

## BioGaia AB Year-end report 2014 (18 pages)

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



### CEO's comments:

“A sales growth of 22% (including licence revenue from Nestlé 53 %) and an operating margin of 26%<sup>1)</sup> for the full year 2014, can only be summed up as a successful year,” says Peter Rothschild, CEO of BioGaia AB. “The fourth quarter showed even better growth than the full year and it is once again gratifying to see that almost all of our markets are growing at a solid pace and that the BioGaia brand is becoming increasingly established, particularly among paediatricians, as the safest and most effective probiotic on the market,” adds Peter Rothschild.

### Full year 2014

Net sales amounted to SEK 481.8 million (315.9), an increase of SEK 165.9 million (53 %). Net sales include license revenue of SEK 95.4 million from Nestlé. Excluding license revenue from Nestlé, net sales totalled SEK 386.4 million, an increase of 22% (excluding foreign exchange effects, 18%).

Net sales in the Paediatrics Business Unit reached SEK 313.7<sup>1)</sup> million (238.6), up by SEK 75.1 million (31%).

Net sales in the Adult Health Business Unit amounted to SEK 69.4 million (75.6), a decrease of SEK 6.2 million (-8%).

Operating profit was SEK 196.9 million (81.7), an increase of SEK 115.2 million (141%). Excluding license revenue from Nestlé, operating profit was SEK 101.5 million, an increase of 24% (excluding foreign exchange effects and operating expenses for the subsidiary IBT, 21%).

Profit after tax was SEK 148.0 million (64.2), up by SEK 83.8 million (130%). Excluding license revenue from Nestlé, profit after tax was SEK 73.6 million, an increase of 15%.

Earnings per share totalled SEK 8.53 (3.57). Excluding license revenue from Nestlé, earnings per share were SEK 4.23.

The period's cash flow was SEK -25.0 million (-140.8). Cash and cash equivalents at 31 December 2014 amounted to SEK 210.7 million (234.3).

The Board proposes to the upcoming AGM an ordinary dividend of SEK 3.46 per share and an extraordinary dividend of SEK 1.54 per share, for a total dividend of SEK 5.00 per share.

### Fourth quarter 2014

Net sales reached SEK 121.4 million (90.2), an increase of SEK 31.2 million (35%) (excluding foreign exchange effects, 28%).

Net sales in the Paediatrics Business Unit totalled SEK 97.8 million (65.6), an improvement of SEK 32.2 million (49%).

Net sales in the Adult Health Business Unit amounted to SEK 23.0 million (24.1), a decrease of SEK 1.1 million (-4%).

Operating profit was SEK 30.6 million (23.8), an increase of SEK 6.8 million (29 %) (excluding foreign exchange effects and operating expenses for the subsidiary IBT, 23%).

Profit after tax was SEK 19.1 million (16.3), an improvement of SEK 2.8 million (17%).

Earnings per share totalled SEK 1.04 (0.94).

### Key events in the fourth quarter of 2014

Publication of additional study showing that infants with colic cry less with BioGaia's drops.

Publication of study showing that BioGaia Protectis tablets are effective in constipated adults.

BioGaia decides to invest in MetaboGen AB.

### Key events after the end of the year

Agreement for the sale of drops in Vietnam.

Nestlé launches new products with BioGaia's probiotic.

1) Excluding license revenue from Nestlé. Including license revenue from Nestlé, net sales in the Paediatrics business unit amounted to SEK 409.1 million and operating margin to 41%.

**Teleconference:** You are welcome to take part in a teleconference on the year-end report that will be held today at 9:00 a.m. by CEO Peter Rothschild. To participate in the teleconference please see further information at: [www.biogaia.com/agenda](http://www.biogaia.com/agenda).

BioGaia has published this information in accordance with the Swedish Securities Act. The information was issued for publication on 12 February 2015, 8:00 a.m.

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

## BioGaia AB (publ.)

### Year-end report 2014

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

The Board of Directors and CEO of BioGaia AB (publ.) hereby present the year-end report for the financial year 2014. A description of the company's operations is provided on page 18.

### CEO'S COMMENTS

A successful year with challenges. How does that go together? A sales growth of 22% (including licence revenue from Nestlé 53%) and an operating margin of 26%<sup>1)</sup> for the full year 2014, can only be summed up as a successful year. And this was achieved despite the fact that one of our most important markets, Ukraine, declined significantly. Brazil, where we launched after the summer, showed a strong development and offset the negative trend in Ukraine.

Challenge because we experienced problems with the stability of our bacteria cultures from one of our suppliers. On delivery to us the cultures met specifications, but in the finished product the shelf life was shorter than normally. The problem was detected through BioGaia's own quality control system. We had to devote a lot of time and resources to finding the root of the problem and meeting the immediate need for cultures. Not only did we have to recall a number of products from our partners, which cost us a total of around SEK 11 million in 2014 (SEK 7.5 million in the quarter), but also that our product developers were not able to focus fully on developing new products but were forced to address the acute stability problem. Thanks to our quick initiation of a comprehensive action plan, we now have the stability problem under control. The plan includes both short-term measures and an ambitious development project to build further knowledge in the fermentation area.

The fourth quarter showed even higher growth than the full year and it is once again gratifying to see that almost all of our markets are growing at a solid pace and that the BioGaia brand is becoming more and more established, particularly among paediatricians, as the most effective probiotic on the market. Our sales growth of 35% (28% adjusted for foreign exchange effects) is naturally satisfying, but it refers only to a single quarter, a period that is far too short to draw any far-reaching conclusions.

Clinical studies are our most important marketing tool and two new studies were published during the quarter. An additional study on infants with colic showed significant positive results. Another area where we now have obtained convincing data is constipation, which will open new opportunities to position our products also in this area.

Our subsidiary IBT, which is developing a drug to prevent the disease NEC that affects premature newborns, is going from strength to strength. We have been granted orphan drug status in the USA, had a first meeting with the FDA and EMA, started development of the manufacturing process and hired a bank to help us secure financing through a licensing agreement with a pharmaceutical company. During the year consolidated profit was charged with costs of SEK 6.7 million for operations in IBT.

Our manufacturing company TwoPac is working intensively to receive GMP pharma approval from the Swedish Medical Products Agency at the same time that new machinery and products are being developed at a rapid rate. I am certain that the steps we are taking at TwoPac will be decisive in enabling us to maintain our innovation rate and gain entrance to markets with rigorous regulatory requirements.

Towards the end of the year we decided to invest SEK 12 million over a two-year period in the Gothenburg-based company MetaboGen, which was founded by the highly successful professors Fredrik Bäckhed and Jens Nielsen. The company works with the so-called microbiome, which is the collective genetic material

contained by the large number of bacteria in the gut flora. The assumption is that the microbiome affects the onset of various diseases and that by altering its composition, it is possible to positively impact health. We see this as a natural expansion of the probiotic concept and want to be at the leading edge of this development. Major corporations like Johnson & Johnson and Nestlé are investing aggressively in this area.

During the year we signed agreements to introduce our products in a few major markets such as the UK and India, and are now working intensively to ensure successful launches. In light of the potential in these markets and in Brazil, where we are off to an excellent start, I am optimistic about 2015 and expect BioGaia to maintain a high rate of growth. At the same time, we are continuing to focus on further clinical studies and are investing in TwoPac and IBT. Looking ahead, I therefore anticipate strong growth in the company in both the short and long term.

### FINANCIAL PERFORMANCE 2014

#### Sales

Consolidated net sales amounted to SEK 481.8 million (315.9), which is an increase of SEK 165.9 million (53%). Net sales include license revenue from Nestlé of SEK 95.4 million.

#### License revenue from Nestlé

In February 2012 BioGaia signed several new agreements with Nestlé including the sale of a perpetual license for the use of one of BioGaia's probiotic strains 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 were to be received during the period 2014-2017 on the achievement of predefined milestones. In March 2014 BioGaia and Nestlé signed a supplementary agreement to the original one, which meant among other things that BioGaia received the remaining EUR 10.8 million (SEK 95.4 million).

Nestlé and BioGaia have further broadened and strengthened the cooperation and entered into a supplementary agreement to the original one. The agreement will provide BioGaia with royalties of around SEK 92 million over a three-year period, starting in the second quarter of 2014, for which BioGaia will carry out specific clinical studies on children and develop products in whole new areas.

#### Net sales excluding license revenue

Excluding license revenue from Nestlé, net sales amounted to SEK 386.4 million, an increase of 22% compared to the previous year. Most of the company's sales are denominated in foreign currency, primarily EUR but also USD and JPY. With unchanged exchange rates compared to the same period of last year, net sales (excluding license revenue) would have been SEK 14.1 million lower. Excluding foreign exchange effects, net sales (excluding license revenue) thus rose by 18%. Exchange rate fluctuations affect both revenue and expenses. Operating profit would also have been SEK 9.2 million lower in the event of unchanged exchange rates, which means an increase (excluding license revenue from Nestlé) of 13% compared to the previous year.

#### Sales by segment

Since the autumn of 2013 the company is divided into three business units, Paediatrics, Adult Health and New Business. Support functions have been retained at the central level, but the business units are responsible for product development and sales to their respective target groups. This results in a better focus and more effective decision-making. Starting in the first quarter of 2014, the company reports sales and gross profit for these business units. To facilitate comparison, sales and gross profit for the earlier segments, finished consumer products and component products, have been reported during 2014.

## PAEDIATRIC BUSINESS UNIT

Sales in BioGaia's core unit, Paediatrics, amounted to SEK 409.1 million (238.6), an increase of SEK 170.5 million (71%). Excluding license revenue from Nestlé, sales of paediatric products reached SEK 313.7 million (238.6), representing growth of 31% (excluding foreign exchange effects, 27%).

The increase is mainly attributable to sales of drops, which rose in all markets, primarily in Europe and "Rest of world", but also in North America and somewhat in Asia. In Europe, sales of drops increased in a number of countries in Eastern Europe (Turkey, Poland, Bulgaria, Slovakia and the Czech Republic), as well as Germany and Finland, while sales decreased mainly in Ukraine, but also in somewhat in Sweden. The decrease in Ukraine is due to the current instability in the country. In "Rest of world", sales of drops increased primarily in Brazil, where they were launched in October. Sales were also up in Mexico and Colombia, but declined in South Africa. In North America, sales grew in both Canada and the USA.

Sales of digestive health tablets related to the Paediatrics business unit were also up. Sales increased primarily in "Rest of world", as well as North America, but declined in Europe and were largely unchanged in Asia. The increase in "Rest of world" is mainly attributable to Brazil, where the tablets were launched in September. In North America, sales increased in both the USA and Canada. The decrease in Europe is mainly attributable to Ukraine.

Sales of cultures for infant formula declined slightly compared to the previous year. The agreement regarding infant formula now in force with Nestlé gives them the right to manufacture *L. reuteri* for use in infant nutrition, which would result in lower sales of cultures. BioGaia currently has no information about when, and in such case, to what extent Nestlé will exercise this right. This would have a negative impact on sales, but would not affect profit to a large extent since Nestlé buys cultures for infant formula at a significantly lower price following the sale of the rights for use in infant formula (see above).

Revenue under the agreement with Nestlé from 2013 regarding powder formula with *Lactobacillus reuteri* (for more information see below under Key events after the end of the year) rose somewhat compared to the previous year.

Royalty revenue of SEK 22.9 million (0.0) from the new collaboration agreement with Nestlé (see below) was included in sales for the Paediatrics business unit.

Activities in the Paediatrics business unit during the year were focused on participation in a number of influential conferences, among other things in the USA. These conferences are of vital importance, since they provide opportunity for direct contact with medical professionals from around the world to whom we promote the BioGaia brand. Often, the company hosts satellite symposia at which researchers selected by BioGaia present BioGaia's clinical studies to between 100 and 300 doctors. The company is also preparing the launch of new packaging solutions that will be introduced in 2015.

## ADULT HEALTH BUSINESS UNIT

Net sales in the Adult Health business unit amounted to SEK 69.4 million (75.6), down by SEK 6.2 million (-8%) (excluding foreign exchange effects, -12 %).

The decrease is due to lower sales of digestive health tablets, above all in Finland, where BioGaia's partner has been exposed to aggressive price competition. Sales of digestive health tablets also decreased in Italy.

Sales of oral health tablets grew compared to the previous year. The increase was attributable to both Asia and Europe. In Asia,

sales were up in Japan. The increase in Europa was attributable to several countries, primarily in Eastern Europe.

Sales of yoghurt products in Japan decreased. The company discontinued sales of yogurt products in Japan during September, since the margin has not met expectations and because BioGaia's partner has not invested in consumer marketing to the extent required to reach the volumes necessary to achieve profitability.

Activities in the business unit during the year were focused on clarifying the positioning of the new product Gastrus and on reducing costs for this product and the ORS product. Furthermore, the company is continuing its efforts to clarify the positioning of other products while at the same time studying the conditions for the launch of additional products. In the Adult Health unit, a great deal of fundamental positioning work towards the target groups remains to be done. In certain areas a repositioning is sufficient, but in others it is necessary to carry out complementary clinical studies in order to boost sales.

## FINISHED CONSUMER PRODUCTS

Sales of finished consumer products rose over the previous year by SEK 47.5 million (19%) (excluding foreign exchange effects, 14%) to SEK 303.7 million.

Sales of finished consumer products increased in all regions during the period.

## COMPONENT PRODUCTS

Sales of component products grew by SEK 117.5 million to SEK 176.1 million (201%) compared to the previous year. These sales include license revenue from Nestlé of SEK 95.4 million (see above for more information). Excluding license revenue from Nestlé, sales of component products amounted to SEK 80.7 million (58.6), an increase of 38% (excluding foreign exchange effects, 34%).

Sales were up in Europe but declined in Asia. The decrease in Asia is mainly attributable to sales of cultures to a dairy in South Korea.

Sales of cultures for infant formula decreased somewhat, while revenue from the new product for Nestlé (see above) increased.

Sales of component products include royalties from the new collaboration agreement with Nestlé (see below) of SEK 22.9 million (0.0).

## SALES BY GEOGRAPHICAL MARKET

Sales in Europe grew by SEK 39.5 million (18%)<sup>1)</sup> to SEK 257.8<sup>1)</sup> million.

Sales in the USA and Canada increased by SEK 7.9 million (35%) to SEK 30.3 million.

In Asia, sales declined by SEK 1.3 million (-3%) to SEK 38.8 million.

Sales in "Rest of world" were up by SEK 24.4 million (70%) to SEK 59.5 million.

## THE BIOGAIA BRAND

Of total finished consumer products, 61% (55) % were sold under the BioGaia brand, including co-branding. The target for 2014 was at least a minimum of 60%.

## **Gross profit**

Gross profit was SEK 255.1<sup>1)</sup> million (214.2), which is an increase of SEK 40.9 million (19%) compared to the previous year. The total gross margin declined from 68% to 66%<sup>1)</sup>.

Gross margin for the Paediatrics business unit decreased from 70% to 66%<sup>1)</sup>. The margin has fallen during the year as a result of a lower margin on sales of cultures for infant formula, but also due to costs (of around SEK 11.0 million for the full year 2014) arising from stability problem (see above in CEO's comments). To a certain extent, this has been compensated by royalties from Nestlé with a margin of 100%.

Gross margin for the Adult Health business unit rose from 62% to 64%. The variation is due to a somewhat changed product mix to products with better margins.

## **Operating expenses**

Total operating expenses rose by 20% to SEK 161.3 million. Excluding the subsidiary IBT, operating expenses were up by 15%.

Selling expenses grew by SEK 10.4 million (13%) and amounted to SEK 89.8 million (79.4), which is equal to 23% (25) of net sales<sup>1)</sup>. It was primarily expenses for samples and conferences that increased compared to the previous year. In addition, marketing expenses were up in Japan, partly in connection with the launch of drops during the third quarter.

Administrative expenses amounted to SEK 17.7 million (14.4), which is equal to 5% (5) of net sales<sup>1)</sup>. The increase of SEK 3.3 million (23%) is mainly due to higher personnel expenses and increased administrative expenses in the subsidiary TwoPac (see below).

R&D expenses are reported at SEK 53.9 million (40.6), which is equal to 14% (13) of net sales. The increase of SEK 13.3 million (33%) is mainly attributable to costs for the subsidiary IBT (see below). In addition, development costs rose sharply, mainly due to development projects together with Nestlé resulting from the new collaboration agreement (see below). Furthermore, both patent expenses and personnel expenses were higher during the year. Excluding the costs for IBT, R&D expenses were up by 17%.

Investments in capitalised development expenses totalled SEK 6.1 million (0) and refer to the NEC project in the subsidiary IBT AB.

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

## **Operating profit**

Operating profit was SEK 196.9 million (81.7), an increase of SEK 115.2 million (141%). Excluding license revenue from Nestlé, operating profit was SEK 101.5 million (81.7), an increase of SEK 24%. Excluding the subsidiary IBT, operating profit rose by 32%. Operating margin was 26%<sup>1)</sup> (excluding the subsidiary IBT, 28%).

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

Profit before tax was SEK 192.5<sup>1)</sup> million (83.8), an increase of SEK 108.7 million (130%) compared to the previous year. Net financial items include a foreign exchange loss of SEK -6.6 million (-2.9) on forward exchange contracts in EUR. At 31 December 2014 the company had outstanding forward exchange contracts for EUR 13.3 million at an average exchange rate of SEK 9.07. Forward exchange contracts amounting to EUR 8.7 million will mature for payment in 2015 and the remaining EUR 4.6 million in 2016. 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 2014 (9.48), an exchange gain/loss will be recognised in the future.

## **Profit after tax**

Profit after tax was SEK 148.0 million (64.2), an increase of SEK 83.8 million (130%). Excluding license revenue from Nestlé, profit after tax was SEK 73.6 million (64.2), which is SEK 9.4 million (15%) better than in the previous year.

The tax rate for the Group was 24% (23). 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 31 December 2014 amounted to SEK 35.2 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.

The company has an ongoing tax matter related to a write-down of receivables from the Japanese subsidiary. In the event of a negative outcome, this could result in additional tax expenses of SEK 3.1 million. If the outcome is positive, there is opportunity to receive an additional tax income of SEK 3.8 million for previous years.

## **Earnings per share**

Earnings per share were SEK 8.53 (3.57). Excluding license revenue from Nestlé, earnings per share amounted to SEK 4.23.

## **Cash flow**

The Group's cash and cash equivalents at 31 December 2014 totalled SEK 210.7 million (234.3). Cash flow for the period amounted to SEK -25.0 million (-140.8). Cash flow for the period included license revenue from Nestlé of SEK 95.4 million (0), dividends of SEK 120.9 million (172.7) and tax payments of SEK 66.8 million (10.8).

## **Equity**

Consolidated equity at 31 December 2014 amounted to SEK 344.6 (316.9). The Group's equity/assets ratio was 83% (83).

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 2012 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. A provision of SEK 1.1 million for this obligation was made in the second quarter, 2014 since at the current share price there is a risk that the subsidy must be paid.

## **Dividend**

The Board of Directors of BioGaia AB proposes to the upcoming AGM an ordinary dividend of SEK 3,46 per share and an extraordinary dividend of SEK 1,54 per share, for a total dividend of SEK 5,00 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 18.4 million (16.6), of which SEK 17.3 million (14.7) refers to TwoPac AB.

Investments in capitalised development expenses amounted to SEK 6.1 million (0) and refer to the development of a product for the NEC project in the subsidiary IBT AB.

### **Subsidiary in Japan**

Net sales in the wholly owned subsidiary in Japan reached SEK 17.1 million (15.2). Operating profit in the Japanese subsidiary amounted to SEK -6.1 million (-7.7). The growth in sales is primarily attributable to dental products. In 2015 BioGaia Japan will work with the launch of drops and will continue the successful focus on oral health products through BioGaia's distributor, which markets the products at dental clinics.

### **Subsidiary TwoPac AB**

Net sales in the wholly owned subsidiary TwoPac amounted to SEK 44.7 million (37.5). Operating profit was SEK 7.7 million (9.9). Profit after tax was SEK 5.5 million (7.3). The drop in profit is mainly explained by higher personnel expenses as a result of more stringent quality requirements and higher costs for development of new products. The increased quality requirements are internally driven to a certain extent, but are also motivated by BioGaia's desire to have the facility approved for pharmaceutical production by the Swedish Medical Products Agency. Furthermore, additional resources have been devoted to qualification and validation of new machinery.

TwoPac manufactures and develops products only for BioGaia.

### **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 (0.5) during the period. Operating profit amounted to SEK -2.9 million (-2.6). The company experienced quality problems during the year, which meant that sales did not gain momentum as expected. The company's assessment is that the problems have now been solved and that sales will increase during 2015. CapAble has now also started to market LifeTop Straw with probiotics.

### **Subsidiary IBT AB**

In November 2013, 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, and 0.9% by Board member Anders Ekblom, (former Global Head of R&D Science & Technology Integration at AstraZeneca AB and CEO of AstraZeneca AB). The remaining 90.1% is owned by BioGaia.

It is the company's assessment that approximately SEK 26 million of the SEK 42 million will be capitalisable in IBT as development expenses, which will result in a cost burden of around SEK 16 million over a two-year period.

Operating profit in IBT during the period amounted to SEK -6.7 million. The company has made investments in capitalised development expenses of SEK 6.1 (0) million. The company does not yet have any revenue.

### **Parent Company**

Net sales in the Parent Company reached SEK 464.2 million (304.6) and profit before tax was SEK 192.6 million (76.9). Cash flow in the Parent Company totalled SEK -27.6 million (-143.2).

## **FINANCIAL PERFORMANCE FOURTH QUARTER 2014**

### **Fourth quarter sales**

Net sales for the fourth quarter amounted to SEK 121.4 million (90.2), an increase of SEK 31.2 million (35%) compared to the same period of last year. Excluding foreign exchange effects, net sales were up by 28%.

Compared to the previous quarter, sales rose by SEK 42.0 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.

### **PAEDIATRIC BUSINESS UNIT FOURTH QUARTER**

Sales in the Paediatrics business unit amounted to SEK 97.8 million (65.6), an improvement of SEK 32.2 million (49%) compared to the same period of last year. Excluding foreign exchange effects, the increase was 42%. These sales include royalties of SEK 7.6 million from Nestlé. Excluding royalties, net sales grew by SEK 24.6 million, which is primarily attributable to sales of drops. Sales of drops increased in all regions, but particularly in "Rest of world" and Europe.

Sales of culture for infant formula increased somewhat compared to the same period of last year, while sales of digestive health tablets declined slightly. Revenue from the agreement signed with Nestlé in 2013 regarding powder formula with *Lactobacillus reuteri* (fore more information see below under Key events after the end of the year) also up compared to the same period of last year.

Compared to the previous quarter, sales in the Paediatrics business unit grew by SEK 30.2 million.

### **ADULT HEALTH BUSINESS UNIT FOURTH QUARTER**

Sales in the Adult Health business unit amounted to SEK 23.0 million (24.1), a decrease of SEK 1.1 million (4 %). Excluding foreign exchange effects, sales declined by 9%. The explanation for the decrease is that the subsidiary in Japan discontinued sales of yoghurt products in the fourth quarter.

Sales of digestive health tablets increased compared to the same period of last year, mainly in Europe but also in Asia. Sales of oral health tablets also rose, compared to the same period of last year, in all regions where the oral health tablets are sold, i.e. Europe, Asia and North America.

Compared to the previous quarter, sales in the Adult Health business unit improved by SEK 11.7 million.

### **FINISHED CONSUMER PRODUCTS FOURTH QUARTER**

Sales of finished consumer products reached SEK 94.9 million (75.1), an increase of SEK 19.7 million (26%) compared to the same period of last year.

Compared to the previous quarter, sales of finished consumer products were up by SEK 38.6 million.

### **COMPONENT PRODUCTS FOURTH QUARTER**

Sales of component products amounted to SEK 26.1 million (15.0), an increase of SEK 11.1 million (74%) compared to the same period of last year. This figure includes royalties from Nestlé of SEK 7.6 million. Compared to the previous quarter, sales of component products rose by SEK 3.5 million.

### Gross profit for the fourth quarter

Gross profit amounted to SEK 76.2 million (59.1), an increase of SEK 17.1 million (29%) compared to the same period of last year. Gross margin was 63%, compared to 66% in the same period of last year. Excluding royalties from Nestlé in the fourth quarter (see below), gross margin was 60%. The lower margin is primarily attributable to costs arising from the stability problem in the products, which meant that profit for the quarter was charged with SEK 7.5 million in additional expenses. The lower margin is also due to culture for infant formula for Nestlé (see above), where the margin has fallen further compared to the same period of last year. These items affect the Paediatrics business unit, where the margin decreased from 68% to 62% compared to the same period of last year. For the Adult Health business unit, the margin strengthened from 58% to 68%, which is mainly explained by the fact that the fourth quarter of last year included sales of yoghurt products with a low margin.

### Other operating expenses in the fourth quarter

Total operating expenses rose by 36% in the quarter. Excluding costs for the subsidiary IBT, total operating expenses increased by 30%.

Selling expenses for the fourth quarter were up compared to the same quarter of last year, from SEK 22.8 million to SEK 26.2 million (16%). This is due to higher costs primarily for samples, but also for other marketing activities. Compared to the previous quarter of 2014, selling expenses increased by SEK 5.3 million.

Administrative expenses were up by SEK 1.5 million (41%) compared to the same period of last year and amounted to SEK 5.3 million. This is mainly attributable to higher costs for the subsidiary TwoPac (see above) and increased personnel costs. Compared to the previous quarter, administrative expenses increased by SEK 1.7 million.

R&D expenses for the fourth quarter amounted to SEK 17.8 million (9.7), which is an increase of SEK 8.1 million (84%) compared to the same period of last year. Excluding costs for the subsidiary IBT, R&D expenses rose by 60%. The increase is mainly due to provisions of SEK 3.9 million pertaining to costs for development projects attributable to projects with Nestlé (for more information see below). Personnel and patent expenses were also higher. Compared to the previous quarter, R&D expenses increased by SEK 6.1 million.

### Operating profit for the fourth quarter

Operating profit was SEK 30,6 million (23,8), which is an increase of SEK 6,8 million (29%) compared to the same period of last year. Excluding operating expenses for IBT, the increase was 38%.

### Profit before tax for the fourth quarter

Profit before tax was SEK 27.1 million (21.9), which is an increase of SEK 5.2 million (24%) compared to the same period of last year. Net financial items include a foreign exchange loss of SEK 3.9 million (3.0) on forward exchange contracts in EUR (for more information see above).

### Profit after tax for the fourth quarter

Profit after tax was SEK 19.1 million (16.3), which is an increase of SEK 2.8 million (17%) compared to the same period of last year. The tax rate was 29% (26%). The higher tax rate in the fourth quarter is due to provisions for R&D expenses, which are not tax deductible.

### Cash flow for the fourth quarter

Cash flow was SEK -13.9 million (-9.1). Working capital increased by SEK 19.7 million (22.9), which is mainly due to increased trade receivables.

## KEY EVENTS IN THE FOURTH QUARTER OF 2014

### Launches in the fourth quarter of 2014

Distributor/licensee	Country	Product
Aché	Brazil	Drops
Delta	Ukraine	Drops with Vitamin D
Ewopharma	Croatia	Drops with Vitamin D
Neocare	Belgium	Oral rehydration product
Nestlé	Switzerland	Infant formula with <i>Lactobacillus reuteri</i> Protectis

### Publication of additional study showing that infants with colic cry less with BioGaia's drops

A study carried out in Canada on 52 infants with colic shows that babies given *Lactobacillus reuteri* Protectis cry and fuss less compared to babies given placebo. After seven days of treatment, crying and fussing was reduced by more than 40 minutes per day in infants given *Lactobacillus reuteri* Protectis, whereas there was practically no reduction in the placebo group. Crying and fussing continued to decrease significantly in the *Lactobacillus reuteri* Protectis group throughout the 21-day long study period. This was a significant difference compared to the placebo group.

The study was published in [Journal of Pediatrics](#) on 24 October 2014.

### Publication of study showing that BioGaia Protectis tablets are effective in constipated adults

A study of 40 adults with constipation shows that the patients given *Lactobacillus reuteri* Protectis were significantly less constipated after four weeks compared to the patients given placebo.

The study was published in [J Gastrointestin Lever Dis](#) on 9 December 2014.

### BioGaia invests in MetaboGen AB

BioGaia decided to invest SEK 12 million in MetaboGen AB, based in Gothenburg, Sweden. The investment will be made over a two-year period and will then give BioGaia 35% of the share capital in the company. BioGaia's CEO, Peter Rothschild, is now Chairman of MetaboGen. The investment of SEK 4.0 million was made in the fourth quarter of 2014.

MetaboGen is a research company that was founded in 2011 in Gothenburg by Professor Fredrik Bäckhed at the University of Gothenburg and Professor Jens B. Nielsen at Chalmers University of Technology, together with GU Holding, which commercialises research results and develops companies linked to the University of Gothenburg. MetaboGen conducts research in metagenomics, the research-intensive and rapidly expanding field devoted to sequencing of all genes in the microbial communities, for example in the human gut, to find previously unknown members of and patterns in the microbial diversity related to health and disease. The aim is to develop new treatments and products for different metabolic and other microbial-associated diseases by influencing large parts of the microflora.

## KEY EVENTS AFTER THE END OF YEAR

### Agreement for the sale of drops in Vietnam

BioGaia has today signed an exclusive agreement with VietPhap International Co Ltd for the rights to sell BioGaia ProTectis Drops in Vietnam. The launch is planned to take place during 2015.

### Nestlé launches new product with BioGaia's probiotic

Nestlé has since the end of 2014 initiated the launch of powder formula with *Lactobacillus reuteri* Protectis for children above the age of one year. The products will mainly be sold in emerging markets.

For several years, BioGaia and Nestlé have had a fruitful cooperation to develop products with probiotics. The parties have, as previously announced, entered into an agreement signed 30 May 2013 and giving Nestlé the exclusive rights to use BioGaia's patented probiotic strain *Lactobacillus reuteri* Protectis in an additional range of products. The new product, powder formula for children over the age of one year, is the result of this agreement.

## KEY EVENTS EARLIER IN 2014

### Launches during January to September 2014

Distributor/licensee	Country	Product
Aché	Brazil	Digestive health tablets
BG Distribution	Hungary	Drops with Vitamin D and digestive health tablets with Vitamin D
Cube Pharmaceutical	Greece	Oral rehydration product with orange flavour and Drops with Vitamin D
Dong Sung	South Korea	Drops and Gastrus digestive health tablets
EwoPharma	Slovenia	Drops with Vitamin D
Ewopharma	Latvia and Lithuania	Tablets with Vitamin D
Exeer	Libya	Drops and oral rehydration product
George Petrou Ltd	Cyprus	Oral health tablets
Infectopharm	Germany	Drops with Vitamin D
Keyuan	China	Drops and Gastrus digestive health tablets
Nestlé	Ukraine, Russia and the CIS countries	Infant formula with <i>Lactobacillus reuteri</i> Protectis
Noos	Italy	Drops with Vitamin D and Vitamin K
Pediact	France	Oral rehydration product
Plac Control	Greece	Oral health tablets
Semper	Norway	Drops and digestive health tablets with strawberry flavour

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

A study on 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 the 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.

### New major agreement with Nestlé including payment of contingent consideration

In February 2012 BioGaia sold the rights for the use of *Lactobacillus reuteri* Protectis in infant formula to Nestlé for the remainder of the patent lifetime. BioGaia received EUR 40 million up front and a commitment for a further EUR 10.8 million during the period from 2014 to 2017 upon the achievement of certain milestones. The first milestone payment of EUR 3.6 million was received and recognised in February 2014.

Nestlé and BioGaia have further broadened and strengthened the cooperation and in March this year entered into a supplementary agreement to the original one. The agreement will provide BioGaia with royalties of around SEK 92 million (approximately EUR 10.4 million) over a three-year period, starting in the second quarter of 2014, for which BioGaia will carry out specific clinical studies in the paediatric area. In addition, BioGaia will develop new products for Nestlé in whole new areas.

Furthermore, the agreement means that BioGaia immediately received the remaining milestone payments of EUR 7.2 million from the 2012 agreement. Consequently, the entire contingent consideration of EUR 10.8 million (SEK 95.4 million) was recognised and paid in the first quarter of 2014.

### Publication of study showing that it is possible to prevent common infections in children

Healthy children attending daycare centres have a significantly lower risk of getting diarrhoea or respiratory tract infections when given a daily supplement of *Lactobacillus reuteri* Protectis, as shown by a study on 336 children that was conducted in Mexico. The study confirms previously published data and proves that preventative treatment with *L. reuteri* Protectis in healthy children reduces episodes of diarrhoea. Furthermore, the study demonstrated a reduction in respiratory tract infections among the children given supplements of Protectis. Moreover, the children receiving *Lactobacillus reuteri* Protectis had fewer days with fever, used less antibiotics and had fewer days of absence from daycare. The study was published in the medical journal Pediatrics on 17 March 2014.

### Agreement for the sale of drops in India

In June BioGaia signed a non-exclusive agreement with Pharma Base SA for the rights to sell BioGaia's ProTectis Baby Drops in India. Pharma Base will cooperate with a local distributor for marketing and sales of the drops, which will be sold under BioGaia's own brand. Registration of the product will be started in 2014 and the launch is planned for 2015.

### Agreement for the sale of drops in the UK

In June BioGaia signed an agreement with Nestlé Nutrition UK that gives its subsidiary SMA exclusive rights to sell BioGaia's ProTectis Baby Drops in the United Kingdom and Ireland. The drops will be sold under the BioGaia brand with elements of SMA's brand, which is very well known in the UK. The launch is planned to take place in 2015.

### Decision to extend the existing production plant at the subsidiary TwoPac in Eslöv

In 2012 a new production plant was completed in Eslöv and was mainly financed by loans from BioGaia AB. In June 2014 BioGaia made a decision for the subsidiary TwoPac to extend the existing production plant in Eslöv. BioGaia will invest around SEK 16 million in the new facility over the three-year period.

## **EMPLOYEES**

The number of employees in the Group at 31 December 2014 was 95 (85).

### ***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 wholly owned 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 6.3 million. BioGaia's assessment is that there is no indication of impairment of these assets. In the Parent Company, all current receivables from the Japanese subsidiary have been written off. The loan to the Japanese subsidiary and shares in the company 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 made total group contributions of SEK 12.7 million during the period from 2010 to 2013. Profit before tax and group contribution for 2014 amounted to SEK -2.9 million (-2.6). On the balance sheet date, assets in CapAble were reported at SEK 3.6 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.

Infant Bacteria Therapeutics AB (IBT), which is 90.1% owned by BioGaia, was established in November 2013. At that time, the Board of BioGaia made a decision to invest in phase one of a long-term project aimed at developing a drug with rigorous hygiene, analysis and documentation requirements, to treat the highly fatal disease Necrotising Enterocolitis (NEC), which affects premature infants. BioGaia will invest up to SEK 42 million in the project over a two-year period. BioGaia AB has made conditional shareholder contributions of SEK 11.0 million to IBT. On the balance sheet date, assets in IBT were reported at SEK 7.6 million in the Group. BioGaia's assessment is that IBT 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 2013.

## **ACCOUNTING POLICIES**

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.

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. 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 2013, aside from a number of minor amendments to existing standards and new interpretations that are effective as of 1 January 2014. These are not assessed to have any significant impact on the profit or financial position of the Group or the Parent Company aside from increased disclosures.

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

Since the autumn of 2013 the company is divided into three business units, Paediatrics, Adult Health and New Business. As of 2014 the company reports sales and gross profit for these business units. To facilitate comparison, sales and gross profit for finished consumer products and component products will also be reported during 2014.

## **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 the majority under the company's own brand, 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:	182,186
Profit for the year:	149,590
Together amounting to:	331,776

The Board of Directors and the CEO propose that the company pay an ordinary dividend of SEK 3.46 per share, and, in view of the company's good liquidity and strong balance sheet, an extraordinary dividend of SEK 1.54 per share, amounting to a total dividend of SEK 5,00 per share. This is equal to a total distribution of SEK 86.4 million. It is proposed that the remaining profit of SEK 245.4 million be carried forward to new account.

1) Excluding license revenue from Nestlé of SEK 95.4 million. Including license revenue from Nestlé, operating margin amounted to 41%, total net sales to SEK 481.8 million, net sales of component products to SEK 176.1 million, net sales in the Paediatrics business unit to SEK 409.1 million, net sales in Europe to SEK 353.2 million, gross profit to SEK 350.4 million, operating profit to SEK 196.8 million, profit before tax to SEK 192.5 million and profit after tax to SEK 148.0 million. Operating margin amounted to 41%. Earnings per share amounted to SEK 8.53.

**Statements of comprehensive income - Group**

(Amounts in SEK 000s)

	<b>Jan-Dec</b>	Jan-Dec	<b>Oct-Dec</b>	Oct-Dec
	<b>2014</b>	2013	<b>2014</b>	2013
Net sales	<b>386,405</b>	315,875	<b>121,374</b>	90,221
License revenue	<b>95,397</b>	-	-	-
Cost of goods sold	<b>-131,338</b>	-101,711	<b>-45,173</b>	-31,111
<i>Gross profit</i>	<b>350,464</b>	214,164	<b>76,201</b>	59,110
Selling expenses	<b>-89,759</b>	-79,396	<b>-26,192</b>	-22,768
Administrative expenses	<b>-17,666</b>	-14,356	<b>-5,281</b>	-3,741
Research and development expenses	<b>-53,867</b>	-40,555	<b>-17,807</b>	-9,699
Other operating income	<b>7,711</b>	1,796	<b>3,639</b>	871
<i>Operating profit</i>	<b>196,883</b>	81,653	<b>30,560</b>	23,773
Interest income	<b>2,382</b>	5,081	<b>246</b>	1,165
Foreign exchange gain/loss, forward contracts	<b>-6,592</b>	-2,882	<b>-3,891</b>	-3,011
Financial expenses	<b>-148</b>	-92	<b>-19</b>	-17
<i>Profit before tax</i>	<b>192,525</b>	83,760	<b>26,896</b>	21,910
Tax	<b>-44,536</b>	-19,572	<b>-7,829</b>	-5,616
<b>PROFIT FOR THE PERIOD</b>	<b>147,989</b>	64,188	<b>19,067</b>	16,294
<b><u>Items that will be reclassified to profit or loss</u></b>				
Gains/losses arising on translation of the financial statements of foreign operations	<b>642</b>	-1,419	<b>-55</b>	-697
<b>Comprehensive income for the period</b>	<b>148,631</b>	62,769	<b>19,012</b>	15,597
<b><u>Profit for the period attributable to:</u></b>				
Owners of the Parent Company	<b>147,406</b>	61,722	<b>17,889</b>	16,300
Non-controlling interests	<b>583</b>	2,466	<b>1,178</b>	-6
	<b>147,989</b>	64,188	<b>19,067</b>	16,294
<b><u>Comprehensive income for the period attributable to:</u></b>				
Owners of the Parent Company	<b>148,048</b>	60,303	<b>17,834</b>	15,603
Non-controlling interests	<b>583</b>	2,466	<b>1,178</b>	-6
	<b>148,631</b>	62,769	<b>19,012</b>	15,597
<b><u>Earnings per share</u></b>				
Basic earnings per share (average number of shares), SEK	<b>8.53</b>	3.57	<b>1.04</b>	0.94
Diluted earnings per share, SEK	<b>8.53</b>	3.56	<b>1.04</b>	0.94
Number of shares, thousands	<b>17,271</b>	17,271	<b>17,271</b>	17,271
Average number of shares, thousands	<b>17,271</b>	17,271	<b>17,271</b>	17,271
Number of outstanding warrants, thousands	<b>87</b>	87	<b>87</b>	87
Number of outstanding warrants with a dilutive effect, thousands	-	87	-	87
Number of shares after dilution, thousands	<b>17,271</b>	17,358	<b>17,271</b>	17,358

**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

	31 Dec	31 Dec
(Amounts in SEK 000s)	2014	2013
<b>ASSETS</b>		
Intangible assets	6,075	-
Property, plant and equipment	72,752	60,286
Other financial assets	4,000	-
Other non-current receivables	20	17
<i>Total non-current assets</i>	<b>82,847</b>	60,303
Current assets excl. cash and cash equivalents	122,095	88,845
Cash and cash equivalents	210,666	234,271
<i>Total current assets</i>	<b>332,761</b>	323,116
<b>TOTAL ASSETS</b>	<b>415,608</b>	383,419
<b>EQUITY AND LIABILITIES</b>		
Equity attributable to owners of the Parent Company	344,492	317,341
Non-controlling interests	99	-484
Total equity	344,591	316,857
Provision for deferred tax	192	85
Other provisions	3,900	-
Interest-free current liabilities	66,925	66,477
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>415,608</b>	383,419
<b>Pledged assets</b>	<b>2,000</b>	2,000

**CONSOLIDATED CASH FLOW STATEMENTS**

	Jan-Dec	Jan-Dec	Oct-Dec	Oct-Dec
(Amounts in SEK 000s)	2014	2013	2014	2013
<i>Operating activities</i>				
Operating profit	196,883	81,653	30,560	23,773
Depreciation/amortisation	5,652	5,541	1,680	1,753
Other non-cash items	-853	-308	-86	-291
	201,682	86,886	32,154	25,235
Gains/losses on realised forward exchange contracts	-1,186	193	-597	-246
Paid tax	-66,829	-10,799	-15,591	-5,311
Interest received and paid	2,214	4,996	212	1,153
Cash flow from operating activities before changes in working capital	135,881	81,276	16,178	20,831
Changes in working capital	-11,498	-2,835	-19,495	-22,876
<i>Cash flow from operating activities</i>	<b>124,383</b>	78,441	<b>-3,317</b>	-2,045
<i>Cash flow from investing activities</i>	<b>-28,481</b>	-16,628 <sup>1)</sup>	<b>-10,619</b>	-7,024
<i>Cash flow from financing activities</i>	<b>-120,892</b>	-202,620 <sup>1)</sup>	<b>5</b>	-
Cash flow for the period	-24,990	-140,807	-13,931	-9,069
Cash and cash equivalents at beginning of period	234,271	374,974	224,125	243,193
Exchange difference in cash and cash equivalents	1,385	104	472	147
Cash and cash equivalents at end of period	<b>210,666</b>	234,271	<b>210,666</b>	234,271

1) In 2013 figures a reclassification of SEK 29,910 thousand between Cash flow from investing activities and Cash flow from financing activities has been done.

**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

(Amounts in SEK 000s)

	Jan-Dec 2014	Jan-Dec 2013
At beginning of period	316,857	456,794
Dividends	-120,897	-172,710
Purchase of 50% of TwoPac AB	-	-30,000
Sale of 9% of IBT AB	-	4
Comprehensive income for the period	148,631	62,769
<b>At end of period</b>	<b>344,591</b>	<b>316,857</b>

**REPORTING BY SEGMENT – GROUP**

(Amounts in 000's)

<u>Income by segment – business unit</u>	Jan-Dec 2014	Jan-Dec 2013	Oct-Dec 2014	Oct-Dec 2013
Paediatrics	313,716	238,586	97,794	65,629
License revenue (Paediatrics)	95,397	-	-	-
Adult Health	69,446	75,616	22,998	24,072
Other	3,243	1,673	582	520
	<b>481,802</b>	<b>315,875</b>	<b>121,374</b>	<b>90,221</b>

<u>Gross profit by segment – business unit</u>	Jan-Dec 2014	Jan-Dec 2013	Oct-Dec 2014	Oct-Dec 2013
Paediatrics	208,445	166,161	60,254	44,876
License revenue (Paediatrics)	95,397	-	-	-
Adult Health	44,229	47,023	15,578	13,878
Other	2,393	980	369	356
	<b>350,464</b>	<b>214,164</b>	<b>76,201</b>	<b>59,110</b>

<u>Revenue by segment – product area</u>	Jan-Dec 2014	Jan-Dec 2013	Oct-Dec 2014	Oct-Dec 2013
Finished consumer products	303,603	256,164	94,784	75,108
Component products	80,724	58,592	26,095	15,033
License revenue (component products)	95,397	-	-	-
Other products	2,078	1,119	495	80
	<b>481,802</b>	<b>315,875</b>	<b>121,374</b>	<b>90,221</b>

<u>Gross profit by segment – product area</u>	Jan-Dec 2014	Jan-Dec 2013	Oct-Dec 2014	Oct-Dec 2013
Finished consumer products	207,512	180,088	62,003	50,962
Component products	45,477	33,384	13,703	8,068
License revenue (component products) 1)	95,397	-	-	-
Other products	2,078	692	495	80
	<b>350,464</b>	<b>214,164</b>	<b>76,201</b>	<b>59,110</b>

**Revenue by geographical market**

	Jan-Dec 2014	Jan-Dec 2013	Oct-Dec 2014	Oct-Dec 2013
Net sales				
Europe	257,808	218,301	73,416	56,041
License revenue (Europe) 1)	95,397	-	-	-
USA and Canada	30,273	22,412	12,769	8,840
Asia	38,778	40,100	12,015	13,993
Rest of world	59,546	35,062	23,174	11,347
	<b>481,802</b>	315,875	<b>121,374</b>	90,221

**CONSOLIDATED KEY RATIOS <sup>1)</sup>**

	Jan-Dec 2014	Jan-Dec 2014 <sup>2)</sup>	Jan-Dec 2013
Net sales, SEK 000s	481,802	386,405	315,875
Operating profit, SEK 000s	196,883	101,486	81,653
Profit after tax, SEK 000s	147,989	73,579	64,188
Return on			
- average equity	45%	25%	16%
- average capital employed	60%	35%	22%
Capital employed, SEK 000s	348,683	270,373	316,942
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	87	87	87
Average number of outstanding warrants with a dilutive effect, thousands	-	-	87
Number of shares after dilution, thousands	17,271	17,271	17,358
Basic earnings per share, SEK	8.53	4.23	3.57
Diluted earnings per share, SEK	8.53	4.23	3.56
Basic equity per share, SEK	19.95	15.64	18.37
Diluted equity per share, SEK	19.95	15.64	18.28
Equity/assets ratio	83%	85%	83%
Operating margin	41%	26%	26%
Profit margin	40%	25%	27%
Average number of employees	90	90	82

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

2) Excluding non-recurring revenue from Nestlé of SEK 95.4 million (see above under "Financial performance in 2014")

**PARENT COMPANY INCOME STATEMENTS**

(Amounts in SEK 000s)

	Jan-Dec 2014	Jan-Dec 2013
Net sales	368,809	304,624
License revenue	95,397	-
Cost of goods sold	-139,971	-108,840
<i>Gross profit</i>	<i>324,235</i>	<i>195,784</i>
Selling expenses	-68,720	-59,662
Administrative expenses	-15,075	-13,302
Research and development expenses	-46,346	-40,461
Other operating income	7,851	1,796
<i>Operating profit</i>	<i>201,945</i>	<i>84,155</i>
Impairment loss on receivable from subsidiary	-2,835	-8,960
Impairment loss on shares in subsidiary	-2,874	-2,589
Net financial items	-3,611	4,314
Profit before appropriations and tax	192,625	76,920
Change in tax allocation reserve	-	109,341
Profit before tax	192,625	186,261
Tax expense	-43,035	-41,604
<b>PROFIT FOR THE PERIOD</b>	<b>149,590</b>	<b>144,657</b>

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

	31 Dec 2014	31 Dec 2013
Intangible assets	-	-
Property, plant and equipment	1,360	2,058
Shares in group companies	69,129	52,394
Shares in other companies	4,000	-
Non-current receivables from subsidiaries	41,013	29,513
<i>Total non-current assets</i>	<i>115,502</i>	<i>83,965</i>
Current assets excl. cash and cash equivalents	111,084	76,594
Cash and cash equivalents	201,988	228,456
<i>Total current assets</i>	<i>313,072</i>	<i>305,050</i>
<b>TOTAL ASSETS</b>	<b>428,574</b>	<b>389,015</b>
<b>EQUITY AND LIABILITIES</b>		
Equity	350,300	321,607
Other provisions	3,900	-
Interest-free current receivables	74,374	67,408
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>428,574</b>	<b>389,015</b>
<b>Pledged assets</b>	<b>2,000</b>	<b>2,000</b>

**PARENT COMPANY CASH FLOW STATEMENTS**

	Jan-Dec 2014	Jan-Dec 2013
<u>Operating activities</u>		
Operating profit	201,945	84,155
Depreciation/amortisation	867	1,157
Other non-cash items	-1,160	-310
Gain/losses on realised foreign exchange contracts	-1,186	193
Paid tax	-64,828	-9,816
Interest received and paid	2,961	5,603
Cash flow from operating activities before changes in working capital	138 599	80 982
Changes in working capital	-16 827	-7 218
<i>Cash flow from operating activities</i>	121,772	73,764
<i>Cash flow from investing activities</i>	-28,499	-44,218
<i>Cash flow from financing activities</i>	-120,897	-172,710
Cash flow for the period	-27,624	-143,164
Cash and cash equivalents at beginning of period	228,456	371,448
Exchange difference in cash and cash equivalents	1,156	172
Cash and cash equivalents at end of period	201,988	228,456

**PARENT COMPANY STATEMENTS OF CHANGES IN EQUITY**

(Amounts in SEK 000s)	Jan-Dec 2014	Jan-Dec 2013
At beginning of year	321,607	349,660
Dividends	-120,897	-172,710
Profit for the period	149,590	144,657
<b>At end of period</b>	<b>350,300</b>	<b>321,607</b>

## RELATED PARTY TRANSACTIONS

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

Annwall & Rothschild Investment AB hold 740,668 class A shares and 759,332 class B shares, which is equal to 8.7% of the share capital and 34.1% of the votes in BioGaia AB. Annwall & Rothschild Investment AB is owned by Peter Rothschild, CEO of BioGaia, and Jan Annwall, a member of the Board of BioGaia AB. The only transaction that has taken place during the period is the payment of a dividend of SEK 7 per share. No other transactions between BioGaia and Annwall & Rothschild Investment AB have taken place during the period.

Bo Möllstam is Technical Director and a member of BioGaia's executive management. He is not employed by the company but is contracted as a consultant and invoices his fees through a company. Bo Möllstam is a partner in Synergon AB, which invoiced an amount of SEK 9.7 million to BioGaia AB during the year. Of this total, SEK 5.5 million refers to forwarded patent expenses and the remainder consists of consulting fees.

Helen Olsson is HR Director and a member of the executive management. She is not employed by the company but is contracted as a consultant and invoices her fees through a company. Helen Olsson is a partner in Spirean AB, which invoiced an amount of SEK 0.8 million to BioGaia AB during the year.

### RELATED PARTY TRANSACTIONS – PARENT COMPANY

(Amounts in SEK 000s)

*The following transactions have taken place with BioGaia Japan*

	Jan-Dec 2014	Jan-Dec 2013
Interest income	0	1 565
Loan provided	-2,835	-7,419
Sale of goods	0	4,410

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

	Jan-Dec 2014	Jan-Dec 2013
Interest income	696	610
Loan provided	-11,500	-5,000
Purchase of goods	-44,689	-37,487

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

	31 Dec 2014	31 Dec 2013
Non-current receivables from TwoPac AB (incl. subsidiary)	39,991	28,491
<b>Current transactions with related parties</b>		
Current receivables from TwoPac AB	172	1914
Current liabilities to TwoPac AB	-4,319	-1,643
	-4,147	271

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

	Jan-Dec 2014	Jan-Dec 2013
Shareholder contributions rendered	-10,000	-1,000
Group contributions rendered	-6,730	-229
Purchase of services	-408	-

## **FINANCIAL CALENDAR**

The annual report for 2014 will be distributed to all shareholders during the last week of March 2015. At that time it will also be available on BioGaia's website and can be ordered by telephone +46 8-555 293 00 or by email to [info@biogaia.se](mailto:info@biogaia.se).

12 February 2015	Teleconference at 9:00 a.m.
7 May 2015	Interim report 1 January – 31 March 2015.
7 May 2015	Annual General Meeting at 4:00 p.m. at Lundqvist & Lindqvist Klara Strands konferens, Klarabergsviadukten 90 in Stockholm. Shareholders who wish to have a matter dealt with at the AGM must submit a request by 20 March 2015 to the Board Chairman, David Dangoor, BioGaia AB, Box 3242, SE-103 64 STOCKHOLM, Sweden, or by e-mail to the company's senior legal counsel, Per Erik Andersson, at <a href="mailto:pea@biogaia.se">pea@biogaia.se</a>
18 August 2015	Interim report 1 January – 30 June 2015
23 October 2015	Interim report 1 January – 30 September 2015

**The Board of Directors and the CEO give their assurance that 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 2015**

**David Dangoor**  
Board Chairman

**Jan Annwall**  
Board member

**Stefan Elving**  
Board member

**Inger Holmström**  
Board member

**Jan Litborn**  
Board member

**Brit Stakston**  
Board member

**Jörgen Thorball**  
Board member

**Paula Zeilon**  
Board member

**Peter Rothschild**  
CEO

# Auditor's report on review of interim financial information (interim report) prepared in accordance with IAS 34 and Chapter 9 of the Annual Accounts Act (1995:1554)

## Introduction

We have reviewed the condensed interim financial information (interim report) of BioGaia AB (publ), corporate identity number 556380-8723, at 31 December 2014 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 ISRE 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 2015

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 95 employees, of whom 34 are based in Stockholm, 28 in Lund, 22 in Eslöv, three in Raleigh, USA, six in Hiroshima, Japan, and two in Shanghai, China.

### **Business model**

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

The products are sold through nutrition and pharmaceutical companies in 85 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**

BioGaia's strains of *Lactobacillus reuteri* are some of the world's most well researched probiotics, especially in young children. To date, 137 clinical studies using BioGaia's human strains of *Lactobacillus reuteri* have been performed on around 11,700 individuals of all ages. The results have been published in 108 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:**

2015-02-10	Nestlé launches new product with BioGaia's probiotic
2015-01-12	BioGaia signs exclusive agreement in Vietnam
2014-12-11	BioGaia-product effective in constipated adults

**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.com](http://www.biogaia.com)**  
**For additional information, contact:**  
**Peter Rothschild, CEO, BioGaia AB, telephone +46 8-555 293 20**  
**Margareta Hagman, Executive Vice President, BioGaia AB, telephone +46 8-555 293 04**