Amounts in SEK 000s)	<b>Jan-Sept</b>	Jan-Sept	Jan-Dec
	<b>2012</b>	<b>2011</b>	<b>2011</b>
At beginning of year	212,756	176,632	176,632
Dividends	-103,626	-34,542	-34,542
Group contributions	-	-	-1,813
Subscription warrant programme	1,274	-	-
Profit for the period	313,023	54,151	72,479
<b>At end of period</b>	<b>423,427</b>	196,241	212,756

## RELATED PARTY TRANSACTIONS – PARENT COMPANY

(Amounts in SEK 000s)

The Parent Company holds 100% of the shares in BioGaia Biologics Inc. USA, BioGaia Japan Inc., Tripac AB and Infant Baby AB.

The Parent Company holds 90.1% of the shares in CapAble AB.

The Parent Company holds 50% of the shares in TwoPac AB, which is reported as a group company.

Annwall & Rothschild Investment AB holds 740,668 class A shares and 1,259,332 class B shares, which is equal to 11.6% of the share capital and 36.2% of the votes. Annwall & Rothschild Investment AB is owned by Peter Rothschild, President of BioGaia, and Jan Annwall, a member of the Board of the Parent Company. The only transaction carried out during 2012 is the payment of a dividend of SEK 6. No other transactions have taken place between BioGaia and Annwall & Rothschild Investment AB.

### The following transactions have taken place with *BioGaia Japan*

	Jan-Sept 2012	Jan-Sept 2011	Jan-Dec 2011
Interest income	1,278	1,650	2,244
Loan provided	-1,670	3,567	-4,451
Sale of goods	2,400	2,244	3,759

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

### The following transactions have taken place with TwoPac AB (incl. subsidiary)

	Jan-Sept 2012	Jan-Sept 2011	Jan-Dec 2011
Interest income	479	332	487
Loan provided	-8,000	-11,091	-11,091
Purchase of goods	-20,579	-17,173	-26,179

### The closing balance at the end of the period was as follows:

	30 Sept 2012	30 Sept 2011	31 Dec 2011
Non-current receivables from TwoPac AB (incl. subsidiary)	23,491	15,491	15,491
<b>Current transactions with related parties</b>			
Current receivables from TwoPac AB	169	48	349
Current liabilities to TwoPac AB	-3,603	-3,438	-3,339
	<b>-3,434</b>	-3,390	-2,990

No significant transactions have taken place with other closely related companies.



<u>CONSOLIDATED KEY RATIOS 1)</u>	Jan-Sept	Jan-Sept 2012	Jan-Sept
	2012	excl. licence revenue 2)	2011
Return on			
- average equity	93%	25%	28%
- average capital employed	128%	35%	41%
Capital employed, SEK 000s	441,880	179,505	208,564
Number of shares, thousands	17,271	17,271	17,271
Average number of shares, thousands	17,271	17,271	17,271
Number of outstanding warrants, thousands	89	89	-
Average number of outstanding warrants with a dilutive effect, thousands	-	-	-
Number of shares after dilution, thousands	17,271	17,271	17,271
Basic earnings per share, SEK	18.07	2.90	3.24
Diluted earnings per share, SEK	18.07	2.90	3.24
Basic equity per share, SEK	25.43	10.24	12.12
Diluted per equity per share, SEK	25.43	10.24	12.12
Equity/assets ratio	84%	85%	83%
Operating margin	72%	27%	34%
Profit margin (profit before tax)	75%	34%	34%
Average number of employees	69	69	61

1) The definitions of key ratios correspond to those in the annual report.

2) Key ratios excluding licence revenue from Nestlé (see above under "Financial performance during the period from 1 January to 30 September 2012)

## FINANCIAL CALENDAR

23 October 2012	9:30 a.m. Teleconference with President Peter Rothschild. To participate in the conference, call +46 8-506 857 59.
8 February 2013	Year-end report 2012
26 April 2013	Interim report 1 January – 31 March 2013
26 April 2013	Annual General Meeting, 1:00 p.m. in Stockholm. Shareholders who wish to have a matter addressed at the AGM must submit a request no later than 15 March 2013 by mail to Board Chairman, BioGaia AB, Box 3242, SE-103 64 STOCKHOLM, Sweden, or by e-mail to <a href="mailto:mr@biogaia.se">mr@biogaia.se</a>
22 August 2013	Interim report 1 January – 30 June 2013
23 October 2013	Interim report 1 January – 30 September 2013

**This interim report provides a true and fair picture of the business activities, financial position and results of operations of the Parent Company and the Group, and describes the significant risks and uncertainties to which the Parent Company and the Group companies are exposed.**

**Stockholm, 23 October 2012**

**David Dangoor**  
Board Chairman

**Jan Annwall**  
Board member

**Stefan Elving**  
Board member

**Thomas Flinck**  
Board member

**Inger Holmström**  
Board member

**Jörgen Thorball**  
Board member

**Paula Zeilon**  
Board member

**Peter Rothschild**  
President

This interim report has not been examined by the company's independent auditors.

## BioGaia AB

### **The Company**

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

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

BioGaia has 74 employees, of whom 26 are based in Stockholm, 22 in Lund, 16 in Eslöv, two in Raleigh, USA, six in Hiroshima, Japan, and two in Shanghai, China.

### **Business model**

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

The products are sold through nutrition, food, natural health and pharmaceutical companies in some 70 countries worldwide.

BioGaia holds patents for the use of *Lactobacillus reuteri* and certain packaging solutions in all major markets.

### **The BioGaia brand**

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

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

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

### **Research and clinical studies**

*Lactobacillus reuteri* is one of the world's most well researched probiotics, especially in young children. To date, 92 clinical studies using BioGaia's human strains of *Lactobacillus reuteri* have been performed on around 7,700 individuals of all ages. The results have been published in 63 articles in scientific journals.

Studies have been performed on:

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

### **REPORTING OF CLINICAL STUDIES**

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

#### **Latest press releases from BioGaia:**

2012-10-15 BioGaia's probiotics safe and effective in premature infants  
2012-10-12 BioGaia signs exclusive distribution agreement for its probiotic drops and tablets in Pakistan  
2012-09-17 *Lactobacillus reuteri* Protectis show to reduce colic in infants

**BioGaia AB Box 3242, SE-103 64 STOCKHOLM**

**Street address: Kungsbrogatan 3A, Stockholm**

**Telephone: +46 8-555 293 00, Corp. identity no. 556380-8723 [www.biogaia.se](http://www.biogaia.se)**

**For additional information contact:**

**Peter Rothschild, President, BioGaia AB, telephone +46 8-555 293 00**

**Margareta Hagman, Executive Vice President, BioGaia AB, telephone +46 8-555 293 00**