

BioGaia®

Clinically Proven Probiotics



BioGaia AB
October, 2016

BioGaia AB



The founders Peter Rothschild and Jan Annwall

- Founded in 1990
- 103 employees
- Offices in Stockholm, Lund, Eslöv, Raleigh, Shanghai, and Hiroshima
- Contract manufacturing
- Products in 90 markets through distributors
- Holds 440 patents in 32 families
- Listed on the OMX Nordic Exchange in Stockholm 1998

BioGaia – a healthcare company working with probiotics

Mission: BioGaia performs research and development to provide clinically effective, healthful and user friendly probiotic products.

Vision: BioGaia aims to be the groundbreaking leader in probiotics through:

- Innovative research
- Unique formulation and packaging
- Excellence in IP
- Global outreach
- Social responsibility
- Being an attractive workplace
- Strong brand recognition



BioGaia's global network

Partners

Pharma and Health Food companies

BioGaia

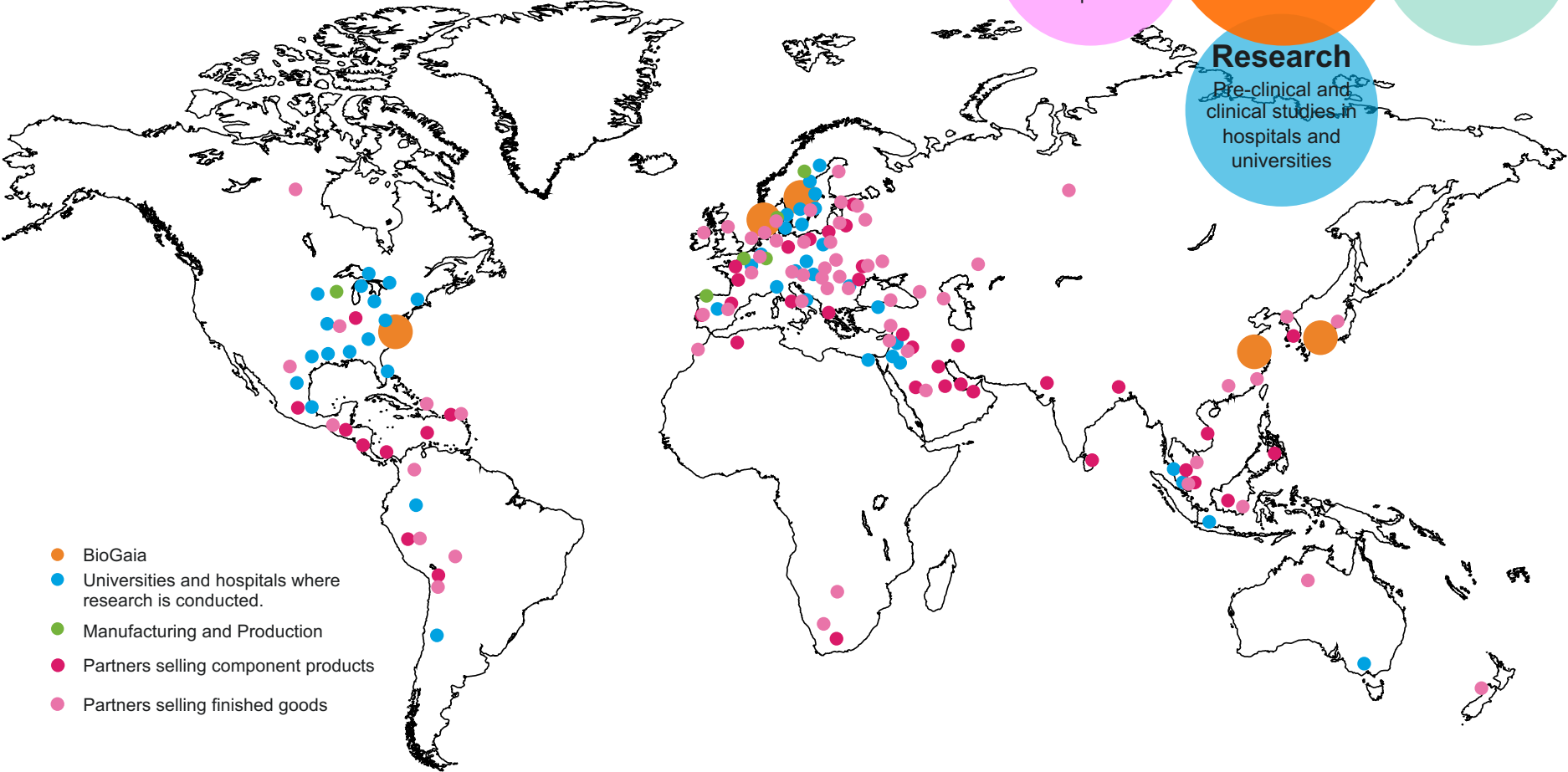
Product development, product strategies, research, Quality, market support

Suppliers

Contract Manufacturing

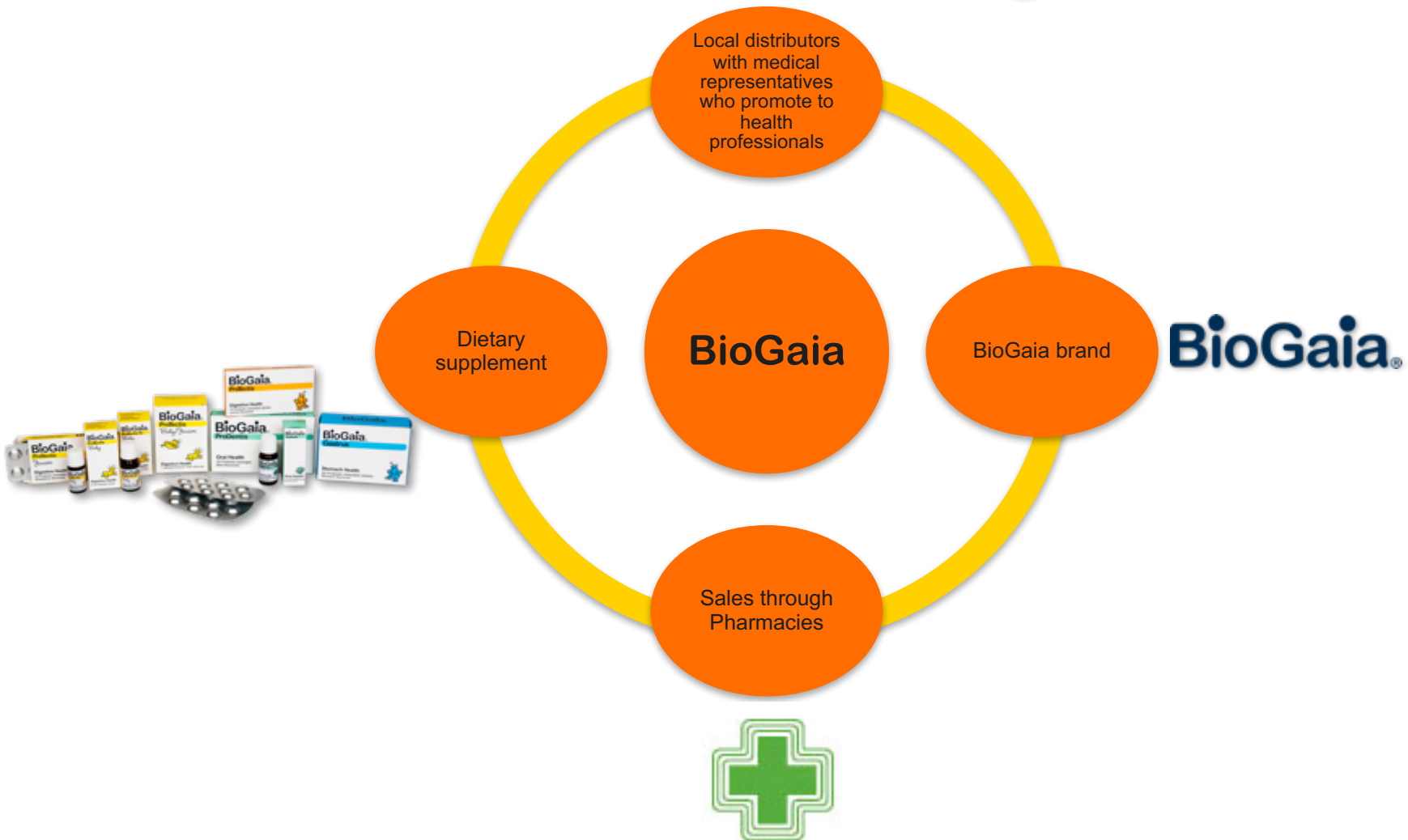
Research

Pre-clinical and clinical studies in hospitals and universities



- BioGaia
- Universities and hospitals where research is conducted.
- Manufacturing and Production
- Partners selling component products
- Partners selling finished goods

BioGaia's partner network



BioGaia's partner support

- Clinical trials
- Marketing and PR support
- BioGaia Academy
- Workshops
- Participation in medical congresses
- Speakers at symposiums
- Education of sales representatives
- www.biogaia.com
- Social media 
- Customer support 24/7/365



BioGaia Brand

- Branding for Health professionals
- Sold in 55 countries
- 62% of sales of finished consumer products (drops, digestive health tablets, oral health tablets, oral rehydration solution) were sold under the BioGaia brand, including co-branding, in 2015
- Build value, less dependence on distributors and patents



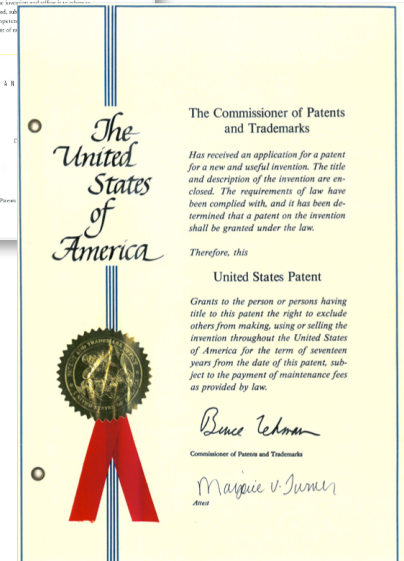
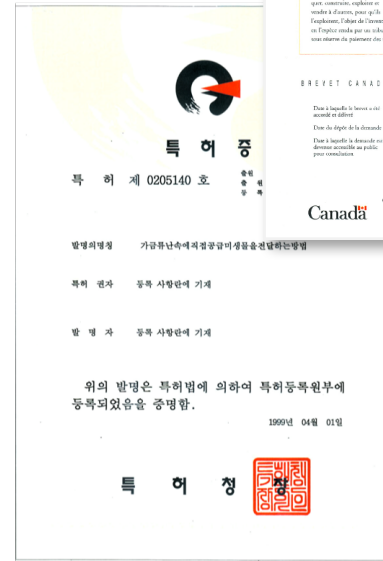
Intellectual Property Rights

- 440 issued patents in 32 families
- Trademarks in 66 countries + EU
- 70 Internet-domains

BioGaia®



www.biogaia.com



L. reuteri Protectis, Gastrus and Prodentis

Clinically Proven Probiotics



Clinical trials supporting the use of BioGaia Probiotics

Lactobacillus reuteri Protectis, Prodentis and Gastrus

163 completed clinical trials in 14,000 individuals

- **114** randomised, double-blind / blind, placebo-controlled studies in 10,500 subjects
- **47** open studies in 3,500 subjects
- **56** studies in 0-3y in 7,300 subjects

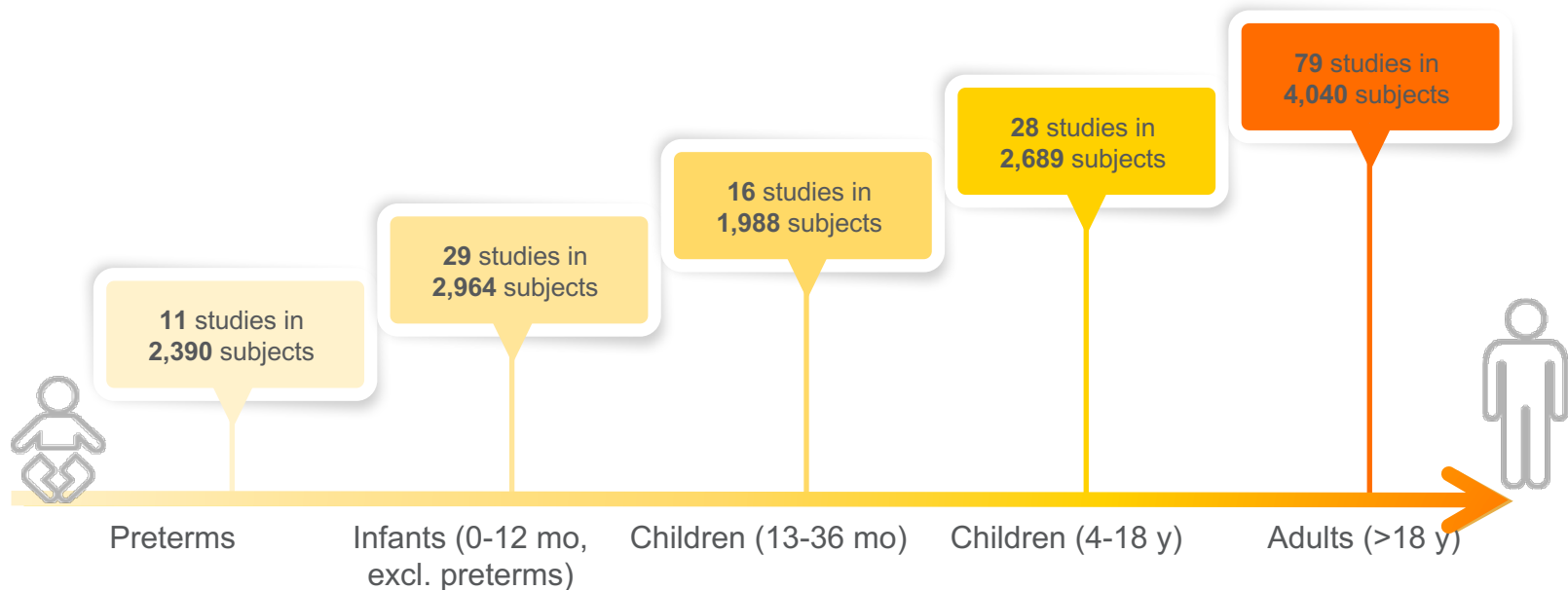


133 scientific articles and 10 doctoral theses



Clinical trials with all BioGaia probiotics in different age groups

163 completed clinical trials (48% children) in 14,031 individuals (71% children)



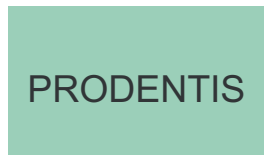
BioGaia Probiotics and Indications



- Functional gastrointestinal disorders
 - Colic
 - Regurgitation
 - Constipation
 - Functional abdominal pain
- Acute gastroenteritis
- Support of gastrointestinal health
- Antibiotic-associated side-effects



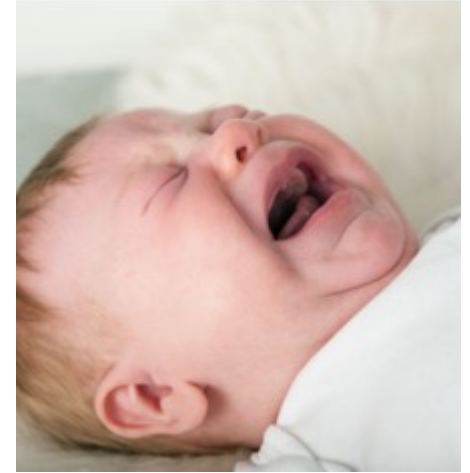
- HP-infection
- Eradication treatment associated side-effects



- Gingivitis
- Periodontitis



L. reuteri Protectis in infantile colic



Five treatment studies showing beneficial effects

- Significant reduction of daily crying time
- Significantly higher number of responders
- Improved family quality of life

Five meta-analyses with the same conclusion

- *L. reuteri* Protectis is the only probiotic proven effective in infantile colic

One treatment recommendation

Two prevention studies in healthy infants

- Significant reduction of daily crying time
- Fewer paediatric consultations
- Reduction in both public and private costs for managing functional gastrointestinal disorders

L. reuteri Protectis in functional constipation in children and adults

Three treatment studies showing beneficial effect

- Increased bowel movements
- 100% “normalization” of stool frequency
- Equally effective as lactulose, with less side effects

One systematic review

- *L. reuteri* Protectis the only probiotic with data on functional constipation in children

One prevention study in healthy infants

- Significantly increased bowel movements when used preventively



L. reuteri Protectis in functional abdominal pain (FAP)

Three double blind, randomized controlled treatment trials showing

- less stomach pain compared to placebo
- reduced severity of abdominal pain
- reduced frequency of abdominal pain

One published systematic review

- *L. reuteri* Protectis the only probiotic with effect in FAP

One Cochrane report supporting probiotic use in FAP



L. reuteri Protectis in acute gastroenteritis (AGE)

Six treatment studies

- Reduced duration and severity of acute diarrhoea
- Less vomiting
- Significant effects from the second day of treatment
- Effects seen in both hospitalised and outpatient children

Meta-analysis

- Significant reduction in the duration of diarrhoea

ESPGHAN recommendation 2014

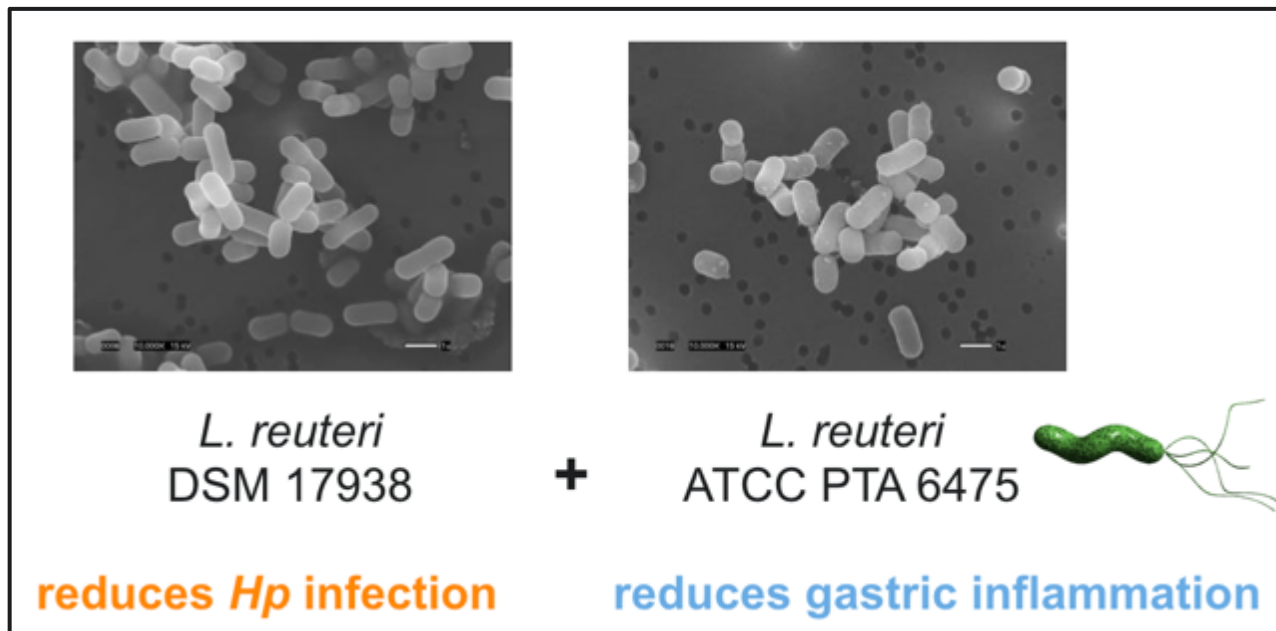
- *L. reuteri* Protectis on the positive recommendation list for managing AGE



L. reuteri Gastrus in *H. pylori* therapy

Two *H. pylori* related clinical studies showing significant effects:

- Reduced side effects and symptoms
- Reduced gastritis severity and activity
- Improved eradication rates



Clinical studies with *L. reuteri* Prodentis on Periodontitis



Author, Year	Results
Teughels 2013	In patients with deep pockets supplementation of <i>Lactobacillus reuteri</i> Prodentis as an adjunct to SRP leads to significant reduction in the need for surgery
Tekçe 2015	In patients with deep pockets supplementation of <i>Lactobacillus reuteri</i> Prodentis as an adjunct to SRP leads to additional PD reduction of 1 mm at 1-year follow-up
Ince 2015	Adjuvant probiotic therapy provides additional benefit over initial periodontal therapy on clinical and biochemical parameters over 180 days.
Szkaradkiewicz 2013	<i>L. reuteri</i> induces in most of the patients with chronic periodontitis a significant reduction in pro-inflammatory cytokine response and improvement of clinical parameters
Vicario 2012	<i>L. reuteri</i> supplementation in patients with initial- to-moderate chronic periodontitis resulted in significant improvements in clinical conditions compared with placebo.
Vivekananda 2010	<i>L. reuteri</i> Prodentis is suggested as an addition to mechanical debridement and during the maintenance phase of periodontal treatment.

Clinical studies with *L. reuteri* Prodentis on gingivitis and other oral symptoms



Author, Year	Results
Schlagenhauf 2016	Supplementation of <i>L. reuteri</i> Prodentis significantly reduced inflammation and plaque compared to placebo in 45 pregnant women with gingivitis.
Kraft-Bodi 2015	Daily use of <i>L. reuteri</i> Prodentis reduces the prevalence of oral Candida in frail elderly patients.
Stensson 2013	Daily supplementation with <i>L. reuteri</i> from birth and during the first year of life is associated with reduced caries prevalence and gingivitis score in the primary dentition at 9 years of age.
Romani 2015	<i>L. reuteri</i> Prodentis delays regrowth of caries-associated <i>Streptococcus mutans</i> after full-mouth disinfection.
Keller 2012	Daily use of <i>L. reuteri</i> Prodentis showed beneficial effect on oral malodour assessed by organoleptic scores.
Çaglar 2008	The probiotic lozenge containing <i>L. reuteri</i> Prodentis significantly reduced salivary <i>Streptococcus mutans</i> streptococci.

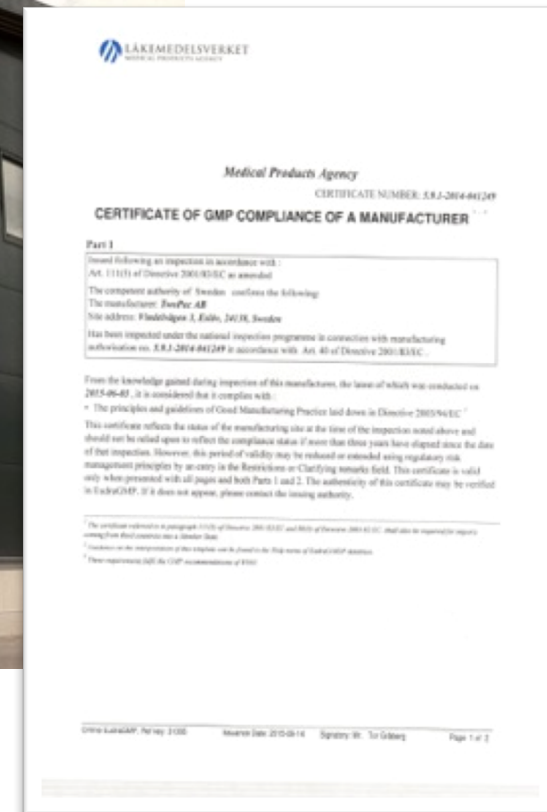
Nestlé cooperation and Subsidiaries

Cooperation with Nestlé

- Agreement 2008 (Infant formula)
- New licence agreement infant formula 2012 (EUR 50.8 million)
- Drops in the US
- Growing Up Milk for children above the age of one (Royalty agreement 2013, launch end of 2014)
- Extended collaboration (Royalty SEK 92.0 million over three years from q2 2014) (New segment)
- Other on-going development projects

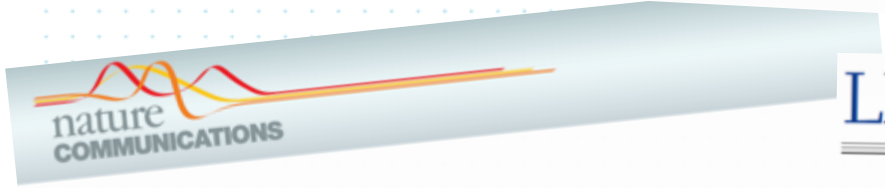


TwoPac TwoPac AB (100% owned by BioGaia)



MetaboGen (27% owned by BioGaia) is creating new opportunities for novel therapeutics and next generation probiotics

We use the microbiome to understand more about health and disease.



LETTER

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ARTICLE

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Symptomatic atherosclerosis is associated with an altered gut metagenome

Fredrik H. Karlsson¹, Frida Fåk^{2,3,*}, Intawat Nookaew^{1,*}, Valentina Tremaroli^{2,3}, Björn Fagerberg^{2,3}, Dina Petranovic¹, Fredrik Bäckhed^{2,3} & Jens Nielsen¹

Gut metagenome in European women with normal, impaired and diabetic glucose control

Fredrik H. Karlsson^{1*}, Valentina Tremaroli^{2*}, Intawat Nookaew¹, Göran Bergström², Carl Johan Behre², Björn Fagerberg², Jens Nielsen¹ & Fredrik Bäckhed^{2,3}



CAPABLE AB (90.1% owned by BioGaia)

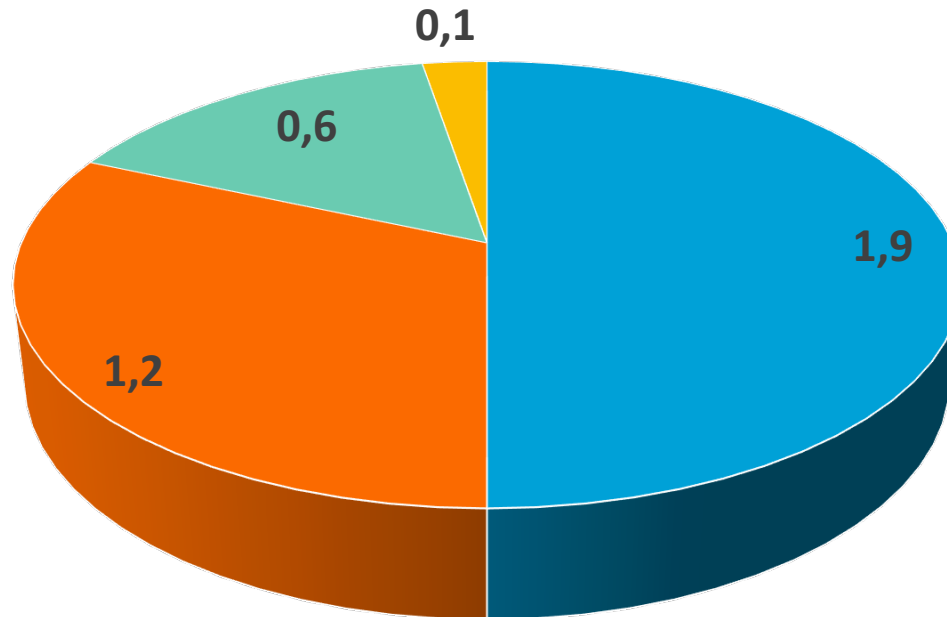


- Providing innovative packaging solutions allowing the development of new unique beverages
- Exclusive LifeTop™ Cap and LifeTop™ Straw supplier



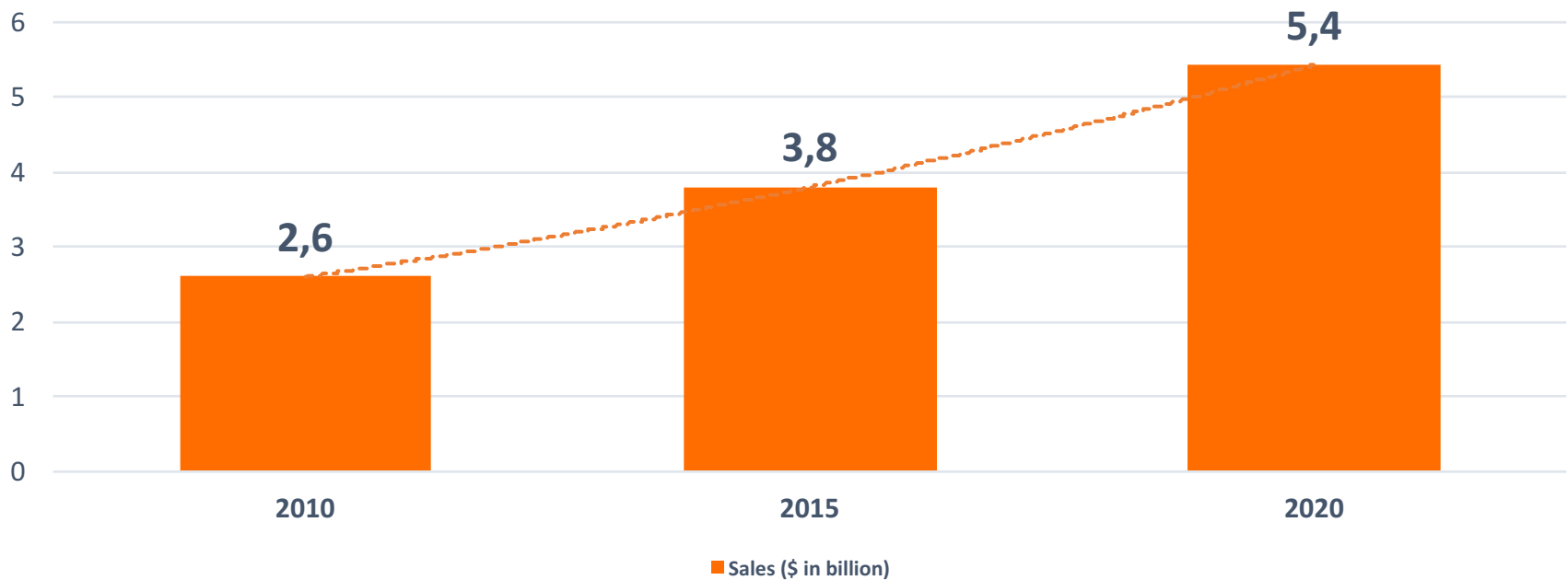
Our Market and Our Competitors

Our Market: Global probiotic supplement market 2015 (\$ 3,8 billion)



■ America ■ EU ■ Asia Pacific ■ Rest of world

Our Market: Global probiotic supplement sales (Sales 2015 projected to 2020)



From 2015 to 2020, CAGR of 7,4% assumed according report from Global Market Insight

BioGaia Competitors

- Companies developing, producing, and selling probiotics (Probi)
- Well studied probiotic strains (L. GG from Valio)
- Non probiotic products/ drugs (Imodium, Simethicone (Minifom))
- Probiotic products with strong brands (Enterogermina)
- Pharma companies (Sanofi)
- Functional Food (ProViva)

Importance of strain specificity

	Probiotic bacteria	Car
Group	Lactic acid bacteria	German car
Genus	<i>Lactobacillus</i>	Volkswagen
Species	<i>Lactobacillus reuteri</i>	VW Golf
Strain	<i>L. reuteri</i> Protectis	VW Golf 2.0 Turbo



VW Golf I and the VW Golf VI GTI, similar cars, but you do not expect the same output



Different breeds have different characteristics and are suitable for different tasks

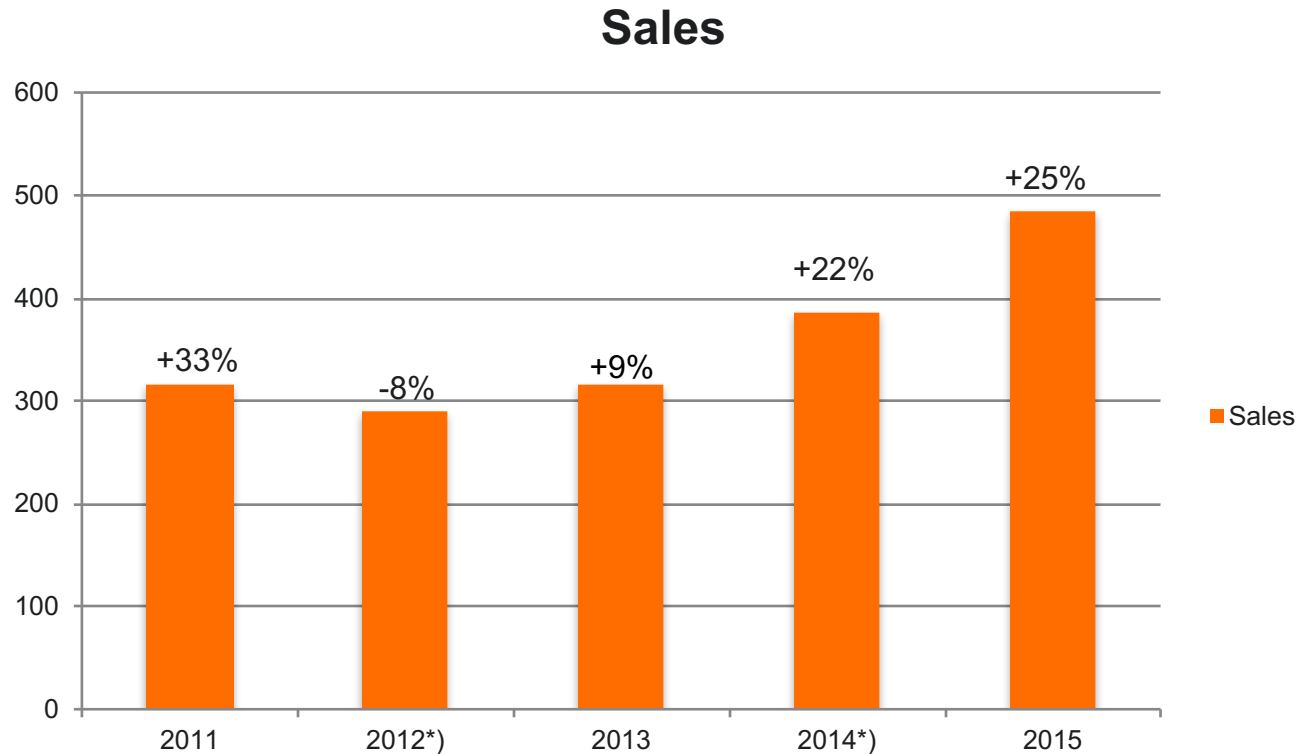


Try convincing your teenage daughter that an iPhone 3 is just as good as an iPhone 6

Our Sales Development and Our Market Presence

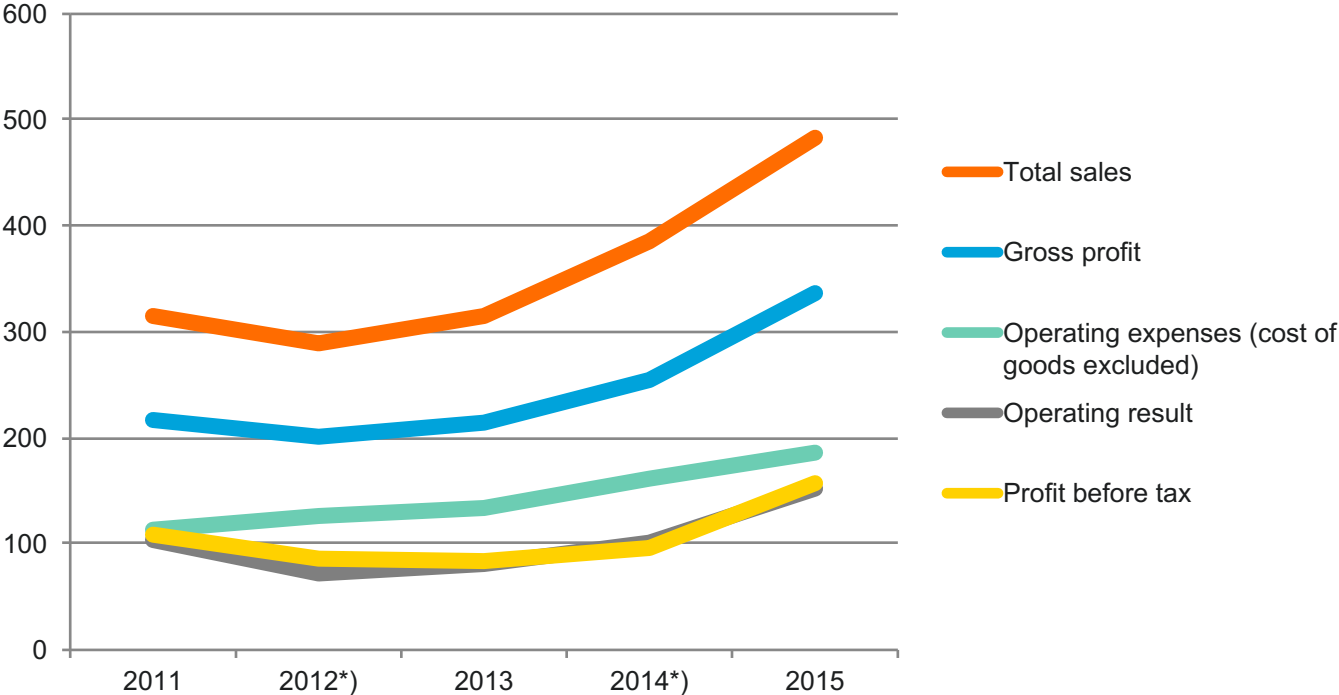
Sales development 2011 to 2015

Average growth: 15%



***) Excluding Licence revenue from Nestlé of 356 MSEK / 95,4 MSEK**

Sales and result per year (MSEK)



*) Excluding License revenue from Nestlé

Sales per business unit (MSEK)

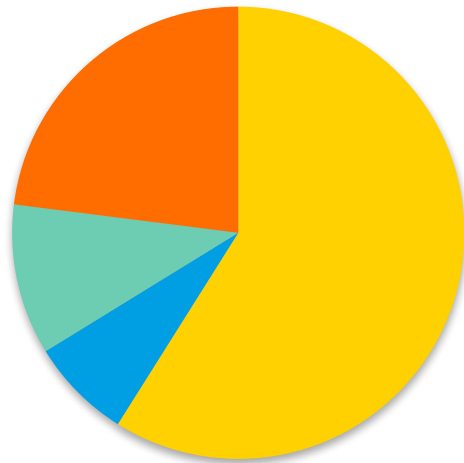
	2015	2014 ²⁾	Change %	Change % ¹⁾
Pediatrics	389,6	301,2	29%	19%
Adult health	74,7	69,4	8%	2%
Other	19,0	15,7	21%	21%
Total sales	483,2	386,4	25%	16%

1) Excluding currency effects

2) Excluding licence revenue of SEK 95.4 million

Sales per geographical market (MSEK) (excl. License revenue from Nestlé)

	2015	2014	Change	Change %
Europe	284,8	257,8	27,0	10%
USA and Canada	35,2	30,3	4,9	16%
Asia	52,1	38,8	13,3	34%
Rest of the world	111,1	59,5	51,6	87%
	483,2	386,4	96,8	25%



- Europe 59% (67)
- USA and Canada 7% (8)
- Asia 11% (10)
- Rest of world 23% (15)

First nine months 2016

Income Statement January - September

	q1-q3 2016	q1-q3 2015	Change	Excl. currency effect:
Net sales Paediatrics	313,8	313,0	0%	0%
Net sales Adult Health	69,4	54,6	27%	24%
Net sales other	12,8	11,3	13%	13%
Total sales	395,9	378,9	4%	4%
Cost of goods sold	-112,2	-115,6		
Gross profit	283,8	263,2	8%	
<i>Gross margin</i>	<i>72%</i>	<i>69%</i>		
Operating expenses BioGaia	-135,6	-125,4	8%	
Participation in associated companies' result	-0,4	-		
Exchange gain/loss on operation	5,4	3,0		
Operating profit	153,1	140,8	9%	9%
<i>Operating margin</i>	<i>39%</i>	<i>37%</i>		
Exchange gain/loss on forward exchange contracts	-5,6	1,6		
Interest income	1,2	0,1		
Profit before tax	148,7	142,5	4%	
<i>Profit margin</i>	<i>38%</i>	<i>38%</i>		
Tax	-36,3	-30,3		
Profit after tax from continuing operations	112,4	112,2	0%	

Income statement rolling 12 months

	q3 2016	q3 2015	Change	Excl currency effect:
Total sales	500,3	500,2	0%	-1%
Cost of goods sold	-143,2	-160,8		
Gross profit	357,1	339,4	5%	
<i>Gross margin</i>	71%	68%		
Operating expenses BioGaia	-175,6	-172,4	2%	
Participation in associated companies' result	-0,5	-		
Exchange gain/loss on operation	4,1	6,8		
Operating profit	185,1	173,8	7%	10%
<i>Operating margin</i>	37%	35%		
Exchange gain/loss on forward exchange contracts	-2,1	-2,3		
Interest income	1,2	0,3		
Profit before tax	184,2	171,8	7%	
<i>Profit margin</i>	37%	34%		
Tax	-46,6	-38,7		
Profit after tax from continuing operations	137,6	133,1	3%	

Balance sheet (MSEK)

	30-Sep	Dec, 31
<u>Assets</u>	<u>2016</u>	<u>2015</u>
Intangible assets	-	16,2
Tangible assets	82,4	83,9
Shares in Associated companies	7,5	8,0
Current assets	159,7	138,2
Cash and cash equivalents	201,6	226,9
Total assets	451,2	473,2
 <u>Equity and liabilities</u>		
Equity attributable to owners of the Parent company	369,3	395,9
Non-controlling interests	-	-
Total equity	369,3	395,9
Deferred tax liability	0,3	0,3
Interest-free current liabilities	81,6	77,0
Total equity and liabilities	451,2	473,2

Key events first January - September 2016

- Separate listing of IBT
- Meta-analysis confirms effectiveness of BioGaia ProDentis in periodontitis
- Agreement with BioWellTech for the sales of BioGaia ProDentis in Hong Kong
- Two meta-analyses confirm effectiveness of BioGaia ProTectis in infantile colic
- BioGaia ProTectis effective in treating abdominal pain in children
- BioGaia's ProDentis reduces pregnancy gingivitis
- Agreement for drops, tablets, and ORS in Kenya, Nigeria and Ghana

Q3 2016

Sales during the quarter and rolling 12 months per business unit

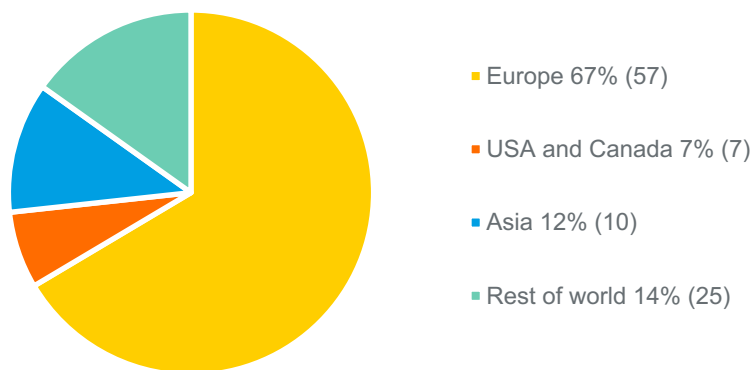
	q3 2016	q3 2015	Change %	Change % ¹⁾	Oct 15- Sep 16	Jul 14- Jun 15	Change %	Change % ¹⁾
Pediatrics	99,0	88,9	11%	11%	390,4	406,6	-4%	-5%
Adult health	22,6	12,6	79%	70%	89,4	77,6	15%	12%
Other	4,4	4,5	-2%	-2%	20,5	16,0	28%	28%
Total sales	126,0	106,0	19%	17%	500,3	500,2	0%	-1%

1) Excluding currency effects

Sales per geographical market (MSEK)

	q3 2016		q3 2015		Change		12 months		12 months		Change	
	q3 2016	q3 2015	Change	%	12 months	12 months	Change	Change	12 months	12 months	Change	Change
	q3 2016	q3 2015	Change	%	Sep 16	Sep 15	MSEK	%	Sep 16	Sep 15	MSEK	%
Europe	79,5	53,5	26,0	49%	333,5	287,0	46,5	16%				
USA and Canada	3,2	4,8	-1,6	-33%	37,8	37,1	0,7	2%				
Asia	17,3	11,4	5,9	52%	60,7	50,3	10,4	21%				
Rest of world	26,0	36,3	-10,3	-28%	68,3	125,8	-57,5	-46%				
	126,0	106,0	20,0	19%	500,3	500,2	0,1	0%				

Sept 2016 Rolling 12



Gross margin per business unit during the quarter and rolling 12 months

	q3 2016		Oct 15- Sep 16	Jul 14- Mar 15
Pediatrics	73%	67%	72%	66%
Adult health	64%	66%	64%	70%
Other	100%	94%	98%	96%
Total sales	72%	68%	71%	68%

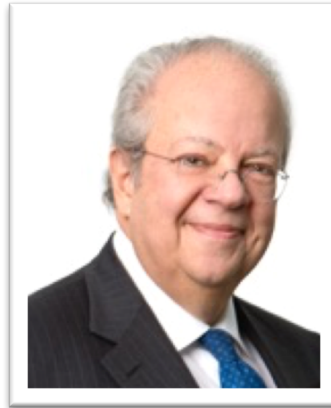
Board of Directors



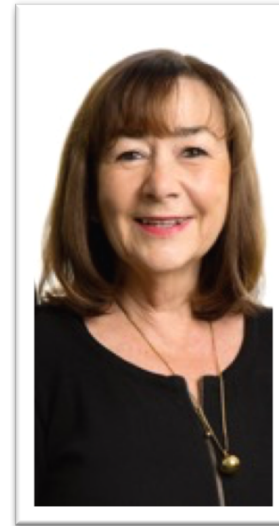
Paula Zeilon



Stefan Elfving



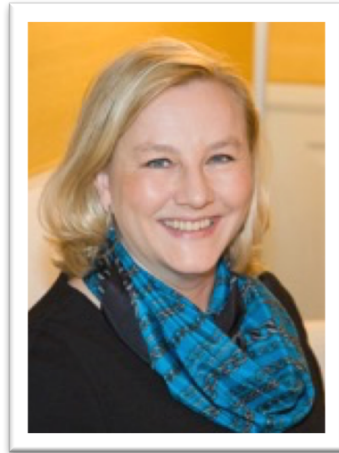
Chairman
David Dangoor



Ingrid Holmström



Jan Annwall



Ewa Björling



Brit Stakston



Anthon Jahreskog

Major Shareholders 30 September, 2016

	A	B	Share	No. of		
	shares	shares	capital	votes	Capital	Votes
			SEK			
	000's	000's	000's	000's	%	%
1 Annwall & Rothschild Inv. AB	741	759	1 500	8 166	8,7%	34,0%
2 Banque Öhman S.A		1 257	1 257	1 257	7,3%	5,2%
3 Fjärde AP-fonden		1 018	1 018	1 018	5,9%	4,2%
4 Swedbank Robur fonder		883	883	883	5,1%	3,7%
5 David Dangoor (inkl bolag)		569	569	569	3,3%	2,4%
6 Livförsäkringsaktiebolaget Skandia		526	526	526	3,0%	2,2%
7 CBNY Norges Bank		525	525	525	3,0%	2,2%
8 Mingdale Company		462	462	462	2,7%	1,9%
9 State Street Bank & Trust com., Boston		419	419	419	2,4%	1,7%
10 SSB and Trust company, Boston		356	356	356	2,1%	1,5%
Other shareholders		10 150	10 150	10 150	56,6%	40,9%
Total:	741	16 924	17 663	24 330	100%	100%

Total number of shareholders 30 September 2016: 7,739

Foreign owners: 43.5% of capital (31.4% of votes)

Present focus

- **Extend product line with partners**
- **ProDentis and Gastrus roll-out**
- **Launch of Easy Dropper**
- **Japan, US, India, and UK**
- **Internal change activities, process improvement and strengthening of the organization**

