

## BioGaia AB Year-end report 2013 (17 pages)

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



### President's comments:

"In 2013 the sales focus for new contracts was on the BRIC countries, and it is encouraging to see that we have made real progress in nearly all of these markets. 2014 will be a very exciting year as we look forward to interesting launches in markets like Brazil. We should also have a good possibility to build up our sales in the USA, a market we still assess to have great potential," says Peter Rothschild, President of BioGaia.

### Full year 2013

Net sales reached SEK 315.9 million (289.2<sup>1)</sup>), an increase of SEK 26.7 million (9%). Excluding foreign exchange effects, net sales improved by 12%.

Net sales of finished consumer products amounted to SEK 256.2 million (237.6), representing growth of SEK 18.6 million (8%). Excluding foreign exchange effects, net sales improved by 11%.

Net sales of component products amounted to SEK 58.6 million (50.6<sup>1)</sup>), an increase of SEK 8.0 million (16%). Excluding foreign exchange effects, net sales rose by 17%.

Operating profit was SEK 81.7 million (72.1<sup>1)</sup>), an improvement of 9.6 million (13%). Excluding foreign exchange effects, operating profit rose by 16%.

Profit after tax was SEK 64.2 million (63.7<sup>1)</sup>), an increase of SEK 0.5 million (1%). Net financial items include a foreign exchange loss of SEK 2.9 million on forward exchange contracts in EUR. Profit for the previous year included a corresponding foreign exchange gain of SEK 5.7 million.

Earnings per share totalled SEK 3.57 (3.52<sup>1)</sup>).

The period's total cash flow was SEK -140.8 million (203.8). Last year's cash flow included payment of SEK 356.0 million in licence revenue from Nestlé. Cash and cash equivalents at 31 December 2013 totalled SEK 234.3 million (375.0).

The Board proposes to the upcoming AGM an ordinary dividend of SEK 3.35 and an extraordinary dividend of SEK 3.65, for a total dividend of SEK 7.00 per share.

### Fourth quarter 2013

Net sales amounted to SEK 90.2 million (72.4), up by SEK 17.8 million, (25%). Excluding foreign exchange effects, net sales increased by 26%.

Net sales of finished consumer products totalled SEK 75.1 million (65.6), an improvement of SEK 9.5 million (14%). Excluding foreign exchange effects, net sales were up by 16%.

Net sales of component products amounted to SEK 15.0 million (6.8), an increase of SEK 8.2 million (121%). Excluding foreign exchange effects, net sales grew by 118%.

Operating profit was SEK 23.8 million (13.1), an increase of SEK 10.7 million (82%). Excluding foreign exchange effects, net sales improved by 80%.

Profit after tax was SEK 16.3 million (15.8), an increase of SEK 0.5 million (3%). In the fourth quarter of last year, provisions were made to untaxed reserves, leading to a positive tax effect of SEK 2.3 million.

### Key events in the fourth quarter of 2013

Decision to invest in development of drug against NEC.

New agreement for the sale of drops and tablets in Brazil.

Two new studies on BioGaia Gastrus published.

BioGaia expands network in the oral health area.

Meta-analysis regarding *L. reuteri* Protectis and colic.

### Key events after the end of the fourth quarter

Publication of study showing that colic can be prevented.

No significant differences in BioGaia's diabetes study

1) Excluding license revenue from Nestlé. Net sales and profit for the previous year also included license revenue of SEK 356.0 million from Nestlé for a perpetual license to use *Lactobacillus reuteri* Protectis in infant formula during the remaining term of the patent, which is regarded as non-recurring revenue. Including license revenue from Nestlé, net sales amounted to SEK 645.2 million, operating profit to SEK 428.1 million, profit after tax to SEK 329.9 million and earnings per share to SEK 18.93 for 2012.

**Teleconference:** 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 [www.biogaia.com/agenda](http://www.biogaia.com/agenda).

BioGaia has published this information in accordance with the Swedish Securities Market Act. The information was issued for publication on 12 February 2014, 8.00 a.m. CET.

This is a translation of Swedish version of the interim report. When in doubt, the Swedish wording prevails

## BioGaia AB (publ.)

### YEAR-END REPORT 2013

*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 year-end report for the financial year 2013. A description of the company's operations is provided on page 17.

### PRESIDENT'S COMMENTS

Sales for 2013 rose by 12% including foreign exchange effects. This was not one of our best years, but in light of the fact that we also this year were affected by distributor changes and that we sold the rights to the infant formula area to Nestlé during 2012, this growth is really good. Finished consumer products increased by 11% and could have been significantly higher if we had not suffered from setbacks in the transition from our former distributor in the USA to Nestlé's subsidiary Gerber. The launch took place in the summer, but distribution was still not satisfactory by the end of the year. We are working with Gerber to address this situation. In spite of these problems, consumer sales have now reached roughly the same level that we had with our old distributor, although we have not yet seen the increase we had counted on. Other countries that have been affected by distributor changes are Spain and Portugal, but we are now noting normal growth in these markets.

In Italy and Finland, our two largest markets, sales fell somewhat over the year (for comment see below under Sales by segment). However, many other markets in Europe, as well as Chile and South Africa, showed very positive development.

Operating profit improved by 16% including foreign exchange effects thanks to effective control of our costs, which rose by only 6% despite the fact that we have launched a project to develop a drug for the highly fatal disease NEC, which can affect premature infants. This initiative is being carried out through a new subsidiary, Infant Bacterial Therapeutics, and during the summer we were granted orphan drug designation for this product by the American Food and Drug Administration (FDA).

In 2013 the sales focus for new contracts has been on the **BRIC** countries, and it is encouraging to see that we have made real progress in nearly all of these markets. In **Brazil**, we have signed a contract with the large and well reputed company Aché. Aché will start selling our products after the summer of 2014 and we have good hopes that Brazil will become a highly important market for us. In **Russia** we already have a distributor but have realised that several partners are needed in order to reach the Russian market, and we have now started the work to appoint an additional distributor for this vast country. In **India**, which is an extremely complex market, we are working at full steam to find one or more suitable partners. In **China**, we signed a distribution contract with the government-owned company Keyuan which will start to sell our products during 2014.

Our collaboration with Nestlé has continued and deepened. In the early summer we signed a new agreement with Nestlé for a whole new category of products. The launch will take place in the second half of 2014, but we have already started to earn revenue under the contract. We are also working on a number of additional development projects with Nestlé.

In Japan our partner Nippon Access also launched yoghurt products in the second half of 2013, which has led to increased sales but lower margins. Our assessment is that we will attain profitability in Japan during 2014.

Another key event during the year is that we acquired the remaining 50% of TwoPac. The acquisition will improve our possibilities to develop new and innovative products.

BioGaia has continued to invest heavily in clinical trials. The most important study for the year (which was published in January 2014) was perhaps the major study showing that infants who are given our oil drops reduce the risk of colic, regurgitation and constipation. The study was published in *JAMA Pediatrics*, one of the most respected scientific journals in the world, and means that there is reason to claim that all newborns should be given our oil drops.

Our study on diabetes patients did not have the outcome we had wished for. Given the results of our earlier pilot study and certain preclinical data, however, we will continue to explore this area in hope of finding another path to a possible solution.

BioGaia is still a small company, but we have grown rapidly and are working around the world with a large number of products across a range of indication areas. In order to maintain our momentum and retain short decision-making paths and entrepreneurial spirit in the company, we changed our organisation in the autumn of 2013. The company is now divided into three business areas, Pediatrics, Adult and New Business. At the central level we have retained support functions, but the business areas are responsible for product development and sales to their respective target groups. This will create a better focus and more efficient decision-making. As of 2014, we will therefore report sales and gross profit by business area in our segment reporting and thereby discontinue the earlier division between finished consumer products and component products.

Sales in the fourth quarter rose by 26% (adjusted for foreign exchange effects). Finished consumer products increased by 16% and component products grew by full 118%. Operating profit was up by 80%, adjusted for foreign exchange effects.

2014 will be a very exciting year as we look forward to interesting launches in markets like Brazil. We should also have a good possibility to build up our sales in the USA, a market we still assess to have great potential. As usual, we will introduce new products and start a number of interesting clinical trials. The area we work in is attracting widespread interest from researchers around the world, and BioGaia is well placed to take part and capitalise on new findings in this area.

I am convinced that BioGaia has a very strong position in both the long and short term.

### FINANCIAL PERFORMANCE DURING 2013

#### **Sales**

Consolidated net sales reached SEK 315.9 million (289.2)<sup>1)</sup>, which is an increase of SEK 26.7 million (9%).

Most of the company's sales are denominated in foreign currency, primarily EUR but also USD and JPY. With unchanged exchange rates, net sales would have been SEK 7.8 million higher. Excluding foreign exchange effects, net sales (excluding license revenue) thus increased by 12%. Exchange rate fluctuations reduce both revenue and expenses. Operating profit would have been SEK 2.2 million higher in the event of unchanged exchange rates, which is an increase of 16% compared to the previous year.

Total net sales for 2012 amounted to SEK 645.2 including license revenue from Nestlé of SEK 356 million that is regarded as non-recurring revenue. In February 2012 BioGaia signed several new agreements with Nestlé including the acquisition of a perpetual license to use BioGaia's probiotic in infant formula during the remaining term of the patent. The purchase price was EUR 50.8 million, of which EUR 40.0 million (SEK 356 million) was received and recognised in the first quarter of 2012. The additional payments of EUR 10.8 million will be received during the period 2014-2017 on the achievement of predefined milestones. Due to the sale of the license, culture sales to Nestlé have fallen since the third quarter of 2012 due to a significantly lower margin on these sales.

### Sales by segment

#### FINISHED CONSUMER PRODUCTS

Sales of finished consumer products rose over the previous year by SEK 18.6 million (8%) to SEK 256.2 million. Excluding foreign exchange effects, the increase was 11%.

Sales of finished consumer products grew in Europe, Asia and "Rest of world", but declined in the USA and Canada.

Sales in Europe increased in Ukraine, Sweden, Turkey and France, but fell in Finland, Italy and Eastern Europe, primarily in Poland and Bulgaria. In Finland sales were down from the previous year due to a large inventory build-up in Q4 2012. Consumer sales in Finland remain at a very good level. The drop in sales in Italy is explained by lower sales in Q3 resulting from inventory reduction by the distributor. However, in Q4 sales rebounded in Italy (see below) and part of the decrease from Q3 was recovered. In Poland and Bulgaria, sales are down due to aggressive price competition and the economic situation. The increase in "Rest of world" is mainly attributable to South Africa and Chile. In Asia, the increase in sales was attributable to several countries.

The decrease in North America is attributable to lower sales of tablets to Fleet, since the company purchased large inventories in connection with the launch last year. Gerber launched drops during the summer and sales have risen by 50% compared to the previous year. Sales of dental products were also up in the USA and Canada.

#### COMPONENT PRODUCTS

Sales of component products rose by SEK 8.0 million<sup>1)</sup> to SEK 58.6 million (16%) compared in the previous year. Excluding foreign exchange effects, net sales improved by 17%.

Sales were up primarily in Europe<sup>1)</sup> but also in Asia.

Since the third quarter of 2012, sales of component products in Europe have fallen as a consequence of the agreement with Nestlé in 2012 (see above), but due to revenue arising from the new agreement with Nestlé (see below), net sales from Nestlé have now increased compared to the previous year.

The agreement now in force gives Nestlé the right to manufacture *L. reuteri* for use in infant nutrition, which would result in lower sales of cultures. BioGaia has no information about when Nestlé will exercise this right and to what extent this will affect BioGaia's sales.

The sales growth in Asia was attributable to a dairy in South Korea.

### Sales by geographical market

Sales in Europe increased by SEK 15.0 million (7%)<sup>1)</sup>. Both sales of finished consumer products and component products increased (see above).

Sales in the USA and Canada declined by SEK 6.0 million (21%), which is due to lower sales to Fleet (see above).

Sales in Asia grew by SEK 7.7 million (24%). Both sales of finished consumer products and component products increased (see above).

Sales in "Rest of world" improved by SEK 10.0 million (40%), which is explained by higher sales of finished consumer products primarily in South Africa and Chile.

### The BioGaia brand

Of total finished consumer products, 55% (51) were sold under the BioGaia brand, including so-called co-branding.

#### **Gross profit**

Gross profit amounted to SEK 214.2 million (201.1)<sup>1)</sup> which is an increase of 13.1 million (7%) compared to the previous year. Including licence revenue from Nestlé, gross profit for 2012 was SEK 557.1 million.

The total gross margin fell from 70%<sup>1)</sup> to 68%. The gross margin for finished consumer products decreased from 72% to 70%. This is due to a lower margin in Q3 and Q4 since BioGaia's partner in Japan, Nippon Access, launched yoghurt products with a lower margin during the period. The gross margin for component products decreased from 59%<sup>1)</sup> to 57%. This is due to a lower margin on sales of culture to Nestlé, since BioGaia sells the culture at a significantly lower price following the sale of the rights for the use of *Lactobacillus reuteri* Protectis in infant formula.

#### **Operating expenses**

Selling expenses were up by SEK 2.0 million (3%) to SEK 79.4 (77.4) million, which is equal to 25% (27) of net sales. Personnel expenses increased, while external costs for marketing activities decreased.

Administrative expenses amounted to SEK 14.4 million (13.4), which is equal to 5% (5) of net sales. The increase of SEK 1.0 million (7%) is attributable to higher personnel expenses.

R&D expenses are reported at SEK 40.6 million (35.8), which is equal to 13% (12) of net sales. The increase of SEK 4.8 million (13%) is mainly due to increased external expenses for research and clinical studies, but also higher personnel expenses. Expenses for the Necrotising enterocolitis (NEC) project (see below) amounted to SEK 2.9 (0) million during the year.

The depreciation component of R&D expenses was SEK 0.3 million (0.6). Investments in capitalised development expenses totalled SEK 0 million (0).

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

#### **Operating profit**

Operating profit was SEK 81.7 million (72.1)<sup>1)</sup>, which is SEK 9.6 million (13%) higher than in the previous year.

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

Profit before tax was SEK 83.8 million (86.2) (excluding the previous year's licence revenue from Nestlé), which is SEK 2.4 million (3%) lower than in the previous year, mainly due to a loss on forward exchange contracts (see below). Including licence revenue from Nestlé, profit before tax for 2012 was SEK 442.2 million.

Net financial items include a foreign exchange loss of SEK 2.9 million on forward exchange contracts in EUR. Profit for the previous year included a corresponding foreign exchange gain of SEK 5.7 million. At 31 December 2013 the company had outstanding forward exchange contracts for EUR 13.7 million at an average exchange rate of SEK 8.79. Forward exchange contracts amounting to EUR 9.9 million will mature for payment in 2014, and the remaining EUR 3.8 million in 2015. The actual exchange gain/loss depends on the exchange rate on the maturity date of the contracts. If the EUR rate on the maturity date is lower/higher than that at 31 December 2013 (8.92), an exchange gain/loss will be recognised in the future.

### **Profit after tax**

Profit after tax was SEK 64.2 million (63.7)<sup>1</sup>, which is SEK 0.5 million (1%) better than in the previous year.

The tax rate for the Group was 23% (25). The Group pays tax on profits in the Swedish companies. The Swedish companies made provisions to untaxed reserves in 2012 of SEK 112.3 million. Tax allocation reserves were reversed during 2013.

The loss in Japan is not deductible against the Swedish profits. Loss carryforwards in the Japanese subsidiary at 31 December 2013 amounted to SEK 50.0 million. The deferred tax asset for these has not been recognised, since a sustainable profit level has not yet been shown in the Japanese subsidiary.

### **Earnings per share**

Earnings per share amounted to SEK 3.57 (3.52)<sup>1</sup>.

### **Cash flow**

The Group's cash and cash equivalents at 31 December 2013 totalled SEK 234.3 million (375.0). Cash flow for the period amounted to SEK -140.8 million (203.8). Cash flow for 2012 included the payment of SEK 356.0 million in licence revenue from Nestlé.

Cash flow for 2013 includes dividends of SEK 172.7 million, tax payments of SEK 10.8 million, investments in TwoPac of SEK 14.7 million and the acquisition of shares in TwoPac of SEK 30.0 million.

### **Equity**

Consolidated equity amounted to SEK 316.9 million (456.8). The Group's equity/assets ratio was 83% (88).

In June 2012 BioGaia carried out the warrant programme that was resolved on by the Annual General Meeting the same year. A total of 87,000 warrants were subscribed for, of which the management subscribed for 41,000. The warrants were issued at a market price of SEK 14.27 each following valuation according to the Black & Scholes formula, which provided the Parent Company with proceeds of SEK 1.3 million. Each warrant entitles the holder to subscribe for one class B share for SEK 241.90 on 1 June 2015. Volatility was estimated at 40%.

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

In order to achieve a high level of participation, the AGM decided to pay a subsidy of SEK 10 per warrant (after 1 June 2015) to the employees who have subscribed for subscription warrants but have not exercised the right to buy shares. No provisions for this obligation have yet been made, since the assessment is that with the applicable market price, all holders should exercise the right to buy shares. However, the need will be continuously evaluated.

### **Dividend**

The Board of BioGaia AB proposes to the upcoming AGM an ordinary dividend of SEK 3.35 and an extraordinary dividend of SEK 3.65, for a total dividend of SEK 7.00 per share. For more information, see below under "Proposed appropriation of profits".

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

Investments in property, plant and equipment amounted to SEK 16.6 million (29.4), of which SEK 14.7 million (27.5) refers to TwoPac AB.

### **Subsidiary in Japan**

Net sales in the Japanese subsidiary amounted to SEK 15.2 million (15.1). Operating profit in the Japanese subsidiary was SEK -7.7 million (-4.6). Sales are largely unchanged compared to the previous year, but due to sales of yoghurt products with a significantly lower margin and initial marketing activities in connection with the launch, operating profit has decreased. It is BioGaia's assessment that profitability will be attained in 2014.

### **Subsidiary TwoPac AB**

TwoPac AB has been owned 50% by BioGaia and 50% by TwoPac's management. Since 1 January 2011, TwoPac is consolidated in the BioGaia Group. On 1 July 2013 BioGaia acquired the remaining 50% of TwoPac (see below).

Net sales in TwoPac amounted to SEK 37.5 million (29.3). Operating profit was SEK 9.9 million (8.8). Profit after tax was SEK 7.3 million (6.2).

### **Subsidiary CapAble AB**

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

Net sales in CapAble totalled SEK 0.5 million (0.1). Operating profit was SEK -2.6 million (-2.6). Following extensive rebuilding of the production machinery, the first delivery was made to the company's customer in the USA. If no new problems arise in the machinery and the customer continues to order to the same extent as in the fourth quarter, CapAble should attain profitability in 2014.

### **Parent Company**

Net sales in the Parent Company reached SEK 304.6 million (634.5) and profit before tax and appropriations was SEK 76.9 million (434.9).

Since it is uncertain whether the receivables from BioGaia Japan will be recovered in the foreseeable future, a provision has been made for the amount in question. This has resulted in an impairment loss of SEK 9.0 million (8.6), which has had a negative impact on profit. In addition, the shares in CapAble have been written down by SEK 2.6 million (2.6). For more information, see below under "Significant risks and uncertainties; Group and Parent Company".

Profit after tax was SEK 144.7 million (239.3). A tax allocation reserve of SEK 109.3 million was reversed during 2013.

Cash flow in the Parent Company totalled SEK -143.2 million (209.9).

## **FINANCIAL PERFORMANCE IN THE FOURTH QUARTER OF 2013**

### **Fourth quarter sales**

Net sales for the fourth quarter amounted to SEK 90.2 million (72.4), an increase of SEK 17.8 million (25%) compared to the same period of last year. Excluding foreign exchange effects, net sales were up by 26%.

Compared to the previous quarter, sales rose by SEK 28.0 million, which is mainly due to lower activity among distributors and suppliers in connection with the customary summer holiday in Europe during the third quarter.

Sales of finished consumer products amounted to SEK 75.1 million (65.6), an increase of SEK 9.5 million (14%) compared to the same period of last year. Excluding foreign exchange effects, sales of finished consumer products improved by 16%. Sales were up in Asia, the USA, Canada and "Rest of world", but declined in Europe. In Asia, the increase is mainly attributable to Japan. In the USA, growth is attributable to sales to the new distributor of drops in the USA, Gerber, and sales of dental products. In "Rest of world", sales increased in South Africa and Chile. Sales in Europe improved primarily in Italy, Ukraine and Spain, but fell in Finland and a few countries in Eastern Europe, primarily Poland and Bulgaria. The decrease in Finland is due to large purchases in Q4 2012 (see above). In Poland and Bulgaria, sales are down as a result of aggressive price competition and the economic situation.

Sales of component products reached SEK 15.0 million (6.8), an increase of SEK 8.2 million (121%) compared to the same period of last year. Excluding foreign exchange effects, sales of component products rose by 118%. This growth was primarily attributable to Europe, but also Asia. The increase in Europe is explained by revenue under the new agreement with Nestlé (see below). In Asia, the increase is due to a dairy in South Korea.

### **Gross profit for the fourth quarter**

Gross profit amounted to SEK 59.1 million (48.1), an improvement of SEK 11.0 million (23%) compared to the same period of last year. The gross margin was 66 % (66). The gross margin for finished consumer products fell from 71% to 68% as a result of the product mix. During the second half of the year, BioGaia's partner in Japan, Nippon Access, launched yoghurt products with a lower margin than for other finished consumer products. For component products, the gross margin rose from 19% to 54%, mainly due to revenue under the new agreement with Nestlé (see below).

### **Other operating expenses in the fourth quarter**

Selling expenses for the fourth quarter increased compared to the same quarter of last year, from SEK 21.5 million to SEK 22.8 million (6%). This is explained by higher personnel expenses and increased marketing expenses in Japan in connection with the launch of yoghurt products. Compared to the third quarter of 2013, selling expenses were up by SEK 5.5 million.

Administrative expenses were unchanged at SEK 3.7 million. Compared to the previous quarter, administrative expenses increased by SEK 0.9 million.

R&D expenses amounted to SEK 9.7 million (10.6), which is a decrease of SEK 0.9 million (8%) compared to the same period of last year. The decrease is due to lower costs for clinical studies during the quarter. Compared to the third quarter, R&D expenses rose by SEK 0.7 million.

### **Operating profit for the fourth quarter**

Operating profit was SEK 23.8 million (13.1), which is an increase of SEK 10.7 million (82%) compared to the same period of last year. Excluding foreign exchange effects, operating profit improved by 80%.

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

Profit before tax was SEK 21.9 million (13.6), which is an increase of SEK 8.3 million (61%) compared to the same period of last year. Net financial items include a foreign exchange loss of SEK -3.0 million (-1.6) on forward exchange contracts in EUR (for more information see above).

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

Profit after tax was SEK 16.3 million (15.8), which SEK 0.5 million (3%) better than in the same period of last year. In the fourth quarter of last year, provisions were made to untaxed reserves, leading to a positive tax effect of SEK 2.3 million. The untaxed reserves were reversed in the fourth quarter of 2013.

### **Cash flow for the fourth quarter**

Cash flow amounted to SEK -9.1 million (-29.5). Working capital rose by SEK 22.9 million during the quarter, which is primarily attributable to increased trade receivables.

## **KEY EVENTS IN THE FOURTH QUARTER OF 2013**

### **Launches in the fourth quarter of 2013**

| Distributor/licensee | Product  | Country            |
|----------------------|--|--------------------|
| Ewopharma            | Drops  | Bosnia-Herzegovina |
| Nestlé               | Infant formula with <i>Lactobacillus reuteri</i> Protectis | Ecuador            |
| Semper               | Digestive health tablets with strawberry flavour           | Denmark            |

### **BioGaia invests in development of drug against NEC**

In November, the Board of BioGaia made a decision to invest in the first phase of a long-term project aimed at developing a drug with rigorous hygiene, analysis and documentation requirements, to treat the highly fatal disease Necrotising Enterocolitis (NEC), which affects premature infants.

BioGaia will invest up to SEK 42 million in the project over a two-year period. The project will be driven by BioGaia's subsidiary Infant Bacterial Therapeutics (IBT), of which 9% is owned by the company's President, Staffan Strömberg, and its Research Director, Eamonn Connolly. The remaining 91% is owned by BioGaia.

IBT will develop a new formulation and a manufacturing process that are wholly adapted to the stringent quality requirements placed by the FDA (the U.S. Food and Drug Administration) for a biological drug and the product's area of use in neonatal intensive care units. The company's assessment is that around SEK 26 million of the total of SEK 42 million will be capitalised in IBT, which will result in costs of approximately SEK 8 million per year in 2014 and 2015. If the drug development is not realised, it is BioGaia's intention to market the formulation under another product category.

In August the company was granted "Orphan Drug Designation" for the use of *Lactobacillus reuteri* in a drug to treat NEC. This could give possibilities to tax credits, incentives from the US government, 7-year exclusivity and certain support from a department of the FDA in the application process leading to an approved drug.

### **BioGaia signs agreement for drops and tablets in Brazil**

BioGaia has signed a long-term agreement with Aché, for the exclusive rights to sell BioGaia's probiotic drops and tablets in Brazil. The products will be co-branded and the launch is planned for mid-2014.

### **Two studies on BioGaia Gastrus published**

Two studies in patients infected with *Helicobacter pylori* show that supplementation with the new probiotic *Lactobacillus reuteri* Gastrus reduced side effects of eradication therapy by a third. In the studies, conducted at university hospitals in Italy and Egypt, the patients supplemented with *Lactobacillus reuteri* Gastrus reported less symptoms and less side effects from the eradication therapy compared to patients given placebo. The probiotic decreased both frequency and severity of side effects and was especially effective in reducing pain, diarrhoea and bloating. The studies have been published in *Journal of Clinical Gastroenterology*, 27 Nov 2013 (Francavilla) and in *Therapeutic Advances in Gastroenterology*, 4 Sept 2013 (Emara).

### **BioGaia expands network in oral health field**

In October BioGaia signed four different distribution agreements for the exclusive rights to sell its oral health products. Agreements have been made with Streuli Pharma AG for Switzerland, Plac Control for Greece, PharmaPal Drugstore LLC for United Arab Emirates and George Petrou Ltd for Cyprus. Furthermore, Sunstar has relaunched the products in Germany during the autumn.

## **KEY EVENTS AFTER THE END OF THE FOURTH QUARTER**

### **Publication of study showing that colic can be prevented**

A study of 468 healthy newborns, which was published in January 2014, shows that infants given the probiotic *Lactobacillus reuteri* Protectis cried less than half as long as infants given a placebo. The infants given *Lactobacillus reuteri* Protectis also had significantly fewer daily regurgitations and were less constipated compared to infants in the placebo group.

The study was published in the highly regarded medical journal JAMA on 13 January 2014.

### **No significant differences in BioGaia's diabetes study**

In May 2012 BioGaia initiated a double-blind, placebo-controlled study to investigate the effects of *Lactobacillus reuteri* Protectis on blood glucose in type 2 diabetics. Despite positive results from an earlier pilot study, no significant differences between the groups were seen in this study.

Continued efforts are being made to analyse if a change in some of the essential parameters in the study or in the study design may be a possible approach for a solution.

## **KEY EVENTS EARLIER IN 2013**

### **Launches during January to September 2013**

| Distributor/licensee    | Product  | Country   |
|-------------------------|--|---|
| BG Distribution         | Digestive health tablets with strawberry flavour           | Hungary   |
| Cube Pharmaceutical     | Digestive health tablets                                   | Greece  |
| Ewopharma               | Digestive health tablets with Vitamin D                    | Bulgaria  |
| Ferozsons Laboratorium  | Drops and digestive health tablets with lemon flavour      | Pakistan  |
| Gerber Products Company | Drops  | USA   |
| Laboratoire PediAct     | Digestive health tablets with strawberry flavour           | France  |
| Nestlé                  | Infant formula with <i>Lactobacillus reuteri</i> Protectis | Colombia, Denmark, Sweden, Central and Western Africa region, Israel, Syria, Thailand, Yemen and Iraq |
| Nestlé Mexico           | Drops  | Mexico  |
| Nippon Aesc             | Yoghurt with <i>Lactobacillus reuteri</i> Prodentis        | Japan   |
| Noos/Italchimichi       | Digestive health tablets with Vitamin D                    | Italy   |
| Pharmaforte             | Oral health tablets and oral health drops                  | Singapore   |
| Sunstar                 | Oral health tablets and oral health drops                  | Relaunch in Germany   |
| Verman                  | Digestive health tablets with Vitamin D                    | Finland   |

### **BioGaia acquires remaining 50% of TwoPac AB**

TwoPac AB was formed in 2002 to manufacture and develop packaging solutions for probiotics. At present the company primarily produces probiotic drops, but also manufactures straws on behalf of BioGaia. The company's revenue consists entirely of sales to BioGaia. In 2012 the company completed a new factory in Eslöv, Sweden, that was financed mainly with loans from BioGaia. TwoPac is consolidated in the Group since 1 January 2011.

BioGaia has previously owned 50% of TwoPac AB and the remaining shares have been held by TwoPac's management. BioGaia acquired the remaining 50% of TwoPac AB on 1 July 2013 for SEK 30 million. A controlling influence was acquired already on 1 January 2011, although no shares were purchased at the time since the assessment was that BioGaia had a controlling influence as of that date. As a result, only cash and cash equivalents and total equity were affected by the acquisition of the remaining 50% as of 1 July 2013.

TwoPac AB has thus become a wholly owned subsidiary of BioGaia AB. The motives for the acquisition are to gain full control over part of the company's product manufacturing, but above all to together with TwoPac in effective development of new products that can be manufactured at a reasonable cost.

Per Hjalmarsson, a former shareholder and the President of TwoPac, is continuing to lead the company's operations.

### **New study shows that *Lactobacillus reuteri* Prodentis improves treatment of patients with periodontal disease**

A double-blind, placebo-controlled study of patients with chronic periodontitis showed that treatment with *Lactobacillus reuteri* Prodentis as an adjunct to standard treatment significantly improved efficacy by 47%. The study was published in mid-August in *Journal of Clinical Periodontology*.

### ***Lactobacillus reuteri* Protectis only probiotic effective in treating colic**

According to a recently published review and meta-analysis on prevention and treatment of colic, BioGaia's probiotic strain *L. reuteri* Protectis is the only probiotic shown to significantly reduce crying time in breast-fed infants diagnosed with colic. The study was published online on 7 October 2013 in the journal JAMA Pediatrics.

### **Agreement for drops and tablets in South Korea**

At the beginning of May BioGaia signed an agreement with Dong Sung Pharmaceutical Company Ltd for the exclusive rights to sell BioGaia's ProTectis drops and ProTectis and Gastrus digestive health tablets through the retail pharmacy channel in South Korea. The products will be sold under BioGaia's own brand.

### **Agreement for drops and tablets in China**

In mid-May BioGaia signed an agreement with Beijing Keyuan Xinhai Pharmaceutical Co Ltd for the exclusive rights to sell BioGaia ProTectis drops and ProTectis and Gastrus digestive health tablets through the retail pharmacy channel in China. The products will be sold under BioGaia's own brand.

### **Agreement with Nestlé for new category of products**

At the end of May BioGaia signed a new supply and license agreement with Nestlé for the inclusion of BioGaia's patented *Lactobacillus reuteri* in a new category of products. The long-term agreement gives Nestlé exclusive rights to utilise this probiotic in an additional range of products in a large number of countries, with a focus on emerging markets.

### **EMPLOYEES**

The number of employees in the Group (including TwoPac AB) at 31 December 2013 was 85 (76).

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

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

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

The Japanese subsidiary has operated at a loss since the start in 2006. The business model previously used was found to be unsuccessful and in 2010 a decision was made 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 9.3 million. 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.

CapAble, which is 90.1% owned by BioGaia AB, was started in November 2008 to manufacture and sell the patented LifeTop Cap. The shares in the subsidiary CapAble amount to a total of SEK 6.9 million in the Parent Company. CapAble has operated at a loss since the start in 2008. BioGaia made total conditional shareholder contributions of SEK 6 million to CapAble in 2009 and 2010. BioGaia AB has made total group contributions of SEK 9.2 million during the period from 2010 to 2013. Profit before tax for 2013 amounted to SEK -2.6 million (-2.6). On the balance sheet date, assets in CapAble were reported at SEK 3.3 million. BioGaia's assessment is that CapAble will show profitability in coming years, for which reason there was no indication of impairment on the balance sheet date.

In February 2012 BioGaia signed several new agreements with Nestlé including the sale to Nestlé of the rights 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 as revenue in 2012 according to generally accepted accounting practices. The additional payments of EUR 10.8 million will be received during the period 2014-2017 on the achievement of predefined milestones. The company assesses the probability of achieving these milestones as high, but feels that the degree of uncertainty is still too large to recognise this revenue in accordance with generally accepted accounting practices.

For further information, see the administration report and Notes 28 and 29 of the annual report for 2012.

### **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 2012, aside from a number of minor amendments to existing standards and new interpretations that are effective as of 1 January 2013. These are not assessed to have any significant impact on the Group's or the Parent Company's profit or financial position aside from increased disclosures.

### **New segment reporting as of 2014**

In the autumn of 2013 BioGaia changed its organisation (for more information see above under "President's comments"). The company is now divided into three business areas, Pediatrics, Adult and New Business. At the central level BioGaia has retained support functions, but the business areas are responsible for product development and sales to their respective target groups. As of 2014 BioGaia will therefore report sales and gross profit by business area in its segment reporting, and will thereby discontinue the earlier division between finished consumer products and component products. In the first quarter of 2014 the division between the new segments will be established and in quarter 1 2014, segment information will be provided based on the new organisation. Comparative figures for the new segments will be reported for 2013.

## **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 40% of profit after tax.

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.

## **PROPOSED APPROPRIATION OF PROFITS**

The following funds in the Parent Company are at the disposal of the Annual General Meeting (SEK 000s):

|                        |                |
|------------------------|----------------|
| Retained profit:       | 158,426        |
| Profit for the year:   | <u>144,657</u> |
| Together amounting to: | 303,083        |

The Board of Directors and the President propose that the company pay an ordinary dividend of SEK 3.35, and, in view of the company's good liquidity and strong balance sheet, an extraordinary dividend of SEK 3.65, amounting to a total dividend of SEK 7.00 per share. This is equal to a total distribution of SEK 120.9 million. It is proposed that the remaining profits of SEK 182.2 million be carried forward to new account.

1) Excluding license revenue from Nestlé. Net sales and profit for the previous year also included license revenue of SEK 356.0 million from Nestlé for a perpetual license to use *Lactobacillus reuteri* Protectis in infant formula during the remaining term of the patent, which is regarded as non-recurring revenue. Including license revenue from Nestlé, net sales amounted to SEK 645.2 million, operating profit to SEK 428.1 million, profit before tax to SEK 442.2 million, profit after tax to SEK 329.9 million and earnings per share to SEK 18.93 for 2012.

## Statements of comprehensive income - Group

(Amounts in SEK 000s)

|   | Jan-Dec<br>2013 | Jan-Dec<br>2012 | Oct-Dec<br>2013 | Oct-Dec<br>2012 |
|---|-----------------|-----------------|-----------------|-----------------|
| Net sales   | 315,875         | 289,248         | 90,221          | 72,403          |
| License revenue   | -               | 356,004         | -               | -               |
| Cost of goods sold  | -101,711        | -88,179         | -31,111         | -24,308         |
| <i>Gross profit</i>   | <i>214,164</i>  | 557,073         | <i>59,110</i>   | 48,095          |
| Selling expenses  | -79,396         | -77,361         | -22,768         | -21,466         |
| Administrative expenses   | -14,356         | -13,423         | -3,741          | -3,687          |
| Research and development expenses   | -40,555         | -35,788         | -9,699          | -10,561         |
| Other operating income  | 1,796           | -               | 871             | 758             |
| Other operating expenses  | -               | -2,431          | -               | -               |
| <i>Operating profit</i>   | <i>81,653</i>   | 428,070         | <i>23,773</i>   | 13,139          |
| Interest income   | 5,081           | 8,569           | 1,165           | 2,050           |
| Foreign exchange gain, forward contracts  | -2,882          | 5,676           | -3,011          | -1,612          |
| Financial expenses  | -92             | -73             | -17             | -25             |
| <i>Profit before tax</i>  | <i>83,760</i>   | 442,242         | <i>21,910</i>   | 13,552          |
| Tax   | -19,572         | -112,371        | -5,616          | 2,255           |
| <b>PROFIT FOR THE PERIOD</b>  | <b>64,188</b>   | 329,871         | <b>16,294</b>   | 15,807          |
| <b>Items that will be reclassified to profit or loss</b>                              |                 |                 |                 |                 |
| Gains/losses arising on translation of the financial statements of foreign operations | -1,419          | -1,059          | -697            | -687            |
|   | <b>62,769</b>   | 328,812         | <b>15,597</b>   | 15,120          |
| <b>Profit for the period attributable to:</b>   |                 |                 |                 |                 |
| Owners of the Parent Company  | 61,722          | 326,970         | 16,300          | 14,855          |
| Non-controlling interests   | 2,466           | 2,901           | -6              | 952             |
|   | <b>64,188</b>   | 329,871         | <b>16,294</b>   | 15,807          |
| <b>Comprehensive income for the period attributable to:</b>                           |                 |                 |                 |                 |
| Owners of the Parent Company  | 60,303          | 325,911         | 15,603          | 14,168          |
| Non-controlling interests   | 2,466           | 2,901           | -6              | 952             |
|   | <b>62,769</b>   | 328,812         | <b>15,597</b>   | 15,120          |
| <b>Earnings per share</b>   |                 |                 |                 |                 |
| Basic earnings per share (average number of shares), SEK                              | 3.57            | 18.93           | 0.94            | 0.86            |
| Diluted earnings per share, SEK   | 3.56            | 18.93           | 0.94            | 0.86            |
| Number of shares, thousands   | 17,271          | 17,271          | 17,271          | 17,271          |
| Average number of shares, thousands   | 17,271          | 17,271          | 17,271          | 17,271          |
| Number of outstanding warrants, thousands   | 87              | 87              | 87              | 87              |
| Number of outstanding warrants with a dilutive effect, thousands                      | 87              | -               | 87              | -               |
| Number of shares after dilution, thousands  | 17,358          | 17,271          | 17,358          | 17,271          |

**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

|   | 31 Dec         | 31 Dec         |
|---|----------------|----------------|
| (Amounts in SEK 000s)                               | 2013           | 2012           |
| <b>ASSETS</b>                                       |                |                |
| Intangible assets                                   | 60,286         | 49,193         |
| Other non-current receivables                       | 17             | 17             |
| <i>Total non-current assets</i>                     | <b>60,303</b>  | <b>49,210</b>  |
| Current assets excl. cash and cash equivalents      | 88,845         | 92,838         |
| Cash and cash equivalents                           | 234,271        | 374,974        |
| <i>Total current assets</i>                         | <b>323,116</b> | <b>467,812</b> |
| <b>TOTAL ASSETS</b>                                 | <b>383,419</b> | <b>517,022</b> |
| <b>EQUITY AND LIABILITIES</b>                       |                |                |
| Equity attributable to owners of the Parent Company | 317,341        | 453,303        |
| Non-controlling interests                           | -484           | 3,491          |
| Total equity  | 316,857        | 456,794        |
| Provision for deferred tax                          | 85             | 24,710         |
| Interest-free current liabilities                   | 66,477         | 35,518         |
| <b>TOTAL EQUITY AND LIABILITIES</b>                 | <b>383,419</b> | <b>517,022</b> |
| <b>Pledged assets</b>                               | <b>2,000</b>   | <b>2,000</b>   |

**CONSOLIDATED CASH FLOW STATEMENTS**

|   | Jan-Dec         | Jan-Dec         | Oct-Dec        | Oct-Dec        |
|---|-----------------|-----------------|----------------|----------------|
| (Amounts in SEK 000s)   | 2013            | 2012            | 2013           | 2012           |
| <i>Operating activities</i>   |                 |                 |                |                |
| Operating profit  | 81,653          | 428,070         | 23,773         | 13,139         |
| Depreciation/amortisation   | 5,541           | 4,545           | 1,753          | 521            |
| Other non-cash items  | -308            | 346             | -291           | -277           |
|   | <b>86,886</b>   | <b>432,961</b>  | <b>25,235</b>  | <b>13,383</b>  |
| Gains/losses on realised forward exchange contracts                   | 193             | 2,818           | -246           | 853            |
| Paid tax  | -10,799         | -105,736        | -5,311         | -32,221        |
| Interest received and paid  | 4,996           | 8,496           | 1,153          | 2,025          |
| Cash flow from operating activities before changes in working capital | 81,276          | 338,539         | 20,831         | -15,960        |
| Changes in working capital  | -2,835          | -2,982          | -22,876        | -7,560         |
| <i>Cash flow from operating activities</i>                            | <b>78,441</b>   | <b>335,557</b>  | <b>-2,045</b>  | <b>-23,520</b> |
| <i>Cash flow from investing activities</i>                            | <b>-46,538</b>  | <b>-29,391</b>  | <b>-7,024</b>  | <b>-5,916</b>  |
| <i>Cash flow from financing activities</i>                            | <b>-172,710</b> | <b>-102,373</b> | <b>0</b>       | <b>-21</b>     |
| Cash flow for the period  | -140,807        | 203,793         | -9,069         | -29,457        |
| Cash and cash equivalents at beginning of period                      | 374,974         | 171,534         | 243,193        | 404,065        |
| Exchange difference in cash and cash equivalents                      | 104             | -353            | 147            | 366            |
| Cash and cash equivalents at end of period                            | <b>234,271</b>  | <b>374,974</b>  | <b>234,271</b> | <b>374,974</b> |

**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

| (Amounts in SEK 000s)                                | Jan-Dec        | Jan-Dec        |
|--|----------------|----------------|
|  | 2013           | 2012           |
| At beginning of period                               | 456,794        | 230,355        |
| Dividends  | -172,710       | -103,626       |
| Subscription warrants                                | -              | 1,253          |
| Sale of shares in IBT AB (non-controlling interests) | 4              | -              |
| Acquisition of TwoPac                                | -30,000        | -              |
| Comprehensive income for the period                  | 62,769         | 328,812        |
| <b>At end of period</b>                              | <b>316,857</b> | <b>456,794</b> |

**REPORTING BY SEGMENT – GROUP**

(Amounts in SEK 000s)

| <u>Revenue by segment</u>               | Jan-Dec        | Jan-Dec        | Oct-Dec       | Oct-Dec       |
|---|----------------|----------------|---------------|---------------|
|   | 2013           | 2012           | 2013          | 2012          |
| Finished consumer products              | 256,164        | 237,583        | 75,108        | 65,581        |
| Component products                      | 58,592         | 50,577         | 15,033        | 6,774         |
| License revenue (component products) 1) | -              | 356,004        | -             | -             |
| Other products                          | 1,119          | 1,088          | 80            | 48            |
|   | <b>315,875</b> | <b>645,252</b> | <b>90,221</b> | <b>72,403</b> |

| <u>Gross profit by segment</u>          | Jan-Dec        | Jan-Dec        | Oct-Dec       | Oct-Dec       |
|---|----------------|----------------|---------------|---------------|
|   | 2013           | 2012           | 2013          | 2012          |
| Finished consumer products              | 180,088        | 170,275        | 50,962        | 46,799        |
| Component products                      | 33,384         | 29,935         | 8,068         | 1,292         |
| License revenue (component products) 1) | -              | 356,004        | -             | -             |
| Other products                          | 692            | 859            | 80            | 4             |
|   | <b>214,164</b> | <b>557,073</b> | <b>59,110</b> | <b>48,095</b> |

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**

| <u>Net sales</u>            | Jan-Dec        | Jan-Dec        | Oct-Dec       | Oct-Dec       |
|-----------------------------|----------------|----------------|---------------|---------------|
|                             | 2013           | 2012           | 2013          | 2012          |
| Europe                      | 218,301        | 203,328        | 56,041        | 51,760        |
| License revenue (Europe) 2) | -              | 356,004        | -             | -             |
| USA and Canada              | 22,412         | 28,422         | 8,840         | 7,747         |
| Asia                        | 40,100         | 32,420         | 13,993        | 6,253         |
| Rest of world               | 35,062         | 25,078         | 11,347        | 6,643         |
|                             | <b>315,875</b> | <b>645,252</b> | <b>90,221</b> | <b>72,403</b> |

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

**PARENT COMPANY INCOME STATEMENTS**

(Amounts in SEK 000s)

|   | Jan-Dec<br>2013 | Jan-Dec<br>2012 |
|---|-----------------|-----------------|
| Net sales                                     | 304,624         | 278,515         |
| License revenue                               | -               | 356,004         |
| Cost of goods sold                            | -108,840        | -97,475         |
| <i>Gross profit</i>                           | 195,784         | 537,044         |
| Selling expenses                              | -59,662         | -57,673         |
| Administrative expenses                       | -13,302         | -12,248         |
| Research and development expenses             | -40,461         | -35,868         |
| Other operating income                        | 1,796           | -               |
| Other operating expenses                      | -               | -2,430          |
| <i>Operating profit</i>                       | 84,155          | 428,825         |
| Impairment loss on receivable from subsidiary | -8,960          | -8,574          |
| Impairment loss on shares in subsidiary       | -2,589          | -2,583          |
| Net financial items                           | 4,314           | 17,220          |
| Profit before appropriations and tax          | 76,920          | 434,888         |
| Change in tax allocation reserve              | 109,341         | -109,341        |
| Profit before tax                             | 186,261         | 325,547         |
| Tax expense                                   | -41,604         | -86,270         |
| <b>PROFIT FOR THE PERIOD</b>                  | <b>144,657</b>  | <b>239,277</b>  |

**PARENT COMPANY BALANCE SHEETS****ASSETS**

|  | 31 Dec<br>2013 | 31 Dec<br>2012 |
|--|----------------|----------------|
| Property, plant and equipment                  | 2,058          | 2,275          |
| Shares in group companies                      | 52,394         | 21,160         |
| Non-current receivables from subsidiaries      | 29,513         | 24,513         |
| <i>Total non-current assets</i>                | 83,965         | 47,948         |
| Current assets excl. cash and cash equivalents | 76,594         | 85,009         |
| Cash and cash equivalents                      | 228,456        | 371,448        |
| <i>Total current assets</i>                    | 305,050        | 456,457        |
| <b>TOTAL ASSETS</b>                            | <b>389,015</b> | <b>504,405</b> |
| <b>EQUITY AND LIABILITIES</b>                  |                |                |
| Equity   | 321,607        | 349,660        |
| Tax allocation reserve                         | -              | 109,341        |
| Interest-free current liabilities              | 67,408         | 45,404         |
| <b>TOTAL EQUITY AND LIABILITIES</b>            | <b>389,015</b> | <b>504,405</b> |
| <b>Pledged assets</b>                          | <b>2,000</b>   | <b>2,000</b>   |

**PARENT COMPANY CASH FLOW STATEMENTS**

|   | Jan-Dec  | Jan-Dec  |
|---|----------|----------|
|   | 2013     | 2012     |
| <u>Operating activities</u>   |          |          |
| Operating profit  | 84,155   | 428,825  |
| Depreciation/amortisation   | 1,157    | 1,510    |
| Other non-cash items  | -310     | 308      |
| Gain/losses on realised foreign exchange contracts                    | 193      | 2,818    |
| Paid tax  | -9,816   | -105,690 |
| Interest received and paid  | 5,603    | 9,120    |
| Cash flow from operating activities before changes in working capital | 80,982   | 336,891  |
| Changes in working capital  | -7,218   | -13,512  |
| <i>Cash flow from operating activities</i>                            | 73,764   | 323,379  |
| <i>Cash flow from investing activities</i>                            | -44,218  | -11,123  |
| <i>Cash flow from financing activities</i>                            | -172,710 | -102,373 |
| Cash flow for the period  | -143,164 | 209,883  |
| Cash and cash equivalents at beginning of period                      | 371,448  | 161,865  |
| Exchange difference in cash and cash equivalents                      | 172      | -300     |
| Cash and cash equivalents at end of period                            | 228,456  | 371,448  |

**PARENT COMPANY STATEMENTS OF CHANGES IN EQUITY**

|                                | Jan-Dec        | Jan-Dec        |
|--------------------------------|----------------|----------------|
|                                | 2013           | 2012           |
| (Amounts in SEK 000s)          |                |                |
| At beginning of year           | 349,660        | 212,756        |
| Dividends                      | -172,710       | -103,626       |
| Subscription warrant programme | -              | 1,253          |
| Profit for the period          | 144,657        | 239,277        |
| <b>At end of period</b>        | <b>321,607</b> | <b>349,660</b> |

## **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 and Tripac AB. Since 1 July 2013, the Parent Company also holds 100 % of the shares in TwoPac AB (previously 50%). The Parent Company holds 90.1 % of the shares in CapAble AB and 91% of the shares in Infant Bacterial Therapeutics AB.

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 that took place during 2013 is the payment of a dividend of SEK 10 per share. No other transactions between BioGaia and Annwall & Rothschild Investment AB took place during the period.

In 2013 the Company purchased services from Board member Jörgen Thorball's partly owned company XOventure for approximately SEK 670 thousand. The services related to preclinical work, documentation and product development.

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

|                 | Jan-Dec<br>2013 | Jan-Dec<br>2012 |
|-----------------|-----------------|-----------------|
| Interest income | 1,565           | 2,386           |
| Loan provided   | -7,419          | -1,670          |
| Sale of goods   | 4,410           | 4,518           |

Due to uncertainty about whether the receivable from BioGaia Japan will be recovered in the foreseeable future, a write-down has been made to the net realisable value.

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

|                   | Jan-Dec<br>2013 | Jan-Dec<br>2012 |
|-------------------|-----------------|-----------------|
| Interest income   | 610             | 643             |
| Loan provided     | -5,000          | -8,000          |
| Purchase of goods | -37,487         | -29,314         |

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

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

|   | 31 Dec<br>2013 | 31 Dec<br>2012 |
|---|----------------|----------------|
| Non-current receivables from TwoPac AB (incl. subsidiary) | 28,491         | 23,491         |
| <b><i>Current transactions with related parties</i></b>   |                |                |
| Current receivables from TwoPac AB                        | 1,914          | 164            |
| Current liabilities to TwoPac AB                          | -1,643         | -1,972         |
|   | 271            | -1,808         |

| <b>CONSOLIDATED KEY RATIOS 1)</b>  | <b>Jan-Dec</b> | Jan-Dec | Jan-Dec                                |
|--|----------------|---------|--|
|  | <b>2013</b>    | 2012    | 2012<br>excl. non-recurring<br>revenue |
| Net sales, SEK 000s  | <b>315,875</b> | 645,252 | 289,248                                |
| Operating profit, SEK 000s   | <b>81,653</b>  | 428,070 | 72,066                                 |
| Profit after tax, SEK 000s   | <b>64,188</b>  | 329,871 | 63,667                                 |
| Return on  |                |         |  |
| - average equity   | <b>16%</b>     | 96%     | 29%                                    |
| - average capital employed   | <b>22%</b>     | 124%    | 40%                                    |
| Capital employed, SEK 000s   | <b>316 942</b> | 481 504 | 195 722                                |
| Number of shares, thousands  | <b>17,271</b>  | 17,271  | 17,271                                 |
| Average number of shares, thousands                                      | <b>17,271</b>  | 17,271  | 17,271                                 |
| Number of outstanding warrants, thousands                                | <b>87</b>      | 87      | 87                                     |
| Average number of outstanding warrants with a dilutive effect, thousands | <b>87</b>      | -       | -                                      |
| Number of shares after dilution, thousands                               | <b>17,358</b>  | 17,271  | 17,271                                 |
| Basic earnings per share, SEK  | <b>3.57</b>    | 18.93   | 3.52                                   |
| Diluted earnings per share, SEK  | <b>3.56</b>    | 18.93   | 3.52                                   |
| Basic equity per share, SEK  | <b>18.37</b>   | 26.25   | 10.83                                  |
| Diluted equity per share, SEK  | <b>18.28</b>   | 26.25   | 10.83                                  |
| Equity/assets ratio  | <b>83%</b>     | 88%     | 82%                                    |
| Operating margin   | <b>26%</b>     | 66%     | 25%                                    |
| Profit margin  | <b>27%</b>     | 69%     | 30%                                    |
| Average number of employees  | <b>82</b>      | 70      | 70                                     |

- 1) The definitions of key ratios correspond to those in the annual report.  
2) Excluding licence revenue from Nestlé (see above under "Financial performance during 2013")

## FINANCIAL CALENDAR

The annual report for 2013 will be distributed to all shareholders during the last week of March 2014. At that time it will also be available on BioGaia's website and can be ordered by telephone +46 8-55529300 or by email to [info@biogaia.se](mailto:info@biogaia.se).

|                 |  |
|-----------------|--|
| 6 May 2014      | Interim report 1 January – 31 March 2014   |
| 6 May 2014      | Annual General Meeting at 4:00 p.m. in Stockholm. Shareholders who wish to have a matter dealt with at the AGM must submit a request by 20 March 2014 to the Board Chairman, BioGaia AB, Box 3242, SE-103 64 STOCKHOLM, Sweden, or by e-mail to <a href="mailto:pea@biogaia.se">pea@biogaia.se</a> . |
| 20 August 2014  | Interim report 1 January – 30 June 2014  |
| 22 October 2014 | Interim report 1 January – 30 September 2014   |

**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, 12 February 2014**

**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

## Auditor's report on the review of the interim financial information (interim report)

### Introduction

We have reviewed the condensed interim financial information (interim report) of BioGaia AB (publ), corporate identity number 556380-8723, at 31 December 2013 and for the twelve months then ended. The Board of Directors and President are responsible for the preparation and fair presentation of this interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim financial information based on our review.

### Scope of review

We conducted our review in accordance with the Standard on Review Engagements SÖG 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with ISA (International Standards on Auditing) and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion based on an audit.

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the accompanying financial information does not, in all material aspects, give a true and fair view of the financial position of the Group in accordance with IAS 34 and the Swedish Annual Accounts Act and of the Parent Company in accordance with the Swedish Annual Accounts Act.

Stockholm, 12 February 2014

Grant Thornton Sweden AB

Lena Möllerström Nording  
Authorised Public Accountant

## 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* (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 85 employees, of whom 32 are based in Stockholm, 22 in Lund, 22 in Eslöv, two in Raleigh, USA, six in Hiroshima, Japan and one in Shanghai, China.

### **Business model**

BioGaia's revenue comes mainly from the sale of finished consumer products (digestive health tablets, drops, oral rehydration solution (ORS) and oral health tablets) 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 more than 80 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, 108 clinical studies using BioGaia's human strains of *Lactobacillus reuteri* have been performed on around 9,300 individuals of all ages. The results have been published in 85 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).
- Necrotising enterocolitis (NEC)

### **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:**

|            |  |
|------------|--|
| 2014-01-28 | No significant differences in BioGaia's diabetes study                               |
| 2014-01-14 | It is possible to prevent colic in healthy infants                                   |
| 2013-12-05 | One of the world's most widespread infections – BioGaia's Gastrus improves treatment |

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**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 20**  
**Margareta Hagman, Executive Vice President, BioGaia AB, telephone +46 8-555 293 04**