

BioGaia AB

Interim Management Report 1 January – 31 March 2015 (11 pages)

(Figures in brackets refer to the corresponding period in the previous year)



CEO's comments:

"First-quarter sales rose by 49%, or by 37% after adjustment for foreign exchange effects. While the figures for the quarter are, obviously, satisfactory, a rolling 12-month review gives a far better picture. Also this, shows impressive rates of growth: 23% growth in sales and 19% growth in operating profit, both of these figures after adjustment for foreign exchange effects. The background to these strong results is continued success in all our key markets, with the sole exception of war-torn Ukraine. The strongest engine for growth is our Paediatrics business unit, but sales of our Adult Health products are also starting to pick up again after a few less satisfactory quarters," says Peter Rothschild, CEO of BioGaia AB.

Reporting period 1 January – 31 March 2015

Net sales totalled SEK 138.3 (93.2)¹⁾ million, an increase of SEK 45.6 million; this corresponds to a 49% rise, or 37% after adjustment for foreign exchange effects. Last year's sales of SEK 188.6 million included a non-recurring licence revenue payment of SEK 95.4 million from Nestlé.

Sales for the Paediatrics business unit totalled SEK 112.9 (76.7)¹⁾ million, an increase of SEK 36.2 million; this corresponds to a 47% rise, or 34% after adjustment for foreign exchange effects.

Sales for the Adult Health business unit totalled SEK 19.8 (15.0) million, an increase of SEK 4.8 million; this corresponds to a 32% rise, or 20% after adjustment for foreign exchange effects.

Operating profit was SEK 52.6 (28.4)¹⁾ million, an increase of SEK 24.2 million; this corresponds to an 85% rise, or 54% after adjustment for foreign exchange effects. If costs in the subsidiary IBT are excluded, operating profit for the period was SEK 56.3 million.

Profit after tax was SEK 43.2 (22.6)¹⁾ million, an increase of SEK 20.6 million or 91%.

Earnings per share were SEK 2.50 (1.32)¹⁾.

Cash flow for the period was SEK 37.8 (108.4) million. Cash and cash equivalents on 31 March 2015 totalled SEK 250.0 (342.7) million. A proposal will be made at the 2015 AGM to pay a shareholders' dividend totalling SEK 86.4 million.

1) Excluding licence revenue from Nestlé. If licence revenue from Nestlé is included, sales for the first quarter of 2014 totalled SEK 188.6 million, sales for the Paediatrics business unit totalled SEK 172.1 million, operating profit was SEK 123.8 million, profit after tax was SEK 97.0 million and earnings per share were SEK 5.63.

Telephone conference: You are invited to take part in a teleconference about this interim report that will be held at 09:30 a.m. today by CEO Peter Rothschild. To participate in the teleconference, please see www.biogaia.com/agenda.

BioGaia has published this information in accordance with the Swedish Securities Market Act. The information was released for publication at 08:00 a.m. on 7 May 2015.

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

BioGaia AB (publ.)

Interim Management Report 1 January – 31 March 2015

Figures in brackets refer to the corresponding period in the previous year.

The Board of Directors and CEO of BioGaia AB hereby present their interim management report for the period 1 January – 31 March 2015. A description of the company's operations is provided on page 11.

CEO'S COMMENTS

Sales in the first quarter rose by 49%, or by 37% when adjusted for foreign exchange effects. This raised the rolling 12-month increase in sales figures to 31%, (23% excluding foreign exchange effects). The first quarter also shows a steep 85% rise in operating profit (54% excluding foreign exchange effects) – despite a 42% increase in operating costs. These include non-recurring personnel costs and also costs incurred by the subsidiary, IBT. Without these expenses, operating costs would have risen by 32% for the quarter and 23% over a rolling 12-month period. Compared to the fourth quarter of 2014 the operating expenses decreased by 1%.

While the figures for the quarter are, obviously, satisfactory, a rolling 12-month review gives a far better picture. Also this, shows impressive rates of growth: 23% growth in sales and 19% growth in operating profit, both of these figures after adjustment for foreign exchange effects. The background to these strong results is continued success in all our key markets, with the sole exception of war-torn Ukraine. The strongest engine for growth is our Paediatrics business unit, but sales of our Adult Health products are also starting to pick up after a few less satisfactory quarters.

In the final quarter of 2014 Nestlé launched a powder formula product with *Lactobacillus reuteri* Protectis for children older than 12 months. This is a royalty agreement, with substantial minimum payments throughout the validity of the contract. Powder formulas for children over 12 months old are known as "Growing Up Milks" (GUM) and constitute a larger market than that for infant formula. It is therefore likely that these minimum payments will be surpassed once the product has been launched more and more emerging markets that are covered by the contract. Obviously this will have a positive impact on our sales growth and profits.

I am delighted with the rapid progress that our subsidiary IBT is making with regard to the development of a drug to combat NEC, an often fatal disease that affects premature infants. Originally we had planned to start clinical trials in 2016, but IBT is now already in a position to initiate trials during the current year. In order not to delay development, we will be investing a further SEK 4 million in the company this year. The product now has been given orphan drug status both in Europe and in the USA, and we are looking for licensees who are willing to assist with the ongoing development of the drug.

The Oral Health area is developing positively and we now have fantastic documentation not only with regard to our product's effect on gingivitis and periodontitis but now also on peri-implantitis, that is the loss of bone loss around dental implants. Periodontitis is a common problem in diabetics and therefore it will be interesting to follow the Mexican company that we signed an agreement with during the quarter. The company will focus its sales efforts on this target group by visiting diabetes doctors. With the experience we have from selling the oral health products in some 20 countries, primarily Japan, Spain, Germany and Canada, means that we have started to find the key to a successful sales model that can be implemented to other markets. I anticipate that also this business area will develop strongly in the future.

FINANCIAL PERFORMANCE – FIRST QUARTER 2015

First-quarter sales 2015

Group sales totalled SEK 138.3 (93.2)¹⁾ million, which represents an increase of SEK 45.6 million or 49% compared with the corresponding period last year.

The major part of the company's sales is in foreign currencies, primarily EUR but also USD and JPY. If exchange rates had remained stable at the level they were during the corresponding period in 2014, sales would have been SEK 11.6 million lower. After making adjustments for foreign exchange effects, sales (excluding licence revenue) rose by 37% compared with the corresponding period last year¹⁾.

Changes in exchange rates affect both income and expenses. Operating profit would have been SEK 9 million lower if exchange rates had remained stable. This translates into an increase (excluding licence revenue from Nestlé) of 54% after adjustment for foreign exchange effects compared with the corresponding period last year¹⁾.

The 12-month rolling sales have risen by 31%, or by 23% after adjustment for foreign exchange effects¹⁾.

Licence revenue from Nestlé 2014

During the first quarter of 2014 BioGaia received licence revenue of SEK 95.4 million from Nestlé. First-quarter sales for 2014 including this licence revenue totalled SEK 188.6 million.

In February 2012 BioGaia signed several new agreements with Nestlé. One of the consequences of this was that Nestlé acquired a licence (rights) to use *Lactobacillus reuteri* Protectis in infant formulas for the remaining duration of the patent. The purchase price was EUR 50.8 million; an initial consideration of EUR 40.0 million – corresponding to SEK 356.0 million – was received and recognised in the first quarter of 2012. The balance of the agreed purchase price – EUR 10.8 million or its equivalent in Swedish currency, SEK 95.4 million – was received and recognised in the first quarter of 2014. Licence revenues for 2012 and 2014 are non-recurring income, but as these amounts nonetheless have a significant impact on the key figures, they are stated separately in the Statement of Comprehensive Income, and separate sets of key figures have been calculated that include and exclude licence revenue from Nestlé. Licence revenue relates to the Paediatrics business unit and the European market. Licence revenue is excluded in the comparisons in the text. For comparisons including the licence revenue, please see Note 1.

First-quarter sales by segment 2015

PAEDIATRICS BUSINESS UNIT

Sales for the Paediatrics business unit, the core of BioGaia's business activities, totalled SEK 112.9 (76.7)¹⁾ million, which represents an increase of SEK 36.2 million or 47%. Adjusted for foreign exchange effects, the increase was 34%.

Most of the increase is attributable to sales of drops, which increased in all markets, chiefly in Europe and the Rest of the World, but also in North America and Asia. In Europe sales of drops rose most steeply in Italy, but also in Poland, Spain and France, while they fell in Ukraine as a result of the current instability in the country. Rest of the World sales rose most strongly in Brazil, where the product was launched in October 2014, but also in Chile and Mexico. In North America sales of drops rose in the USA but fell in Canada. The increase in Asia was attributable to Indonesia and Singapore.

Sales of digestive health tablets in the Paediatrics business unit have also increased on all markets but above all in Rest of the World, chiefly in Brazil, where the tablets were launched in September 2014. In Europe sales of digestive health tablets rose in Bulgaria and Spain but fell in Ukraine. North American sales rose in the USA but remained unchanged in Canada. The rise in Asia was attributable to Singapore.

The sale of cultures for infant formulas dipped in comparison with sales for the corresponding period last year.

Royalty income from Nestlé for the rights to use *Lactobacillus reuteri* Protectis in powder formulas for children older than 12 months rose in comparison with the corresponding period last year.

Over the most recent 12-month period sales in the Paediatrics business unit have risen by 38%, or by 30% when adjusted for foreign exchange effects.¹⁾

The Paediatrics Business unit has during the quarter focused on developing synopsis and study protocols and identified countries for four new clinical studies. The studies will strengthen the clinical documentation within BioGaia's core areas. The business unit also works with the commercialisation of packaging solutions. At the beginning of the year BioGaia launched its new digital training manual, a kind of digital encyclopaedia with all the background of probiotic strains, clinical studies and also BioGaia as a company. The training manual is meant to be an education tool but also a knowledge and inspiration bank for BioGaia's distributors. The tool has been well received and the hope is to increase the distributors' level of knowledge and also clarify BioGaia's offer for existing indications.

ADULT HEALTH BUSINESS UNIT

Sales for the Adult Health business unit totalled SEK 19.8 (15.0) million, which is an increase of SEK 4.8 million or 32%. Adjusted for foreign exchange effects the increase compared with the previous year was 20%.

This increase is chiefly due to a rise in sales of digestive health tablets in Europe, primarily in Italy, Finland and Belgium. In Asia and the Rest of the World sales of digestive health tablets in the Adult Health segment remained more or less stable, while no Adult Health digestive health tablets are currently being sold in the North American market.

Sales of oral health tablets also rose in comparison with the corresponding period in 2014, most particularly in Europe, where sales showed the strongest improvement in Italy and Germany, and in Asia, where sales rose in Japan. The oral health tablets are not yet offered for sale in the Rest of the World.

Sales of yoghurt products decreased in comparison with the corresponding period last year. The company stopped selling yoghurt products in Japan in September 2014 as margins had not met expectations.

Over the most recent 12-month period Adult Health sales have risen by 1%. However, when this figure is adjusted to take account of foreign exchange effects, sales have fallen by 5%.

The Adult Health Business Unit is working in various ways to support the expansion of the distribution network for its existing product concepts under the Protectis and Gastrus brands. At the same time, work is ongoing to strengthen these concepts by extending clinical support, product improvements or more direct support for example with marketing material and events. For the mid to long term growth, 2015 will see the start of a large number of clinical studies on new indication areas in particular within the key areas of Gastroenterology and Oral health, both with existing and new products. The Business Unit is working with a limited range of strains and a number of delivery systems to allow future differentiation of indication areas.

"NEW BUSINESS" BUSINESS UNIT

Sales for the "New Business" business unit totalled SEK 6.2 (1.2) million, which is an increase of SEK 5.0 million.

Royalty revenue of SEK 5.2 (0.0) million related to the collaboration agreement signed with Nestlé in 2014, was included in the "New Business" business unit. The royalty revenue, which amounts to, in total, SEK 92.0 million during 2014-2017, has earlier been reported as revenue within the Paediatrics business unit (SEK 22.0 million during 2014) but will in the future be allocated to both business units. In accordance with the terms of the agreement BioGaia has undertaken to conduct clinical studies on children and to develop new products within new areas. BioGaia will recognize the royalty revenue in pace with the degree of completion of the projects.

FIRST-QUARTER SALES BY GEOGRAPHICAL MARKET

Sales in Europe increased by SEK 21.2 million (30%) to SEK 92.0 million, For the past 12-month period sales in Europe rose by 22%¹⁾.

Sales in the USA and Canada rose by SEK 3.3 million (118%) to SEK 6.1 million. For the past 12-month period sales in USA and Canada grew by 46%.

Sales in Asia rise by SEK 3.1 million (30%) to SEK 13.6 million. For the past 12-month period sales in Asia have fallen by 1%.

Sales in the Rest of the World rose by SEK 18 million (198%) to SEK 27.1 million, For the past 12-month period sales rose by 110%.

THE BIOGAIA BRAND

During the first quarter of the year 63% (64%) of finished consumer products (drops, digestive health tablets, oral health tablets, oral rehydration solutions, etc.) were sold under the BioGaia brand, including co-branding.

Gross profit

Gross profit for the reporting period was SEK 97.8 (61.5)¹⁾ million, which represents an increase of SEK 36.3 million or 59% on figures for the corresponding period last year. The total gross margin rose from 66% to 70%¹⁾.

The gross margin for the Paediatrics business unit rose from 67%¹⁾ to 69%. This is due to increased sales of drops, where the margin is somewhat higher than for other finished consumer products, but also to an increase in royalties for the use of bacterial cultures in powder formula for children over 12 months of age and to the collaboration agreement with Nestlé that was signed early in 2014 (with 100% margin). This is partly offset by sales of bacterial cultures for infant formulas where the gross margin is very low.

The gross margin for the Adult Health business unit rose from 59% to 71%. This increase is due mostly to the fact that the sales of yoghurt, where the margins were very low, have been terminated.

Operating expenses during the first quarter of 2015

Total operating expenses rose to SEK 48.6 million, a 42% increase compared with the corresponding period last year. These include non-recurring personnel costs and also costs incurred by the subsidiary, IBT. Without these expenses, operating costs would have risen by 32% for the quarter and 23% over a rolling 12-month period. Comparing to the fourth quarter of 2014 the operating expenses decreased by 1%.

Over the most recent 12-month period operating expenses rose by 30% (excluding IBT 25%).

During 2015 the operating expenses, excluding IBT, are expected to grow by 15-20% primarily due to increased research and development expenses.

Selling expenses rose by SEK 5.8 million, a 30% increase, to a total of SEK 24.8 (19.0) million, which corresponds to 18% (20%)¹⁾ of sales. The main increase in selling expenses compared with the corresponding period last year was in personnel costs, but marketing costs in Japan also rose, partly in connection with the launch of drops. Over the most recent 12-month period sales costs have risen by 21%.

Administrative expenses totalled SEK 4.9 (3.6) million, which corresponds to 4% (4%) of sales¹⁾. The increase of SEK 1.3 million or 37% is due primarily to personnel costs and a rise in administrative expenses in the subsidiary TwoPac (see below). Over the most recent 12-month period the Group's administrative costs have risen by 32%.

Research and development costs totalled SEK 18.9 (11.5) million, which corresponds to 14% (12%) of sales. The increase of SEK 7.4 million or 64% is attributable in part to a SEK 3.6 million rise in costs for the subsidiary IBT (see below). There was also a steep rise in costs for development projects, primarily as a consequence of the collaboration agreement with Nestlé. Costs for patents and personnel costs also rose. Excluding the costs for IBT, R&D costs rose by 53%. Over the most recent 12-month period R&D costs have risen by 46%, or by 30% if the costs for IBT are excluded.

Investments in capitalised expenditure for research and development totalled SEK 2.3 (0) million and relate to the development of a product for the NEC project in the subsidiary IBT AB.

Other operating income/expenses consist of foreign exchange gains/losses on receivables and liabilities of an operating nature.

Operating profit

Operating profit was SEK 52.6 (28.4)¹⁾ million, an increase of SEK 24.2 million, corresponding to an 85% rise, or 54% after adjustment for foreign exchange effects. Operating margin was 38% (30%)¹⁾. If costs in the subsidiary IBT are excluded, operating profit for the period was SEK 56.3 million and the operating margin was 41%.

Financial items and pre-tax profit

Pre-tax profit was SEK 55.9 (29.3)¹⁾ million, which is SEK 26.6 million or 91% more than that for the corresponding period last year. Net financial items include an exchange gain of SEK 3.2 (0.1) million on forward exchange contracts in EUR. On 31 March 2015 the company had outstanding forward exchange contracts for a total of EUR 13.4 million at an average exchange rate of SEK 9.16. Forward exchange contracts amounting to EUR 6.8 million mature for payment during 2015, a further EUR 6.3 million will mature in 2016 and the remaining EUR 0.4 million in 2017. The actual exchange gains or losses will depend on the exchange rates that are in effect on the dates when the contracts mature. If the EUR rate on the maturity date is lower or higher than the rate of SEK 9.33 on 31 March 2015, this will be recognised as an exchange gain or loss in future financial statements.

Profit after tax

Profit after tax was SEK 43.2 (22.6)¹⁾ million, an increase of SEK 20.6 million or 91%.

The tax rate for the Group was 23% (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 March 2015 amounted to SEK 35.5 million. The deferred tax asset for these has not been recognised in the accounts, as the Japanese subsidiary has not yet been able to show a sustainable profit level.

The company has an ongoing tax matter relating to a write-down of receivables from the Japanese subsidiary. In the event of a negative outcome for the company, this could result in additional tax expenses of SEK 3.1 million. A positive outcome on the other hand could pave the way towards receiving an additional tax income of SEK 2.1 million for previous years' activities. The company has received SEK 1.5 million for a part of the tax matter during the quarter.

Earnings per share

Earnings per share were SEK 2.50 (1.32)¹⁾.

Cash flow

Cash flow for the reporting period was SEK 37.8 (108.4) million. Cash flow for the previous year included licence revenue from Nestlé of SEK 95.4 million.

The Group's cash and cash equivalents at 31 March 2015 amounted to SEK 250.0 (342.7) million. It is proposed that the forthcoming AGM be asked to approve a shareholders' dividend totalling SEK 86.4 million.

Equity

Consolidated equity at 31 March 2015 amounted to SEK 388.5 (414.0) million. The Group's equity/assets ratio was 82% (85%).

In June 2012 a warrant programme approved by the 2012 Annual General Meeting was implemented. A total of 87,000 warrants were subscribed for, including subscriptions from corporate management for 41,000 warrants. The warrants were issued at a market price of SEK 14.27 per warrant following valuation according to the Black & Scholes formula; this provided the parent company with proceeds of SEK 1.3 million. Each warrant entitles the holder to subscribe for one class B share at a price of SEK 241.90 on 1 June 2015. Volatility was estimated at 40%. In the event that all of the subscription warrants are exercised, the company's equity will be increased by SEK 21.0 million. This represents a dilution of approximately 0.5% of share capital and 0.4% of the total number of votes upon the full exercise of warrants. In order to encourage a high level of participation, the 2012 AGM decided to pay a subsidy of SEK 10 per warrant (after 1 June 2015) to employees who have subscribed for subscription warrants but not exercised their right to buy shares. A provision of SEK 1.1 million for this obligation was made in 2014 since at the current share price there is a risk that the subsidy must be paid. This assessment of the situation remains.

Dividend

The Board of Directors of BioGaia AB proposes that the forthcoming AGM be asked to approve an ordinary dividend of SEK 3.46 per share and an extraordinary dividend of SEK 1.54 per share, which makes a total dividend of SEK 5.00 per share. This will amount to a shareholders' dividend of SEK 86.4 million.

Investments in property, plant and equipment

Investments in property, plant and equipment totalled SEK 3.3 (4.4) million, of which SEK 3.1 (4.4) million refers to TwoPac AB.

Investments in capitalised expenditure for research and development amounted to SEK 2.3 (0) million 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 were SEK 4.3 (5.1) million. Operating profit in the Japanese subsidiary was SEK -0.9 (-1.3) million.

Subsidiary TwoPac AB

TwoPac AB is a wholly owned subsidiary of BioGaia that develops and manufactures products solely for BioGaia. These products include drops.

Net sales in TwoPac amounted to SEK 13.9 (11.0) million. Operating profit was SEK 3.5 (2.5) million. Profit after tax rose to SEK 2.6 (1.8) million, thanks chiefly to increased sales. The company's operating expenses are also increasing as personnel costs rise to meet the demands of more stringent quality criteria. This internal quality assurance initiative is also motivated by the ambition to seek approval from the Swedish Medical Products Agency for the production of pharmaceuticals at TwoPac's manufacturing facility.

Subsidiary CapAble AB

CapAble, in which BioGaia AB owns a 90.1% stake and the company's president owns the remaining 9.9%, was set up in November 2008 to manufacture and sell the patented LifeTop Cap. Net sales for CapAble were SEK 0 (0) million during the period. Operating profit was SEK -0.7 (-0.9) million. During 2014 and in the first quarter of 2015 the company has experienced quality problems, which have meant that sales have not gained the anticipated momentum. However, the company is confident that the problems have now been solved and that sales will increase during 2015. CapAble has also commenced marketing of the company's LifeTop Straw for probiotics. CapAble signed two agreements for Life Top Straw during the quarter, one with Ganeeden and one with Alimentary Health.

Subsidiary IBT AB

In November 2013, the Board of BioGaia resolved to invest in a 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 newborns. BioGaia resolved to invest up to SEK 42 million in the project. In March 2015 BioGaia decided to invest a further USD 0.5 million – approximately SEK 4.6 million – in the project. (See below.).

The project is run by BioGaia's subsidiary Infant Bacterial Therapeutics (IBT). The IBT president, Staffan Strömberg, and its research director, Eamonn Connolly, together own a 9.0% stake in IBT; board member Anders Ekblom, a former global head of R&D Science & Technology Integration at Astra- Zeneca AB and president of AstraZeneca AB, owns a 0.9% stake; the remaining 90.1% is owned by BioGaia AB.

Operating profit in IBT during the period was SEK -3.7 (-1.5) million. The company has invested SEK 2.3 (0) million in capitalised expenditure for R&D activities during the period. The company has not yet reported any income.

Parent company

Net sales in the parent company totalled SEK 134.5 (88.9)¹⁾ million. Profit before tax was SEK 58.9 (30.2)¹⁾ million. Cash flow in the parent company was SEK -27.6 (105.8) million.

KEY EVENTS DURING THE FIRST QUARTER 2015

Q1 launches, 2015

Distributor/licensee	Country	Product
Pharma Ace	Malaysia	Relaunch of drops
Noos	Italy	Oral health tablets / oral health drops
Dexcel	Israel	Oral health tablets
Nestlé	Pakistan & Middle East	Formula with <i>Lactobacillus reuteri</i> Protectis for children over 12 months

Agreement on sale of drops in Vietnam

In January 2015 BioGaia signed an exclusive agreement with VietPhap International Co Ltd for the right to sell BioGaia ProTectis drops in Vietnam. The launch is planned to take place during 2015.

Nestlé launches new product with BioGaia probiotics

For some years BioGaia and Nestlé have been engaged in a fruitful collaboration to develop products with probiotics. The agreement signed on 30 May 2013 gives Nestlé exclusive rights to use BioGaia's patented probiotic strain *Lactobacillus reuteri* Protectis in powder formula products for infants over 12 months old.

Since late 2014 Nestlé has started the launch of these products. The products will be sold mainly in emerging markets.

Published study shows the efficacy of *Lactobacillus reuteri* Prodentis for patients with dental implants

Inflammation and other complications linked to dental implants are common. Results from a double-blind randomised controlled trial in 34 patients with implants show that 30 days' supplementation with *Lactobacillus reuteri* Prodentis significantly reduces implant-related inflammation.

The study was published in the Journal of Periodontal Research on 25 February 2015.

Agreement relating to oral health products in Mexico

In March BioGaia signed an exclusive agreement with Silanes for the right to sell BioGaia's oral health lozenges in Mexico. The launch is planned to take place during 2015.

BioGaia's subsidiary Infant Bacterial Therapeutics (IBT) is granted orphan designation in Europe for the development of its medicinal product

The BioGaia subsidiary IBT is working on the early stages of development of a drug to prevent necrotising enterocolitis (NEC), a rare but fatal disease that affect premature newborns. In February 2015, following a similar decision by the FDA in August 2013, IBT was granted orphan designation in Europe for its NEC drug.

BioGaia's subsidiary IBT starts study in 2015

The work done by Infant Bacterial Therapeutics (IBT) to develop a drug that can prevent the fatal disease necrotising enterocolitis (NEC) has progressed more quickly than planned. The company is now bringing forward the date for preparing a study of the product's safety and tolerance, rescheduling the start date from 2016 to later this year.

BioGaia has previously made the decision to invest up to SEK 42 million in IBT. To facilitate an earlier start date for the study, a new decision was made in March 2015 to supply additional funding of USD 520,000.

KEY EVENTS DURING AFTER THE FIRST QUARTER 2015

Publication of Chinese study showing the efficacy of BioGaia's drops

A Chinese study of infants suffering from colic shows that babies who were given *Lactobacillus reuteri* Protectis cried significantly less than those who were given a placebo.

These findings, published in the medical journal *Antonie van Leeuwenhoek* on 16 April 2015, are the fifth study to confirm a positive result from treating colic with *Lactobacillus reuteri* Protectis.

EMPLOYEES

On 31 March 2015 the Group had 98 (88) employees.

Incentive programme for employees

In June 2012 BioGaia implemented the warrant programme that had been approved by the Annual General Meeting earlier in the same year. Further information about this incentive programme can be found under the heading "Equity" above.

SIGNIFICANT BUSINESS RISKS AND UNCERTAINTIES – GROUP AND PARENT COMPANY

BioGaia's wholly owned Japanese subsidiary has operated at a loss since it was set up in 2006. On the balance sheet date, assets in the Japanese subsidiary were recognised at SEK 7.1 million. BioGaia's assessment is that there is no need for any impairment of these assets. In the parent company, current receivables from the Japanese subsidiary have been written off. The loan to the Japanese subsidiary and participations in the company have been written down to zero.

CapAble, in which BioGaia AB has a 90.1% stake, was started in November 2008 to manufacture and sell the patented LifeTop Cap bottle closure. The shares in the subsidiary CapAble are recognised at a total of SEK 6.9 million in the parent company. CapAble has operated at a loss since it was set up in 2008. In 2009 and 2010 BioGaia made conditional shareholder contributions to CapAble totalling SEK 6.0 million. BioGaia AB has made group contributions amounting to SEK 12.7 million between 2010 and 2014. In the first-quarter of 2015 profit before tax and group contributions was SEK -0.7 (-0.9) million. On the balance sheet date assets in CapAble were recognised at SEK 3.3 million. Since BioGaia's assessment of the situation is that CapAble will begin to report a profit in the years to come, there is 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 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 newborns. BioGaia will invest up to approximately SEK 47 million in the project. BioGaia AB has made conditional shareholder contributions of SEK 11.0 million and group contributions of SEK 7.0 million to IBT. On the balance sheet date assets in IBT were recognised at SEK 10.1 million in the Group accounts. BioGaia is confident that, in the future, IBT and the company's R&D projects will show profitability, and for this reason there is no indication of impairment on the balance sheet date.

For further information, you are referred to the Administration Report and to Notes 27 and 28 in the Annual Report for 2014.

ACCOUNTING PRINCIPLES

In all material respects, this interim management report has been prepared in accordance with NASDAQ OMX Stockholm's guidelines on interim reporting. The accounting policies applied to the Group's income statement and balance sheet correspond to the accounting policies used in drawing up the most recent annual report. The financial statements and segment information correspond to the presentations made in the interim reports that are drawn up in accordance with IAS 34 so that comparisons between the quarters can be made of the data that is presented. The interim management report includes a report from the CEO; while this is not a specific requirement of NASDAQ OMX Stockholm's guidelines, the information it contains is considered to be important to meet user needs.

New accounting principles

The accounting policies applied are in accordance with those used in the Annual Report for 2014. A number of standards and interpretations have been published but have not yet entered into force.

These merely provide additional information and are not expected to have any significant effect on the profits or financial position of the Group or the Parent Company.

FUTURE OUTLOOK

BioGaia's goal is to create strong value growth and a good return for 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 increasing number of innovative products – mostly marketed under the company's own brand – together with successful clinical trials and a growing distribution network covering a large share of the key markets, the outlook for BioGaia is bright.

1) Excluding SEK 95.4 million in licence revenue from Nestlé. Net sales for the first quarter of 2014 including licence revenue from Nestlé totalled SEK 188.6 million; sales for the Paediatrics business unit totalled SEK 172.1 million, sales in Europe were SEK 172.1 million, gross profit was SEK 156.9 million, operating profit was SEK 123.8 million, pre-tax profit was SEK 124.7 million, profit after tax was SEK 97.0 million and earnings per share were SEK 5.63. Operating margin was 66%.

Statements of comprehensive income - Group

(Amounts in SEK 000s)

	Jan-March 2015	Jan-March 2014	Jan-Dec 2014	April 2014- March 2015	April 2013- March 2014
Net sales	138,846	93,218	386,405	432,033	330,951
License revenue	-	95,397	95,397	-	95,397
Cost of goods sold	-41,010	-31,713	-131,338	-140,635	-107,243
<i>Gross profit</i>	97,836	156,902	350,464	291,398	319,105
Selling expenses	-24,765	-18,995	-89,759	-95,529	-79,067
Administrative expenses	-4,925	-3,588	-17,666	-19,003	-14,420
Research and development expenses	-18,872	-11,524	-53,867	-61,215	-41,863
Other operating income	3,296	984	7,711	10,023	3,923
<i>Operating profit</i>	52,570	123,779	196,883	125,674	187,678
Interest income	143	843	2,382	1,682	4,074
Foreign exchange gain/loss, forward contracts	3,184	77	-6,592	-3,485	-5,951
Financial expenses	-33	-43	-148	-138	-88
<i>Profit before tax</i>	55,864	124,656	192,525	123,733	185,713
Tax	-12,634	-27,689	-44,536	-29,481	-42,235
PROFIT FOR THE PERIOD	43,230	96,967	147,989	94,252	143,478
<u>Items that will be reclassified to profit or loss</u>					
Gains/losses arising on translation of the financial statements of foreign operations	682	170	642	1 154	-670
Comprehensive income for the period	43,912	97,137	148,631	95,406	142,808
<u>Profit for the period attributable to:</u>					
Owners of the Parent Company	43,230	97,207	147,406	93,429	142,220
Non-controlling interests	0	-240	583	823	1,258
	43,230	96,967	147,989	94,252	143,478
<u>Comprehensive income for the period attributable to:</u>					
Owners of the Parent Company	43,912	97,377	148,048	94,583	141,550
Non-controlling interests	0	-240	583	823	1,258
	43,912	97,137	148,631	95,406	142,808
<u>Earnings per share</u>					
Basic earnings per share (average number of shares), SEK	2.50	5.63	8.53	5.41	8.23
Diluted earnings per share, SEK	2.50	5.63	8.53	5.41	8.23
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

(Amounts in SEK 000s)

ASSETS

	March 31 2015	Dec 31 2014	March 31 2014
Intangible assets	8,405	6,075	-
Property, plant and equipment	74,787	72,752	63,331
Financial assets	4,000	4,000	-
Other non-current receivables	23	20	17
<i>Total non-current assets</i>	87,215	82,847	63,348
Current assets excl. Cash and cash equivalents	138,630	122,095	81,547
Cash and cash equivalents	249,953	210,666	342,693
<i>Total current assets</i>	388,583	332,761	424,240
TOTAL ASSETS	475,798	415,608	48, 588
EQUITY AND LIABILITIES			
Equity attributable to owners of the Parent Company	388,404	344,492	414,719
Non-controlling interests	99	99	-725
Total equity	388,503	344,591	413,994
Provision for deferred tax	192	192	85
Other provisions	3,900	3,900	-
Interest-free current liabilities	83,203	66,925	73,509
TOTAL EQUITY AND LIABILITIES	475,798	415,608	487,588
Pledged assets	12,345	2,000	2,000

CONSOLIDATED CASH FLOW STATEMENTS

(Amounts in SEK 000s)

Operating activities

	Jan-March 2015	Jan-March 2014	Jan-Dec 2014
Operating profit	52,570	123,779	196,883
Depreciation/amortisation	1,267	1,369	5,652
Other non-cash items	-1,252	-29	-853
	52,585	125,119	201,682
Gains/losses on realised forward exchange contracts	437	181	-1,186
Paid tax	-14,464	-31,315	-66,829
Interest received and paid	110	800	2,214
Cash flow from operating activities before changes in working capital	38,668	94,785	135,881
Changes in working capital	4,707	17,993	-11,498
<i>Cash flow from operating activities</i>	43,375	112,778	124,383
<i>Cash flow from investing activities</i>	-5,595	-4,409	-28,481
<i>Cash flow from financing activities</i>	-	-	-120,892
Cash flow for the period	37,780	108,369	-24,990
Cash and cash equivalents at beginning of period	210,666	234,271	234,271
Exchange difference in cash and cash equivalents	1,507	53	1,385
Cash and cash equivalents at end of period	249,953	342,693	210,666

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(Amounts in SEK 000s)

	Jan-March 2015	Jan-March 2014	Jan-dec 2014
At beginning of period	344,591	316,857	316,857
Dividends	-	-	-120,897
Comprehensive income for the period	43,912	97,137	148,631
At end of period	388,503	413,994	344,591

REPORTING BY SEGMENT - GROUP

(Amounts in 000s)

Income by segment - business area

	Jan-March 2015	Jan-March 2014	Jan-dec 2014	April 2014- - March 2015	April 2013- - March 2014
Paediatrics	112,886	76,680	313,716	349,922	254,074
License revenue (Paediatrics)	-	95,397	95,397	-	95,397
Adult Health	19,763	15,037	69,446	74,172	73,756
Other	6,197	1,501	3,243	7,939	3,121
	138,846	188,615	481,802	432,033	426,348

Gross profit by segment - business area

	Jan-March 2014	Jan-March 2014	Jan-dec 2013	April 2014- - March 2015	April 2013- - March 2014
Paediatrics	77,666	51,372	208,445	234,739	175,931
License revenue (Paediatrics)	-	95,397	95,397	-	95,397
Adult Health	14,128	8,938	44,229	49,419	45,653
Other	6,042	1,195	2,393	7,240	2,124
	97,836	156,902	350,464	291,398	319,105

Revenue by geographical market

	Jan-March 2015	Jan-March 2014	Jan-dec 2014	April 2014- - mars 2015	April 2013 - mars 2014
Net sales	92,000	70,802	257,808	279,006	228,848
Europe	-	95,397	95,397	-	95,397
License revenue (Europe) 1)	-	95,397	95,397	-	95,397
USA and Canada	6,120	2,814	30,273	33,579	22,925
Asia	13,623	10,523	38,778	41,878	42,166
Rest of world	27,103	9,079	59,546	77,570	37,012
	138,846	188,615	481,802	432,033	426,348

CONSOLIDATED KEY RATIOS 2)	Jan-March	Jan-March	Jan-March	Jan-Dec	Jan-Dec
	2015	2014	2014 ²⁾	2014	2014 ²⁾
Net sales, SEK 000s	138,846	188,615	93,218	481,802	386,405
Operating profit, SEK 000s	52,570	123,779	28,382	196,883	101,486
Profit after tax, SEK 000s	43,230	96,967	22,557	147,989	73,579
Return on					
- average equity	12%	27%	7%	45%	25%
- average capital employed	14%	34%	9%	60%	35%
Capital employed, SEK 000s	392,595	414,079	339,669	348,683	270,373
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
Average 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
Basic earnings per share, SEK	2.50	5.63	1.32	8.53	4.23
Diluted earnings per share, SEK	2.50	5.63	1.32	8.53	4.23
Basic equity per share, SEK	22.49	24.01	19.70	19.95	15.64
Diluted equity per share, SEK	22.49	24.01	19.70	19.95	15.64
Equity/assets ratio	82%	85%	87%	83%	84%
Operating margin	38%	66%	30%	41%	26%
Profit margin	40%	66%	31%	40%	25%
Average number of employees	97	87	87	90	90

- 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.

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. No 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 2.9 million to BioGaia AB during the period. Of this total, SEK 1.8 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 0.3 million to BioGaia AB during the period.

FINANCIAL CALENDAR

7 May 2015	Teleconference at 9:30 a.m.
7 May 2015	Annual General Meeting at 4:00 p.m. at Lundqvist & Lindqvist Klara Strands konferens, Klarabergsviadukten 90 in Stockholm.
18 August 2015	Interim report 1 January – 30 June 2015
23 October 2015	Interim report 1 January – 30 September 2015

Stockholm 7 May, 2015

Peter Rothschild
CEO, BioGaia AB

This interim management 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 98 employees, of whom 36 are based in Stockholm, 29 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 90 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:

2015-04-27	Positive results in first Chinese study with BioGaia's drops in infants with colic
2015-04-08	Notice to attend the Annual General Meeting of BioGaia AB
2015-03-26	BioGaia subsidiary IBT starts trial already this year

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