

## BioGaia AB

### Interim report 1 January - 30 September 2013 (15 pages)

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



#### President's comments:

"As I have pointed out before, we monitor our own performance based on the rolling 12-month figures. Sales of finished consumer products grew by 12%, excluding foreign exchange effects, and component products fell by 25% (due to the Nestlé deal in 2012). But we are aiming higher. In view of the development in most of the countries where we are active and the new product launches we are planning, we have no intention of changing this ambition," says Peter Rothschild, President of BioGaia.

#### Period from 1 January to 30 September 2013

Net sales reached SEK 225.7 million (216.8<sup>1)</sup>), an increase of SEK 8.9 million (4%). Excluding foreign exchange effects, net sales improved by 7%.

Net sales of finished consumer products amounted to SEK 181.1 million (172.0), representing growth of SEK 9.1 million (5%). Excluding foreign exchange effects, net sales improved by 9%.

Net sales of component products amounted to SEK 43.6 million (43.8<sup>1)</sup>), a decrease of SEK 0.2 million (0.5%). Excluding foreign exchange effects, net sales rose by 1%.

Operating profit was SEK 57.9 million (58.9<sup>1)</sup>), down by SEK 1.0 million (2%). Excluding foreign exchange effects, operating profit improved by 2%.

Profit after tax was SEK 47.9 million (51.7<sup>1)</sup>), a decrease of SEK 3.8 million (7%).

Earnings per share totalled SEK 2.63 (2.88<sup>1)</sup>).

The period's total cash flow was SEK -131.7 million (233.3). Last year's cash flow included payment of SEK 356.0 million in licence revenue from Nestlé. Cash and cash equivalents at 30 September 2013 totalled SEK 243.2 million (404.1). Cash flow since 30 September 2012 includes dividends of SEK 172.7 million, tax payments of SEK 37.7 million, equipment investments in TwoPac of SEK 13.3 million and the acquisition of shares in TwoPac of SEK 30.0 million.



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 for the period January-September 2012 amounted to SEK 572.8 million, operating profit to SEK 414.9 million, profit after tax to SEK 314.1 million and earnings per share to SEK 18.07.

**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 23 October 2013, 8:00 a.m. CET.

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

#### Third quarter of 2013

Net sales amounted to SEK 62.2 million (62.8), down by SEK 0.6 million (1%). There were no material foreign exchange effects on sales in the quarter.

Net sales of finished consumer products totalled SEK 46.4 million (50.2), a decrease of SEK 3.8 million (8%).

Net sales of component products amounted to SEK 15.7 million (12.5), an improvement of SEK 3.2 million (26%).

Operating profit was SEK 13.8 million (13.5), an increase of SEK 0.3 million (2%). Excluding foreign exchange effects, operating profit decreased by 3%.

Profit after tax was SEK 13.4 million (14.2), a decrease of SEK 0.8 million (6%).

#### Key events in the third quarter of 2013

BioGaia acquires remaining 50% of TwoPac.

FDA approves BioGaia's request for orphan drug designation.

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

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

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

## BioGaia AB (publ.)

### **INTERIM REPORT 1 JANUARY – 30 SEPTEMBER 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 interim report for the period from 1 January to 30 September 2013. A description of the company's operations is provided on page 15.

#### **PRESIDENT'S COMMENTS**

Sales of component products grew by 26% during the quarter and we can clearly see that our strategy of spreading risks in terms of the type and number of products, new products launches and geographical markets has given us a more stable situation than would otherwise be the case and is commonly seen in our industry.

Sales of finished consumer products fell by 8% during the quarter, most of which was offset by the increase for component products. One explanation behind this, for us unusual, development is decrease of sales to Italy, which is due to reduction of inventory at our distributor there and also the difficult economic situation in Italy. It is naturally difficult to predict when the Italian market will recover, but in September sales of our products in pharmacies returned to normal levels. We have also noted declining sales in Poland as a result of aggressive price competition.

As I have pointed out before, we monitor our own performance based on the rolling 12-month figures. Sales of finished consumer products grew by 12%, excluding foreign exchange effects, and component products fell by 25% (due to the Nestlé deal in 2012). But we are aiming higher. In view of the development in most of the countries where we are active and the new product launches we are planning, we have no intention of changing this ambition. Firstly, we are continuing the work to develop new and innovative products and secondly, we are focusing on introducing our products in several of the major markets such as the BRIC countries, the USA and the UK. When assessing our sales, it is important to keep in mind that the contract we signed with Nestlé in February 2012 means that they bought the license in the infant nutrition area, which gave a revenue and profit of SEK 356 million in 2012. If we had not made the sale, part of that sum would have increased our sales and profit for this year.

During the summer, Nestlé's subsidiary Gerber launched our colic drops for small children in the USA. After a few initial logistical problems, Gerber can now focus on marketing both through its own large force of sales representatives that visit doctors and through more traditional consumer marketing. It is encouraging to see that the first deliveries to Gerber have already essentially resulted in a doubling of sales compared to deliveries to the former distributor last year.

The results of a highly interesting study on patients with periodontal disease were reported during the quarter. The study compared patients receiving only standard treatment to patients being treated with a combination of BioGaia's oral health products and standard treatment. The patients who were given the BioGaia product as an adjunct showed better results on gingival pocket depth leading to a 53% decreased need for surgery. This study will further supplement the 22 studies that we have previously reported on in the oral health area, giving us access to fantastic marketing material that we use to convince dentists to recommend our oral health products to their patients.

In August the FDA approved our request for an orphan drug designation for a product that is intended for premature infants with the deadly disease NEC. This confers a number of advantages should BioGaia choose to register the product as a pharmaceutical. We are currently working to assess the financial investment and amount of time necessary to develop the product as a drug, and a plan of action for making this happen. As pharmaceuticals are not part of BioGaia's current business activities, the company is

exploring how a possible development process should continue in order to avoid deflecting attention from the core business. For this purpose, all business related to this field is handled by the subsidiary Infant Bacterial Therapeutics AB. During the year the project has cost just over SEK 2 million.

#### **FINANCIAL PERFORMANCE DURING THE PERIOD FROM JANUARY TO SEPTEMBER 2013**

##### **Sales**

Consolidated net sales reached SEK 225.7 million (216.8) (excluding the previous year's licence revenue from Nestlé), which is an increase of SEK 8.9 million (4%).

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 7.0 million higher. Excluding foreign exchange effects, net sales (excluding license revenue) thus increased by 7%. Exchange rate fluctuations for EUR, USD and JPY reduce both revenue and expenses. Operating profit would have been SEK 2.4 million higher in the event of unchanged exchange rates, which is an increase of 2% compared to the same period of last year.

Including license revenue from Nestlé, net sales for the period from January to September 2012 amounted to SEK 572.8 million. Net sales for 2012 included 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. Following 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 by SEK 9.1 million (5%) compared to the same period of last year and amounted to SEK 181.1 million. Excluding foreign exchange effects, the increase was 9%.

Sales of finished consumer products grew primarily in Europe and "Rest of world". Sales also rose somewhat in Asia, but fell in the USA and Canada.

Sales in Europe increased in Finland, Ukraine, Sweden, Turkey and France, but fell in Italy and Poland. The decrease in Italy is due to reduction of inventory at the distributor and also the difficult economic situation in the country. In Poland, sales have declined as a result of aggressive price competition. The increase in "Rest of world" is mainly attributable to South Africa. In Asia, sales were up in Indonesia but declined in Japan.

The decrease in the USA and Canada is a result of lower sales of tablets to Fleet, since the company purchased large inventories in connection with the launch last year. The first deliveries to the new distributor of drops in the USA, Gerber, took place in the second and third quarters of 2013 and were roughly twice as high as deliveries to the former distributor during January-September 2012.

For the past 12-month period, sales of finished consumer products have risen by 7%. Excluding foreign exchange effects, the increase was 12%.

##### **COMPONENT PRODUCTS**

Sales of component products were down by SEK 0.2 million to SEK 43.6 million (0.5%) compared to the same period of last year (excluding the previous year's licence revenue from Nestlé). Excluding foreign exchange effects, net sales were up by 1%.

Sales rose somewhat in Europe but declined in Asia due to expiration of a contract with a dairy in Taiwan.

Earlier in the year, sales of component products decreased mainly as a consequence of the agreement with Nestlé in 2012 (see above). However, due to revenue arising from the new agreement with Nestlé (see below), net sales from Nestlé are now on the same level as in 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.

For the past 12-month period, sales of component products have decreased by 26% (25% including foreign exchange effects), which is a result of the license agreement with Nestlé in 2012.

#### Sales by geographical market

Sales in Europe increased by SEK 10.7 million (7%) (excluding the previous year's licence revenue from Nestlé). Sales of finished consumer products rose, while sales of component products increased marginally. For the past 12-month period, sales in Europe fell by 1% (excluding license revenue from Nestlé).

Sales in the USA and Canada were down by SEK 7.1 million (34%), which is due to lower sale to Fleet (see above). Sales to the new distributor of drops in the USA, Gerber, almost doubled compared to sales to the former distributor in the same period of last year, which has reduced the decrease in the USA and Canada. For the past 12-month period, sales were down by 27%.

Sales in Asia were largely unchanged. For the past 12-month period, sales in Asia declined by 4%.

Sales in "Rest of world" improved by SEK 5.3 million (29%), which is explained by higher sales of finished consumer products mainly in South Africa. For the past 12-month period, sales increased by 27%.

#### 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 155.1 million (153.0) (excluding the previous year's licence revenue from Nestlé) which is an increase of SEK 2.1 million (1%) compared to the same period of last year. Including licence revenue from Nestlé, gross profit for January-September 2012 was SEK 509.0 million.

The total gross margin (excluding license revenue) fell somewhat from 71% to 69%.

The gross margin for finished consumer products decreased from 72% to 71%. This is due to a lower margin in the third quarter 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 65% to 58%. 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 perpetual license for use of *Lactobacillus reuteri* Protectis in infant formula. However, gross margin increased during the third quarter mainly as a result of revenue under the new agreement with Nestlé.

#### **Operating expenses**

Selling expenses were up by SEK 0.7 million (1%) to SEK 56.6 million (55.9), which is equal to 25% (26) of net sales. Personnel expenses increased, while costs for marketing activities decreased. For the past 12-month period, selling expenses rose by 5%.

Administrative expenses amounted to SEK 10.6 million (9.7), which is equal to 5% (4) of net sales. The increase of SEK 0.9 million (9%) is attributable to higher personnel expenses. For the past 12-month period, administrative expenses grew by 3%.

R&D expenses are reported at SEK 30.9 million (25.2), which is equal to 14% (12) of net sales. The increase of SEK 5.7 million (23%) is mainly due to increased external expenses for research and clinical studies, but also higher personnel expenses. Expenses of SEK 2.1 million (0) for the Necrotising enterocolitis (NEC) project are included in the period. For the past 12-month period, R&D expenses rose by 18%. The amortisation component of R&D expenses was SEK 0.3 million (0.5). 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 57.9 million (58.9) (excluding the previous year's licence revenue from Nestlé), which is SEK 1.0 million (2%) lower than in the same period of last year.

Including licence revenue from Nestlé, operating profit for January-September 2012 was SEK 414.9 million.

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

Profit before tax was SEK 61.9 million (72.7) (excluding the previous year's licence revenue from Nestlé), which is SEK 10.8 million (15%) lower than in the same period of last year.

Including licence revenue from Nestlé, profit before tax for January-September 2012 was SEK 428.7 million.

Net financial items include a foreign exchange gain of SEK 0.1 million (7.3) on forward exchange contracts in EUR, which is SEK 7.2 million lower than for the same period of last year. At 30 September 2013 the company had outstanding forward exchange contracts for EUR 13.8 million at an average exchange rate of SEK 8.79. Forward exchange contracts amounting to EUR 2.7 million will mature for payment in 2013, EUR 8.4 million in 2014 and the remaining EUR 2.7 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 30 September 2013 (8.70), an exchange gain/loss will be recognised in the future.

#### **Profit after tax**

Profit after tax was SEK 47.9 (51.7) million (excluding the previous year's licence revenue from Nestlé), which is SEK 3.8 million (7%) lower than in the same period of last year.

Including licence revenue from Nestlé, profit after tax for the same period of last year was SEK 314.1 million.

The tax rate for the Group was 23% (29). The Group pays tax on profits in the Swedish companies. The Swedish companies have made provisions to untaxed reserves in 2012. For this, deferred tax of SEK 24.6 million has been recognised.

The loss in Japan is not deductible against the Swedish profits. Loss carryforwards in the Japanese subsidiary at 30 September 2013 amounted to SEK 59.7 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 2.63 (2.88) (excluding the previous year's licence revenue from Nestlé). Including license revenue from Nestlé in 2012, earnings per share for January-September 2012 were SEK 18.07.

### **Cash flow**

The Group's cash and cash equivalents at 30 September 2013 totalled SEK 243.2 million (404.1). Cash flow for the period amounted to SEK -131.7 million (233.3). The nine-month period of 2012 included the payment of SEK 356.0 million in licence revenue from Nestlé.

Cash flow since 30 September 2012 includes dividends of SEK 172.7 million, tax payments of SEK 37.7 million, investments in TwoPac of SEK 13.3 million and the acquisition of shares in TwoPac of SEK 30.0 million.

### **Equity**

Consolidated equity amounted to SEK 301.3 million (441.7). The Group's equity/assets ratio was 83% (84).

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.

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

Investments in property, plant and equipment during the period amounted to SEK 9.5 million (23.5), of which SEK 7.5 million (21.7) refers to TwoPac AB.

### **Subsidiary in Japan**

Net sales in the Japanese subsidiary during the period amounted to SEK 7.9 million (10.4). Operating profit in the Japanese subsidiary was SEK -4.9 million (-4.7). The drop in sales to the distributor is due to lower inventory in connection with rationalisations in distribution and discontinued sales by a drug store chain. The company is taking steps to replace this customer.

### **Subsidiary TwoPac AB**

TwoPac AB was 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 27.1 million (20.6). Operating profit was SEK 7.8 million (6.3). Profit after tax was SEK 5.7 million (4.3).

### **Subsidiary CapAble AB**

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

Net sales in CapAble during the period totalled SEK 0.1 million (0.1). Operating profit was SEK -2.1 million (-1.9). The reason for the lack of sales during the first six months is that the machinery that manufactures LifeTop Cap has been rebuilt to improve the quality of the product. A first trial delivery took place at the beginning of the third quarter and the company's assessment is that the goals for improvement of the product have been met. This means that additional deliveries will be made in the fourth quarter.

### **Parent Company**

Net sales in the Parent Company reached SEK 221.0 million (564.7) and profit before tax and appropriations was SEK 54.8 million (426.1).

Since it is uncertain whether the receivable 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 9.2 million (5.3), which has had a negative impact on profit.

Profit after tax was SEK 42.5 million (313.0). Cash flow in the Parent Company totalled SEK -133.5 million (235.6).



## FINANCIAL PERFORMANCE IN THE THIRD QUARTER OF 2013

### Third quarter sales

Sales for the third quarter amounted to SEK 62.2 million (62.8), down by SEK 0.6 million (1%) compared to the same period of last year. No material foreign exchange effects on sales arose during the quarter compared to the same period of last year.

Compared to the previous quarter, sales fell by SEK 23.1 million, which is mainly due to lower activity among distributors and suppliers in connection with the customary summer holiday in Europe.

Sales of finished consumer products amounted to SEK 46.4 million (50.2), a decrease of SEK 3.8 million (8%) compared to the same period of last year. Sales rose in the USA and Canada and "Rest of world", but declined above all in Europe but also in Asia. The increase in the USA is due to sales to the new distributor of drops in the USA, Gerber. In Europe, sales grew in Finland, Ukraine, Sweden, Turkey and France but fell in Italy and a few Eastern European countries, primarily Poland. The decrease in Italy is due to reduction of inventory at the distributor and also to the ongoing difficult economic situation in the country. In Poland, sales are down as an effect of aggressive price competition.

Sales of component products reached SEK 15.7 million (12.5), an increase of SEK 3.2 million (26%) compared to the same period of last year. This is mainly explained by the fact that revenue from the new agreement with Nestlé (see below) was recognised during the quarter.

### Gross profit for the third quarter

Gross profit amounted to SEK 43.2 million (43.3), a decrease of SEK 0.1 million (0%) compared to the same period of last year. Gross margin was unchanged (69%) compared to the year-earlier period. The gross margin for finished consumer products fell from 71% to 68% as a result of the product mix. During the quarter, BioGaia's partner in Japan, Nippon Access, launched yoghurt products with a lower margin than for other finished consumer products. For component products, gross margin rose from 60% to 73%, mainly due to revenue under the new agreement with Nestlé (see below).

### Other operating expenses in the third quarter

In general, other operating expenses are lower in the third quarter than in other quarters of the year due to the customary summer holiday.

Selling expenses for the third quarter decreased from SEK 17.4 million compared to the same period of last year to SEK 17.3 million (1%). This is explained by lower expenses for marketing activities during the period. Compared to the second quarter of 2013, selling expenses were down by SEK 2.7 million.

Administrative expenses fell by SEK 0.1 million (3%) compared to the same period of last year and amounted to SEK 2.8 million. Compared to the previous quarter, administrative expenses decreased by SEK 1.5 million.

R&D expenses for the third quarter amounted to SEK 9.0 million (7.0), which is an increase of SEK 2.0 million (29%) compared to the same period of last year. The increase is due to higher costs for clinical studies. Compared to the second quarter, R&D expenses declined by SEK 2.6 million.

### Operating profit for the third quarter

Operating profit for the third quarter was SEK 13.8 million (13.5), which is an increase of SEK 0.3 million (2%) compared to the same period of last year. Excluding foreign exchange effects, operating profit decreased by 3%.

### Profit before tax for the third quarter

Profit before tax was SEK 16.5 million (20.1), which is a decrease of SEK 3.6 million (18%) compared to the same period of last year. Net financial items include a foreign exchange gain of SEK 1.7 million (4.3) on forward exchange contracts in EUR (for more information see above).

### Profit after tax for the third quarter

Profit after tax was SEK 13.4 million (14.2), which SEK 0.8 million (6%) lower than in the same period of last year.

### Cash flow for the third quarter

Cash flow was SEK -6.2 million (-9.9). This figure includes SEK 30.0 million referring to the acquisition of the remaining 50% of TwoPac.

## KEY EVENTS IN THE THIRD QUARTER OF 2013

### Launches in the third quarter of 2013

Distributor/licensee	Product	Country
Cube Pharmaceutical	Digestive health tablets	Greece
Nippon Access	Yoghurt with <i>L. reuteri</i> Prodentis	Japan
Nestlé	Infant formula with <i>Lactobacillus reuteri</i> Protectis	Denmark, Sweden, Central and Western Africa region, Syria, Yemen and Iraq
Noos/Italchimichi	Digestive health tablets with Vitamin D	Italy
Sunstar	Oral health tablets and oral health drops	Relaunch in Germany

### 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. In June BioGaia signed an agreement to acquire the remaining 50% of the company.

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 join forces 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, has continued to lead the company's operations.

## **FDA approves BioGaia's request for orphan drug designation**

Necrotising enterocolitis (NEC) is a rare and extremely severe disease that affects premature infants. BioGaia is in a very early stage of investigating the possibilities of developing a drug in this field and has submitted a request for orphan drug designation in the USA. The FDA's (Food and Drug Administration) Office of Orphan Product Development approved BioGaia's request at the beginning of August.

Orphan drugs are either drugs or biologics intended for the treatment, diagnosis or prevention of rare diseases or disorders affecting less than 200,000 patients per year in the USA. An orphan drug designation qualifies the company applying for it to receive certain benefits from the US government, such as tax reductions and marketing incentives, in exchange for developing the drug.

The approval does not change the standard regulatory requirements and processes for obtaining marketing approval for a product. Consequently, all aspects of the development must be investigated, including the clinical safety and efficacy documentation required for a market authorisation.

As pharmaceuticals are not part of BioGaia's current business activities, the company is exploring how a possible development process should continue in order to avoid deflecting attention from the core business. For this purpose, all business related to this field is handled by the subsidiary Infant Bacterial Therapeutics AB.

### ***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 53%. The study was published in mid-August in [Journal of Clinical Periodontology](#).

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

### ***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](#).

## **KEY EVENTS EARLIER IN 2013**

### ***Launches in the first half of 2013***

<b>Distributor/licensee</b>	<b>Product</b>	<b>Country</b>
BG Distribution	Digestive health tablets with strawberry flavour	Hungary
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, Israel and Thailand
Nestlé Mexico	Drops	Mexico
Pharmaforte	Oral health tablets and oral health drops	Singapore
Verman	Digestive health tablets with Vitamin D	Finland

### ***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 starting in 2013. 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 starting in 2013. 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.

This is the third agreement with Nestlé following the sale of the license to use *Lactobacillus reuteri* in infant nutrition to Nestlé in February 2012. The new agreement illustrates the excellent collaboration between the two companies, with cooperation in both the scientific and commercial fields.

## **EMPLOYEES**

The number of employees in the Group (including TwoPac AB) at 30 September 2013 was 85 (74).

### ***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 9.1 million in the Group. BioGaia's assessment is that there is no indication of impairment of these assets. In the Parent Company, all receivables and participations in the Japanese subsidiary have been written down to zero.

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 7.3 million during the period from 2010 to 2012. Profit before tax for January-September amounted to SEK -2.1 million (-2.0). On the balance sheet date, assets in CapAble were reported at SEK 5.4 million in the Group. 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 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 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, financial position or disclosures.

**FUTURE OUTLOOK**

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

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

BioGaia's dividend policy is to pay a shareholder dividend equal to 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.

**Statements of comprehensive income - Group**

(Amounts in SEK 000s)

	Jan-Sept 2013	Jan-Sept 2012	July-Sept 2013	July-Sept 2012	Jan-Dec 2012	Oct 2012- Sept 2013	Oct 2011- Sept 2012
Net sales	225,654	216,845	62,169	62,814	289,248	298,057	299,241
License revenue	-	356,004	-	-	356,004	-	356,004
Cost of goods sold	-70,600	-63,871	-18,959	-19,500	-88,179	-94,908	-89,031
<i>Gross profit</i>	155,054	508,978	43,210	43,314	557,073	203,149	566,214
Selling expenses	-56,628	-55,895	-17,257	-17,423	-77,361	-78,094	-74,183
Administrative expenses	-10,615	-9,736	-2,768	-2,901	-13,423	-14,302	-13,901
Research and development expenses	-30,856	-25,227	-8,995	-6,959	-35,788	-41,417	-35,100
Other operating income	925	-	-	-	-	1 683	-
Other operating expenses	-	-3,189	-394	-2,575	-2,431	-	-4,341
<i>Operating profit</i>	57,880	414,931	13,796	13,456	428,070	71,019	438,689
Interest income	3,916	6,519	1,026	2,429	8,569	5,966	7,640
Foreign exchange gain, forward contracts	129	7,288	1,674	4,267	5,676	-1,483	12,059
Financial expenses	-75	-48	-13	-9	-73	-100	-70
<i>Profit before tax</i>	61,850	428,690	16,483	20,143	442,242	75,402	458,318
Tax	-13,956	-114,626	-3,123	-5,985	-112,371	-11,701	-122,495
<b>PROFIT FOR THE PERIOD</b>	<b>47,894</b>	314,064	<b>13,360</b>	14,158	329,871	<b>63,701</b>	335,823
<b>Items that will be reclassified to profit or loss</b>							
Gains/losses arising on translation of the financial statements of foreign operations	-722	-372	-164	-532	-1,059	-1,941	-340
<b>Comprehensive income for the period</b>	<b>47,172</b>	313,692	<b>13,196</b>	13,626	328,812	<b>61,760</b>	335,483
<b>Profit for the period attributable to:</b>							
Owners of the Parent Company	45,422	312,115	13,428	13,849	326,970		
Non-controlling interests	2,472	1,949	-68	309	2,901		
	47,894	314,064	13,360	14,158	329,871		
<b>Comprehensive income for the period attributable to:</b>							
Owners of the Parent Company	44,700	311,743	13,264	13,317	325,911		
Non-controlling interests	2,472	1,949	-68	309	2,901		
	47,172	313,692	13,196	13,626	328,812		
<b>Earnings per share</b>							
Basic earnings per share (average number of shares), SEK	2.63	18.07	0.78	0.80	18.93		
Diluted earnings per share, SEK	2.63	18.07	0.78	0.80	18.93		
Number of shares, thousands	17,271	17,271	17,271	17,271	17,271		
Average number of shares, thousands	17,271	17,271	17,271	17,271	17,271		
Number of outstanding warrants, thousands	87	87	87	87	87		
Number of outstanding warrants with a dilutive effect, thousands	-	-	-	-	-		
Number of shares after dilution, thousands	17,271	17,271	17,271	17,271	17,271		



**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

	30 Sept	31 Dec	30 Sept
(Amounts in SEK 000s)	2013	2012	2012
<b>ASSETS</b>			
Intangible assets	54,880	49,193	43,874
Other non-current receivables	17	17	17
<i>Total non-current assets</i>	<b>54,897</b>	<b>49,210</b>	<b>43,891</b>
Current assets excl. cash and cash equivalents	66,848	92,838	78,038
Cash and cash equivalents	243,193	374,974	404,065
<i>Total current assets</i>	<b>310,041</b>	<b>467,812</b>	<b>482,103</b>
<b>TOTAL ASSETS</b>	<b>364,938</b>	<b>517,022</b>	<b>525,994</b>
<b>EQUITY AND LIABILITIES</b>			
Equity attributable to owners of the Parent Company	301,739	453,303	439,156
Non-controlling interests	-483	3,491	2,539
Total equity	301,256	456,794	441,695
Provision for deferred tax	24,649	24,710	185
Interest-free current liabilities	39,033	35,518	84,114
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>364,938</b>	<b>517,022</b>	<b>525,994</b>
<b>Pledged assets</b>	<b>2,000</b>	<b>2,000</b>	<b>2,000</b>

**CONSOLIDATED CASH FLOW STATEMENTS**

	Jan-Sept	Jan-Sept	July-Sept	July-Sept	Jan-Dec
(Amounts in SEK 000s)	2013	2012	2013	2012	2012
<i>Operating activities</i>					
Operating profit	57,880	414,931	13,796	13,456	428,070
Depreciation/amortisation	3,788	4,024	1,277	1,383	4,545
Other non-cash items	-17	623	117	547	346
	<b>61,651</b>	<b>419,578</b>	<b>15,190</b>	<b>15,386</b>	<b>432,961</b>
Gains/losses on realised forward exchange contracts	439	1,965	-8	1,298	2,818
Paid tax	-5,488	-73,515	-4,343	-32,221	-105,736
Interest received and paid	3,843	6,471	1,015	2,420	8,496
Cash flow from operating activities before changes in working capital	60,445	354,499	11,854	-13,117	338,539
Changes in working capital	20,041	4,578	16,300	8,805	-2,982
<i>Cash flow from operating activities</i>	<b>80,486</b>	<b>359,077</b>	<b>28,154</b>	<b>-4,312</b>	<b>335,557</b>
<i>Cash flow from investing activities</i>	<b>-39,514</b>	<b>-23,475</b>	<b>-34,348</b>	<b>-5,670</b>	<b>-29,391</b>
<i>Cash flow from financing activities</i>	<b>-172,710</b>	<b>-102,352</b>	<b>0</b>	<b>97</b>	<b>-102,373</b>
Cash flow for the period	-131,738	233,250	-6,194	-9,885	203,793
Cash and cash equivalents at beginning of period	374,974	171,534	249,560	414,499	171,534
Exchange difference in cash and cash equivalents	-43	-719	-173	-549	-353
Cash and cash equivalents at end of period	<b>243,193</b>	<b>404,065</b>	<b>243,193</b>	<b>404,065</b>	<b>374,974</b>

**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

(Amounts in SEK 000s)	Jan-Sept 2013	Jan-Sept 2012	Jan-Dec 2012
At beginning of period	456,794	230,355	230,355
Dividends	-172,710	-103,626	-103,626
Subscription warrants	-	1,274	1,253
Acquisition of TwoPac	-30,000	-	-
Comprehensive income for the period	47,172	313,692	328,812
<b>At end of period</b>	<b>301,256</b>	441,695	456,794

**REPORTING BY SEGMENT – GROUP**

(Amounts in SEK 000s)

<b>Revenue by segment</b>	Jan-Sept 2013	Jan-Sept 2012	July-Sept 2013	July-Sept 2012	Jan-Dec 2012	Oct 2012- Sept 2013	Oct 2011- Sept 2012
Finished consumer products	181,056	172,002	46,446	50,181	237,583	246,637	229,477
Component products	43,559	43,803	15,652	12,461	50,577	50,333	68,348
License revenue (component products) 1)	-	356,004	-	-	356,004	-	356,004
Other products	1,039	1,040	71	172	1,088	1,087	1,416
	<b>225,654</b>	572,849	<b>62,169</b>	62,814	645,252	<b>298,057</b>	655,245

<b>Gross profit by segment</b>	Jan-Sept 2013	Jan-Sept 2012	July-Sept 2013	July-Sept 2012	Jan-Dec 2012	Oct 2012- Sept 2013	Oct 2011- Sept 2012
Finished consumer products	129,126	123,476	31,742	35,621	170,275	175,925	166,401
Component products	25,316	28,643	11,398	7,540	29,935	26,608	42,608
License revenue (component products) 1)	-	356,004	-	-	356,004	-	356,004
Other products	612	855	70	153	859	617	1,201
	<b>155,054</b>	508,978	<b>43,210</b>	43,314	557,073	<b>203,150</b>	566,214

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

**Revenue by geographical market**

	Jan-Sept 2013	Jan-Sept 2012	July-Sept 2013	July-Sept 2012	Jan-Dec 2012	Oct 2012- Sept 2013	Oct 2011- Sept 2012
<b>Net sales</b>							
Europe	162,260	151,568	41,851	44,411	203,328	214,020	212,296
License revenue (Europe) 2)	-	356,004	-	-	356,004	-	356,004
USA and Canada	13,572	20,675	5,089	3,967	28,422	21,319	29,203
Asia	26,107	26,167	6,695	7,787	32,420	32,360	33,758
Rest of world	23,715	18,435	8,534	6,649	25,078	30,358	23,984
	<b>225,654</b>	572,849	<b>62,169</b>	62,814	645,252	<b>298,057</b>	655,245

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-Sept 2013	Jan-Sept 2012	Jan-Dec 2012
Net sales	220,966	208,741	278,515
License revenue	-	356,004	356,004
Cost of goods sold	-79,188	-69,754	-97,475
<i>Gross profit</i>	141,778	494,991	537,044
Selling expenses	-43,328	-41,627	-57,673
Administrative expenses	-9,970	-9,055	-12,248
Research and development expenses	-31,000	-25,200	-35,868
Other operating income	925	-	-
Other operating expenses	-	-3,189	-2,430
<i>Operating profit</i>	58,405	415,920	428,825
Impairment loss on receivable from subsidiary	-9,175	-5,348	-8,574
Impairment loss on shares in subsidiary	-	-	-2,583
Net financial items	5,612	15,534	17,220
Profit before appropriations and tax	54,842	426,106	434,888
Provisions to tax allocation reserve	-	-	-109,341
Profit before tax	54,842	426,106	325,547
Tax expense	-12,319	-113,083	-86,270
<b>PROFIT FOR THE PERIOD</b>	<b>42,523</b>	<b>313,023</b>	<b>239,277</b>

**PARENT COMPANY BALANCE SHEETS**

	30 Sept 2013	31 Dec 2012	30 Sept 2012
<b>ASSETS</b>			
Intangible assets	-	-	-
Property, plant and equipment	2,486	2,275	2,505
Shares in group companies	51,160	21,160	21,160
Non-current receivables from subsidiaries	24,513	24,513	24,513
<i>Total non-current assets</i>	78,159	47,948	48,178
Current assets excl. cash and cash equivalents	57,840	85,009	71,170
Cash and cash equivalents	237,954	371,448	396,792
<i>Total current assets</i>	295,794	456,457	467,962
<b>TOTAL ASSETS</b>	<b>373,953</b>	<b>504,405</b>	<b>516,140</b>
<b>EQUITY AND LIABILITIES</b>			
Equity	219,473	349,660	423,427
Tax allocation reserve	109,341	109,341	-
Interest-free current liabilities	45,139	45,404	92,713
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>373,953</b>	<b>504,405</b>	<b>516,140</b>
<b>Pledged assets</b>	<b>2,000</b>	<b>2,000</b>	<b>2,000</b>

**PARENT COMPANY CASH FLOW STATEMENTS**

	Jan-Sept 2013	Jan-Sept 2012	Jan-Dec 2012
<u>Operating activities</u>			
Operating profit	58,405	415,920	428,825
Depreciation/amortisation	884	1,177	1,510
Other non-cash items	-17	623	308
Gain/losses on realised foreign exchange contracts	439	1,965	2,818
Paid tax	-5,473	-73,482	-105,690
Interest received and paid	4,293	6,939	9,120
Cash flow from operating activities before changes in working capital	58,531	353,142	336,891
Changes in working capital	16,518	-4,218	-13,512
<i>Cash flow from operating activities</i>	<b>75,049</b>	348,924	323,379
<i>Cash flow from investing activities</i>	<b>-35,850</b>	-10,999	-11,123
<i>Cash flow from financing activities</i>	<b>-172,710</b>	-102,352	-102,373
Cash flow for the period	-133,511	235,573	209,883
Cash and cash equivalents at beginning of period	371,448	161,865	161,865
Exchange difference in cash and cash equivalents	17	-646	-300
Cash and cash equivalents at end of period	<b>237,954</b>	396,792	371,448

**PARENT COMPANY STATEMENTS OF CHANGES IN EQUITY**

(Amounts in SEK 000s)

	Jan-Sept 2013	Jan-Sept 2012	Jan-Dec 2012
At beginning of year	349,660	212,756	212,756
Dividends	-172,710	-103,626	-103,626
Subscription warrant programme	-	1,274	1,253
Profit for the period	42,523	313,023	239,277
<b>At end of period</b>	<b>219,473</b>	423,427	349,660

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

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

	Jan-Sept 2013	Jan-Sept 2012	Jan-Dec 2012
Interest income	1,168	1,278	2,386
Loan provided	-4,575	-1,670	-1,670
Sale of goods	3,252	2,400	4,518

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

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

	Jan-Sept 2013	Jan-Sept 2012	Jan-Dec 2012
Interest income	451	479	643
Loan provided	-	-8,000	-8,000
Purchase of goods	-27,088	-20,579	-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:**

	30 Sept 2013	30 Sept 2012	31 Dec 2012
Non-current receivables from TwoPac AB (incl. subsidiary)	23,491	23,491	23,491
<b><i>Current transactions with related parties</i></b>			
Current receivables from TwoPac AB	219	169	164
Current liabilities to TwoPac AB	-4,915	-3,603	-1,972
	-4,696	-3,434	-1,808



<b>CONSOLIDATED KEY RATIOS <sup>1)</sup></b>	<b>Jan-Sept</b>	Jan-Sept	Jan-Sept
	<b>2013</b>	2012	2012 excl. non-recurring revenue <sup>2)</sup>
Net sales, SEK 000s	<b>225,654</b>	572,849	216,845
Operating profit, SEK 000s	<b>57,880</b>	414,931	58,927
Profit after tax, SEK 000s	<b>47,894</b>	314,064	51,689
Return on			
- average equity	<b>12%</b>	93%	24%
- average capital employed	<b>16%</b>	128%	35%
Capital employed, SEK 000s	<b>325,905</b>	441,880	179,505
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	-	-	-
Number of shares after dilution, thousands	<b>17 271</b>	17 271	17 271
Basic earnings per share, SEK	<b>2.63</b>	18.07	2.88
Diluted earnings per share, SEK	<b>2.63</b>	18.07	2.88
Basic equity per share, SEK	<b>17.47</b>	25.43	10.24
Diluted equity per share, SEK	<b>17.47</b>	25.43	10.24
Equity/assets ratio	<b>83%</b>	84%	85%
Operating margin	<b>26%</b>	72%	27%
Profit margin	<b>27%</b>	75%	34%
Average number of employees	<b>81</b>	69	69

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 the period from January to September 2013")

## **CALENDAR**

12 February 2014	Year-end report 2013
6 May 2014	Interim report 1 January – 31 mars, 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, 23 October 2013**

**David Dangoor**  
Board Chairman

**Jan Annwall**  
Board member

**Stefan Elving**  
Board member

**Thomas Flinck**  
Board member

**Inger Holmström**  
Board member

**Jörgen Thorball**  
Board member

**Paula Zeilon**  
Board member

**Peter Rothschild**  
President

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

## 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 31 are based in Stockholm, 23 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 some 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

BioGaia's strains of *Lactobacillus reuteri* are some of the world's most well researched probiotics, especially in young children. To date, 108 clinical studies using BioGaia's human strains of *Lactobacillus reuteri* have been performed on around 8,600 individuals of all ages. The results have been published in 72 articles in scientific journals.

Studies have been performed on:

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

2013-10-10      Meta-analysis: *Lactobacillus reuteri* Protectis only probiotic effective in treating colic  
2013-08-22      BioGaia AB Interim report 1 January – 30 June 2013  
2013-08-16      New study shows: *Lactobacillus reuteri* Prodentis improves periodontal treatment

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