



# Company brochure 2008





# Orion

Orion Corporation is a Finnish stock exchange company which develops, manufactures and markets pharmaceuticals, active pharmaceutical ingredients and diagnostic tests for global markets. Orion has been building well-being for as many as 90 years. Orion's customers are healthcare service providers and professionals, such as doctors, pharmacies, hospitals, healthcare centres, clinics and laboratories.

Pharmaceuticals account for about 95% of Orion's net sales, of which a considerable part comes from proprietary patented pharmaceutical innovations. *Stalevo*<sup>®</sup> and *Comtess*<sup>®</sup>/*Comtan*<sup>®</sup>, for Parkinson's Disease, are the most significant globally marketed products for Orion.

Orion carries on intensive research with the aim of introducing new innovative treatments to global markets. The core therapy areas in Orion's product and research strategy are the central nervous system, cardiology and critical care, and hormonal and urological therapies. In global marketing, Orion enters into licensing partnerships with other pharmaceutical companies.

Orion has also a large portfolio of generic, off-patent prescription medicines, hospital treatments and self-care products. These products are sold mainly in Finland, other Nordic countries, the new EU countries and Germany. In animal health, Orion has the leading market position in its home territory, the Nordic countries. The business division Fermion produces active pharmaceutical ingredients for both Orion and other pharmaceutical companies.

Orion's diagnostic tests are used widely around the world to help in diagnosing patients and to contribute to the follow-up of treatment. The emphasis in this product sector is on easy-to-use and rapid point-of-care tests. The leading brand is the *QuikRead*<sup>®</sup> test for diagnosing infections.

Orion's strategy emphasises profitable growth and increased shareholder value, whilst keeping business risks under control. Orion is strengthening its European presence. The growth is promoted by product, product portfolio and company acquisitions as well as licence agreements, but the best long-term growth opportunities are seen in the proprietary products.



The Annual Report of the Orion Group for the year 2007 consists of this Company Brochure together with the Financial Statements 2007, a separate publication. The Financial Statements publication contains the Report by the Board of Directors including the financial statements, the business segment reviews, the dividend proposal and the Auditors' Report for 2007. Also a description of the governance of the Orion Group is provided, including the introductions of the members of the Board of Directors and the Executive Management Board of the Orion Group as on the start of 2008.

The information and the publications subject to the disclosure obligation of Finnish listed companies are provided and updated on the Orion Group website at [www.orion.fi/investors](http://www.orion.fi/investors).

BUSINESSES	4	Orion in brief
	10	CEO's greeting
	12	Strategy
	14	Business environment
	16	Customers
	20	Proprietary Products
	24	Specialty Products
	26	Animal Health
	28	Fermion
	30	Orion Diagnostica
	32	Research and product development
	36	Supply Chain
	40	Quality
	42	Environment
	44	Personnel
	48	Contacts





# Orion in brief

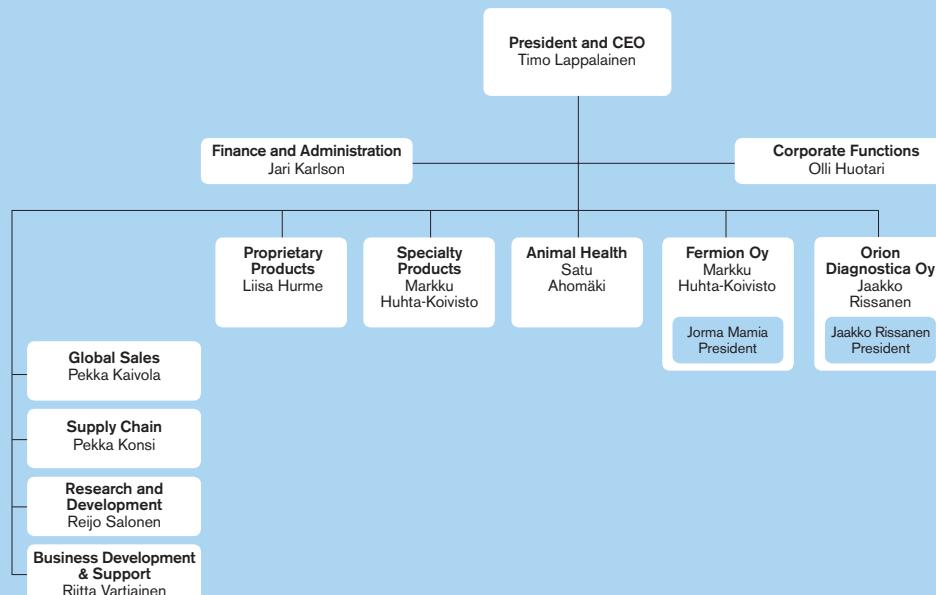
Orion Corporation is the parent company of the Orion Group. The business ID code of Orion Corporation is FI 1999212-6 (VAT FI 19992126).

Orion Corporation is domiciled in Espoo, Finland, with headquarters in Orionintie 1 A, FI-02200 Espoo. The website of the Orion Group can be found at [www.orion.fi/english](http://www.orion.fi/english).

The business areas of the Orion Group are:

- pharmaceuticals (research, development, manufacturing and marketing), accounting for about 95% of the net sales in 2007.
- diagnostic tests (development, manufacturing and marketing), accounting for about 5% of the net sales in 2007.

## ORION GROUP MANAGEMENT ORGANISATION





## PHARMACEUTICALS BUSINESS

Orion develops, manufactures and markets pharmaceuticals and active pharmaceutical ingredients. A growing part of its net sales has stemmed from new, patented proprietary pharmaceutical innovations. The core therapy areas of the company's product and research strategy are diseases of the central nervous system, cardiovascular diseases and critical care as well as urological and oncological therapies.

### The divisions of the Pharmaceuticals business are:

- Proprietary Products (patented prescription medicines)
- Specialty Products (off-patent prescription medicines and self-care products)
- Animal Health
- Fermion (active pharmaceutical ingredients)

**The Proprietary Products** business comprises the human medicines resulting from Orion's in-house R&D. These are the medicines for Parkinson's Disease (PD), *Stalevo*<sup>®</sup> and *Comtess*<sup>®</sup>/*Comtan*<sup>®</sup>, *Precedex*<sup>®</sup>, a sedative used in intensive care, *Simdax*<sup>®</sup> for acute decompensated heart failure and *Fareston*<sup>®</sup> for breast cancer. Proprietary products for human use made up about 45% of the net sales generated by the Pharmaceuticals business in 2007.

**The Specialty Products** business consists of a wide selection of off-patent products, or generics, and self-care products. The products accounted for about 38% of the net sales of the Pharmaceuticals business in 2007. A substantial part of the net sales from these products comes from Finland. The other Nordic countries are also important markets, as are the new EU countries as well as Germany.

**The Animal Health** business comprises veterinary medicines, in which Orion is a major Nordic player. These products made up about 10% of the net sales generated by the Pharmaceuticals business in 2007. Orion has developed four proprietary products for veterinary use: the sedatives *Domitor*<sup>®</sup>, *Dexdomitor*<sup>®</sup> and *Domosedan*<sup>®</sup>, and *Antisedan*<sup>®</sup>, which reverses the sedative effect.

**Fermion** is a fine chemicals company specialising in active pharmaceutical ingredients. It manufactures the active ingredients for Orion's proprietary drugs. In addition, it supplies pharmaceutical ingredients to a number of other

pharmaceutical companies. Fermion's sales to external customers made up about 6% of the net sales generated by the Pharmaceuticals business in 2007.

## DIAGNOSTICS BUSINESS

Orion Diagnostica develops, manufactures and markets in vitro diagnostic testing methods and systems. Its focus is on point-of-care tests which physicians and nurses use in doctors' offices and in small-scale laboratories. The leading brand in the product range is *QuikRead*<sup>®</sup>. The first application, now widely marketed around the world, is a CRP test for the rapid detection of bacterial infections in the body.

Other important diagnostic products are collagen tests that measure bone metabolism. In-house product development has also yielded hygiene tests, used in many business sectors.

## COMPANY LOCATIONS

### Head office and administration:

Orion's head office is located in the Mankkaa district of Espoo, Finland. Also the management of the business divisions and a large part of the production operations are in Espoo.

### Research and development:

Pharmaceutical research centres are located in Espoo, Turku and Kuopio, Finland, and Nottingham, England. Orion Diagnostica's research units are located in Espoo and Oulu, Finland.

### Marketing:

Orion has overseas marketing companies in Sweden, Norway, Denmark, Germany, the United Kingdom, Ireland, Switzerland, Hungary, Estonia and Latvia. In addition, the company has representative offices in most of the eastern European countries and a liaison office in Mumbai, India.

### Production:

Orion manufactures pharmaceuticals in Espoo, Turku and Kuopio, Finland. Diagnostic products are manufactured in Espoo and Turku. Active pharmaceutical ingredients are produced in Hanko and Oulu, Finland.



## ORION AS A LISTED COMPANY

Orion Corporation was listed on the OMX Nordic Exchange Helsinki as a new company on 3 July 2006, after the demerger of the old Orion.

The trading code of Orion's Class A share on the OMX Nordic Exchange Helsinki is "ORNAV" (ISIN Code FI0009014369) and that of the Class B share "ORNBV" (ISIN Code FI009014377). Based on its market capitalisation, Orion belongs to the Large Companies in the Healthcare segment of the OMX Nordic List.

Financial information on Orion is presented in a separate Financial Statements 2007 publication. Orion's website at [www.orion.fi/investors](http://www.orion.fi/investors) offers all information and publications specified in the disclosure obligations of listed companies. Information on trading in Orion shares is also given in this section. Information on the company's ownership base and changes in it is also available on the website.

## FINANCIAL OBJECTIVES

The moderate organic growth of the net sales in the next few years is accelerated via product, portfolio and company acquisitions. Operating profit will be increased and the Equity ratio is maintained at a level of at least 50%.

## DIVIDEND POLICY

In the dividend distribution, Orion takes into account the company's distributable funds and the medium-long and long-term needs of capital expenditure and other financial needs required for the achievement of the financial objectives.

## VISION AND MISSION

Orion is a European pharmaceutical and diagnostics company whose business operations focus on the development of innovative medicinal treatments and diagnostic tests for global markets. The aim is profitable growth and increased shareholder value, whilst keeping operational risks under control.

## ORION'S MAIN STRENGTHS

Orion has a 90-year long expertise and experience of developing, producing and marketing pharmaceuticals.

Orion is Finland's largest company engaged in pharmaceutical research as measured by its annual investments in terms of euros as well as by the number of staff employed at its research units. Over the past 20 years, Orion's in-house pharmaceutical research has brought to market seven proprietary drugs. The core platforms of research expertise are receptors and enzymes related to selected therapy areas and, thereby, the mechanisms of the related active ingredients.

Internationally, Orion has leading expertise in the COMT enzyme, and it applies this knowledge in the drugs it develops for treating Parkinson's disease. Another key area are alpha<sub>2</sub> receptors of the central nervous system, from which platform Orion has developed and brought to market new chemical entities for both human and veterinary indications. Orion furthermore has achieved significant research results in the area of heart failure, primarily in research on the levosimendan molecule, having continuously built up expertise ever since the 1980s. In addition, Orion has a strong know-how concentration in the area of urological and oncological therapies.

Orion has a solid market share of about 9% of the sales of pharmaceuticals in Finland. Measured by numbers of packages sold, Orion is far and away the largest: nearly a third of the drug packages sold in Finnish pharmacies come from Orion. In the international markets, Orion is strongest in Parkinson's disease, for which the company has developed selegiline (Orion's trade names are *Eldepryl*<sup>®</sup> and *Movergan*<sup>®</sup>) and entacapone (*Comtess*<sup>®</sup>/*Comtan*<sup>®</sup>) as well as the optimised levodopa treatment *Stalevo*<sup>®</sup>.

In the field of diagnostics, Orion has strong speciality expertise relating to inflammatory diseases, hormones, specific proteins and bone metabolism.



# Orion Group Values

Our values express how we can and want to commit ourselves to the things we do. With these values we have jointly defined what we desire from Orion as a working community. They are also very personal in respect of our individual relation to work and our colleagues. Our values are meant to be part of our daily life, and we are doing our best to work and live up to them.

## MUTUAL TRUST AND RESPECT

We want to act so that we can trust each other and respect each other's work, thus creating a firm basis for co-operation. Trust springs from keeping promises, and respect from understanding the importance of one another's contribution to the whole process.

## CUSTOMER FOCUS

We want to understand, anticipate and meet our customers' present and future needs. This presupposes that all of us closely co-operate and exceed the limits of normal work communities in order to bring our expertise to our customers.

## INNOVATION

We want to create and develop innovative solutions and ways of working. This challenges each of us to explore new possibilities in our daily work, in co-operation with professionals from various fields and to bring our own expertise into our joint projects.

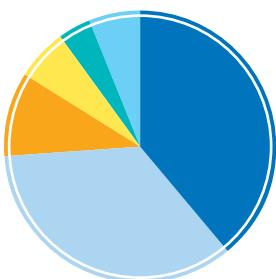
## ACHIEVEMENT

We want to be the best in our field, developing products, services and solutions that promote well-being and health. This challenges each of us as an individual and all of us together to strive for the best in all that we do.

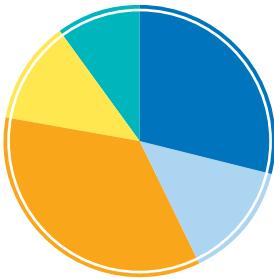
## QUALITY, RELIABILITY AND SAFETY

We want high quality, reliability and safety to underline our actions. This presupposes that all of us, together and as individuals, are accurate and timely in all our procedures.

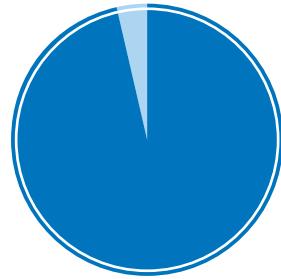
**Net sales by business divisions 2007**



**Net sales by geographic segments 2007**



**Operating profit by business segments 2007**



# Year 2007 in figures

The table below provides selected key figures on Orion's financial performance. The details of the performance are specified in a separate publication, Orion Group Financial Statements 2007. The financial reports published by Orion are available at the company's website [www.orion.fi/investors](http://www.orion.fi/investors).

## Key figures of the Orion Group

EUR million	2007	2006 *	Change %
		Proforma	
Net sales	683.6	641.1	+6.6%
Operating profit (EBIT)	194.0	196.7	-1.4%
% of net sales	28.4%	30.7%	
Profit before taxes	195.5	197.3	-0.9%
% of net sales	28.6%	30.8%	
R&D expenses	97.6	84.1	+16.0%
% of net sales	14.3%	13.1%	
Capital expenditure	35.3	25.5	+38.1%
% of net sales	5.2%	4.0%	
Balance Sheet total	589.5	588.1	+0.2%
Equity ratio, %	75.9%	75.4%	
Gearing, %	-19.3%	-22.6%	
Interest-bearing liabilities	4.0	9.8	-58.9%
Non-interest-bearing liabilities	138.1	134.8	+2.5%
Cash and cash equivalents	90.4	110.0	-17.8%
ROCE (before taxes), %	43.8%	46.5%	
ROE (after taxes), %	32.7%	34.5%	
Earnings per share, EUR	1.03	1.03	-0.2%
Equity per share, EUR	3.17	3.14	+0.9%
Personnel at the end of the period	3 176	3 061	+3.8%

\* The proforma figures for periods before the demerger on 1 July 2006 are based on comparable ones carved out from the financial statements of the demerged Orion.

# CEO's greeting

## ORION, THE NR.1 BRAND IN FINNISH HEALTHCARE

Orion moved into 2008 in excellent shape. We have spent the past year for the most part on the job, but we have also celebrated our 90-year history in many ways. The biggest party was for all Orion employees, taking joy in the fact that we at Orion stand behind the company's achievements and that by being committed to our work, we have customers who are committed to Orion.

Years ago, Orion's founding shareholders placed a strong emphasis on the value of our Finnish identity. Being Finnish has been a distinguishing characteristic of our company all these years, but it was not until our 90-year jubilee that we began to use the Key Flag emblem granted by the Association for Finnish Work. Although our products contain a great deal of ingredients sourced from our extensive international partner network, most of their added value is nonetheless generated in our own product development and supply chain. A pronounced feature of the pharmaceutical industry is networking and working together with partners. This is also the way Orion works.

I dare say that Orion has long been the leading brand in Finnish healthcare, and we want to retain this position in the years ahead as well.

## ORION CAN MAKE THE GRADE BY BEING THE BEST

Only companies that continuously develop their productivity and seek new innovative ways to operate can succeed in the face of ever stiffer competition. Being average will not do. Instead, we must be competitive with the world's best organisations. We want the Orion name and brand to relate to quality and excellence. We want our customers to rely on our products as the best available alternative.

We want to be No. 1 as a partner too. For us, networking efficiently and wisely is a most strategic way of working. Over the past years, we have built partnerships far and wide in all our operations. Managing these alliances has indeed become one of Orion's areas of expertise.

In my view, our key competitive edge is to be found within the company, in our ways of working. Our strong holds are Orion's inbuilt, well-considered and insightful processes, which are hard for competitors to copy. Along with this, our management is dedicated to creating a good working atmosphere and encouraging an innovative spirit in everything we do.

Fostering innovation is vital for Orion's success, and that is why it is an integral part of the way we work each day at Orion.

## ORION'S GROWTH STRATEGY MAPS OUT MULTIPLE OPTIONS

We have put in place at Orion an active organisation that has revitalised our product portfolio amongst others by product acquisitions. The fastest growing markets for us are the new EU countries and Russia.

Orion is also studying carefully its opportunities in the emerging economies on more distant continents. An important development focus at the present time is India, where towards the end of 2007 we established our first bridgehead with a view to tapping into the local networking possibilities for research and production.

Research and development investments have grown manyfold in a few years, and the requirements for documenting pharmaceutical development have also escalated year by year. The need for new medicinal treatments will not, however, go away or even diminish. Without them, medicinal healthcare will not make progress. The pharmaceutical companies have taken on the task of development work calling for wide innovative scope and involving large financial risks with potentially large financial gains, too. Orion wants to be a part of this process.

Actions to contain overall healthcare costs have restored generic drugs to the place they deserve. IMS Health estimates that sales of generics in 2008 will grow by about 14–15 per cent, against overall market growth at about 5–6 per cent. Within healthcare we need both new innovative drugs and good old drugs that have become well established through long years of use. A good drug does not deteriorate when it goes off patent.

Effective diagnoses and correct medication can have a major effect on total healthcare costs and productivity. Truly, medicines are among the most efficient investments within healthcare. However, in the public discussion about high costs, one major cost factor is often forgotten: people themselves and our personal possibility for reducing costs through our own lifestyle and by taking care of our own and others' well-being.

Espoo, 7 February 2008

**Timo Lappalainen**  
President and CEO



Timo Lappalainen took over as President and CEO of Orion on 1 January 2008. He has worked in management positions in Orion's Pharmaceuticals business since 1999, most recently as head of the Proprietary Products and Animal Health divisions.





# Strategy

Orion is seeking to strengthen its presence in Europe. Orion's goal is to speed up the growth of its Specialty Products and Proprietary Products businesses, but growth is also sought within Animal Health and Diagnostics. In countries where Orion has its own sales organisations, organic growth is speeded up through acquisitions of products, product portfolios and companies. In other market areas, Orion seeks close partnerships in order to achieve full European coverage for its products. The aim for Orion is to have Europe-wide control of the marketing authorisations and pricing procedures of the proprietary drugs, because the best long-term growth potential is seen within this product segment.

For Proprietary Products, focusing of research and development within selected therapy areas plays a central role. The emphasis is on the early phases of research and development. As a rule, the costs and risks of Phase 3 clinical research – the most extensive phase – are preferred to be shared with partners. Partnerships and networking are important all across the value chain, both in research and product development and in reaching global markets. Orion aims to increase the in-licensing of developmental molecules and networking. In research and product development, risks are managed by a balanced engagement in the development of new chemical entities and by managing the life cycles of the proprietary products already on the market. Fermion plays an important role as a manufacturer of the active ingredients for Orion's proprietary products and as a developer of their manufacturing processes.

Via active in-licensing Orion acquires new products for the Specialty Products business for the northern, central and eastern European markets.

In the Animal Health business, Orion's own presence covers the Nordic market area, the product range consisting of both Orion-originated and in-licensed products. Orion's innovative animal sedatives are sold by partners on a global scale. In carrying out its R&D activities in the human medicines field, Orion transfers the resultant synergy benefits into animal health with the aim of capitalising on opportunities in the life cycle management of proprietary human drugs.

Within Diagnostics, the needs of customers and markets in the fields of healthcare and industrial hygiene are met by offering innovative, cost-effective, easy-to-use and reliable tests. The flagship product line is QuikRead®. Orion aims to be a leading company in selected areas of point-of-care diagnostics in primary healthcare.

# Business environment

In 2006, drug sales worldwide were about 643 billion US dollars, and they grew by about 7%. The United States' share of global drug sales is about 45%. Japan accounts for about 10% and the EU for about 35%. The audited statistics compiled by the American company IMS Health cover about 95% of drug sales worldwide, and they are based on trade between wholesalers and distributors, i.e. mainly on purchases by pharmacies and hospitals.

In the past 3–4 years, the growth rate has clearly levelled off in the USA and the major European markets, mostly in result of the variety of measures taken by governments to contain the medicinal costs. The fastest growing markets are now those of the new EU member states with renewing and increasingly diversifying product selections. China and India are large and fast-growing future markets. Pharmaceutical companies are seeing also manufacturing and product development opportunities in the emerging markets.

In countries with a high standard of living, people are increasingly susceptible to largely lifestyle illnesses, such as cardiovascular diseases, obesity, diabetes, alimentary disorders, asthma and various mental health problems. The sales statistics are topped by patent-protected compounds featuring new mechanisms of action. In 2006, the audited sales of the ten top-selling drugs amounted to about 60 billion US dollars, nearly 10% of all drug sales. The cholesterol drug Lipitor (atorvastatin) alone generated sales of over 13 billion dollars, about 2.2% of the world total. The ulcer medicine Nexium (esomeprazole) ranked second in the sales statistics with sales of 6.7 billion US dollars, followed by the asthma medicine Seretide/Advair

(fluticasone and salmeterol) with about 6.3 billion US dollars.

There are hundreds of players in the pharmaceutical market, ranging from the big multinationals to very local companies. The world's largest pharmaceutical company is Pfizer, which had net sales in 2006 of over 48 billion US dollars. Frequent changes take place in the size ranking of players due to consolidation. Product portfolios often change owners too. Indeed, part of the new investigational compounds launched by the big pharma companies come via acquisitions and licensing arrangements.

Gauged by the yardstick of the global pharmaceutical market, Orion, with its ca. EUR 600 million in pharmaceutical sales, is a comparatively small player, but still ranks in the top 70. In the Finnish market, Orion has for decades been among the leaders. Over a hundred pharmaceutical companies are represented by a local marketing company in Finland, and about nine out of every ten euros of the Finnish pharmaceutical wholesales flow via the accounts of those companies. Orion attends to the healthcare of Finns by maintaining an extensive product range of reimbursable drugs and by ensuring that its products are always available at pharmacies.

The global diagnostics market is estimated at about USD 33 billion. A few large players dominate the market for centralised automated laboratory systems. In recent years, the trend towards consolidation has also gained pace in the point-of-care test market. All in all, the field is very fragmented, and Orion Diagnostica is medium-sized player in the market. In certain product areas, it has a fairly strong position.

## Drug prices and medicinal costs

In Finland, pharmaceutical companies can set the price on their products freely. But if the drug is to be reimbursable, a reasonable wholesale price is confirmed for it for a fixed period by the Pharmaceuticals Pricing Board, which operates under the Ministry of Social Affairs and Health. The retail

price is set according to a price list that is confirmed by the Government and is the same in every pharmacy. The retail price includes the pharmacy's sales margin, value added tax of 8% as well as a so-called pharmacy fee.

Pharmaceutical wholesale prices in Finland were West

Europe's sixth lowest in 2007. In retail prices of pharmaceuticals, however, Finland was West Europe's seventh most expensive country.

The proportion of drugs of total healthcare expenditure varies from country to country. The share of medicines of Finland's total healthcare

costs are about 16%. Today, the growth of drug sales is due to new, more effective and better tolerated, but more expensive drugs protected by patents. Ageing of the population and increased outpatient care are also boosting demand.



**Sales Representative**  
Camilla Nyberg has  
been with Orion for  
twelve years.

# Orion's customers are healthcare professionals

Orion's customers are healthcare service providers and professionals. Pharmaceuticals and diagnostic products are marketed primarily to physicians, veterinarians, pharmacies, public and private hospitals, healthcare and medical centres. Self-care products are also marketed to consumers. The main customers of Fermion are other pharmaceutical companies.

Extremely in-depth understanding of overall treatment concepts is required in the development and marketing of drugs. The communication must be based on clinically proven facts that have been approved for the summaries of product characteristics. Orion focuses on therapeutic areas in which specialist doctors are the main audience for product information. For instance, knowledge of the mechanism, effectiveness and effects of *Stalevo®* and *Comtess®/Comtan®* is important for neurologists treating Parkinson's patients, because the disease of every patient is different.

## **ORION STRENGTHENS ITS EUROPEAN PRESENCE**

Orion's products are available in over one hundred countries. The company has own sales organisations in 16 European countries. Orion Diagnostica has subsidiaries in Scandinavia and an extensive network of importers and agents in other markets. In line with its strategy, Orion strengthens its presence in Europe by stepping up growth in the Pharmaceuticals business both organically and by means of acquisitions of products, product portfolios and companies. The greatest growth is being sought in the new EU countries and Russia, where the current marketing units constitute the basis for strengthening the company's presence.





**Camilla Nyberg meets physicians in the Helsinki and Western Uusimaa district, informing them about the latest news on Orion's products for respiratory diseases and mental health problems.**

When venturing into new territories, Orion first evaluates the special characteristics and operating patterns of the market, such as its pricing and reimbursement systems and principles for possible generic substitution. The operational structure is then set up and fitted to the local requirements. In those European countries where Orion does not have its own sales organisation, the company strives to engage in close co-operation with pharmaceutical companies having an established position in that territory. Orion nevertheless retains control of its distribution channel, product safety data, pricing procedures and brands.

#### GLOBAL AVAILABILITY VIA PARTNERS

Partnerships and networking play an important role in Orion's strategy. Orion ensures the widest possible market coverage for its proprietary drugs by entering into marketing agreements with pharmaceutical companies whose product portfolios are an ideal fit for Orion's product and which have strong and capable marketing resources. Orion receives an agreed proportion of the sales generated by partners and recognises this income in its net sales. The proportion depends on factors such as the partner's participation in the research costs and the division of the marketing costs between the parties.

The most significant partner for Orion is the Swiss company Novartis, one of the global giants in the pharmaceuticals business, which sells *Stalevo*<sup>®</sup> and *Comtan*<sup>®</sup>. Orion handles sales of *Stalevo*<sup>®</sup> and *Comtess*<sup>®</sup> in most of those European countries where it has its own sales organisations.

The marketing of the *Easyhaler*<sup>®</sup> asthma product family has been out-licensed to several regional partners, such as Hexal in Germany, Ranbaxy in the UK, Menarini in Italy and Abdi Ibrahim in Turkey. Orion's oncological products are marketed by Organon, Upsher-Smith, Pola, Nippon Kayaku and GTx. Pfizer is an important partner in veterinary drugs.

Orion, too, is an important marketing partner for a number of pharmaceutical companies in its own territory. An excellent example of successful co-operation is *Enanton*<sup>®</sup>, (leuproreline acetate), a treatment for prostate cancer marketed by Orion in the Nordic countries under the licence of the Japanese company Takeda. Also research and manufacturing collaboration is done with numerous research groups, universities and pharmaceutical companies. In fact, broad and multiscale networks of collaborative partnerships in research, manufacturing and marketing are very typical to pharmaceutical companies. Smart networking is beneficial for all parties.



## Pharmaceutical distribution and marketing is regulated by law

The marketing of pharmaceuticals is regulated by legislation and complementary rules of the game that are jointly agreed by and for the industry and are written down in the *Code of Practice on the Promotion of Medicines* of EFPIA, the European Federation of Pharmaceutical Industries and Associations. The practices agreed by an individual country can be even more demanding, as they are in Finland, for example.

The Finnish Pharmaceuticals Act allows the promotion of medicines only on the

basis of the facts given in the summary of the product characteristics. Prescription products can be promoted to healthcare providers only, physicians and pharmacies thus being the primary sources of pharmaceutical information for consumers. The *Pharmaca Fennica* database for physicians and pharmacies includes complete summaries of the product characteristics of all drugs approved for use in Finland. Finnish consumers can consult *Lääkeopas*, a generalised book based on this massive database. It features basic information on

the most common drugs, and is available in pharmacies and bookstores.

The information society and information technology pose challenges to legislators. The Internet provides access to reliable but, unfortunately, also possibly wrong or biased information on pharmaceuticals. The Internet has also become a marketplace for booming trade in illegal counterfeit drugs with all their dark sides and risks. In illegal trade, the buyer alone is the one carrying the risk. The only absolutely safe outlet for buying pharmaceuticals is the pharmacy.



Eero Marin from Turku has suffered from Parkinson's Disease for over twenty years. A positive attitude gives him the strength to cope with everyday life.

# P Proprietary Products

At the core of Orion's growth strategy

The Proprietary Products division comprises the human medicines resulting from Orion's in-house R&D – the product group that Orion has identified as having the best long-term growth potential.

As a result of research begun in the 1980s, Orion has brought to market seven proprietary drugs, three of which are for veterinary use. While proprietary drugs accounted for only about 7 per cent of the net sales of Orion's Pharmaceuticals business in 1996, the figure was 28 per cent in 2000 and about 45 per cent in 2007. A particular boost to the growth has come from the medicines for Parkinson's Disease, i.e. *Stalevo*<sup>®</sup> and *Comtess*<sup>®</sup>/*Comtan*<sup>®</sup>, which are based on the entacapone molecule discovery. They are by far the brightest stars in Orion's product portfolio.

#### EXPERTISE IN PARKINSON'S DISEASE

Parkinson's Disease (PD) has become Orion's strongest area of expertise. Orion's first drug for PD was the MAO-B inhibitor selegiline, sold under the trade names *Eldepryl*<sup>®</sup> and *Movergan*<sup>®</sup>. Orion acquired the rights to this molecule at a very early development stage and it came onto the market in 1982.



**Eero Marin's days are full of action. His hobbies include playing guitar, listening to music, sport and outdoor activities. His wife Raija helps with everyday tasks. As the disease progresses, Parkinson's patients need support in basic things like daily hygiene, dressing and eating.**



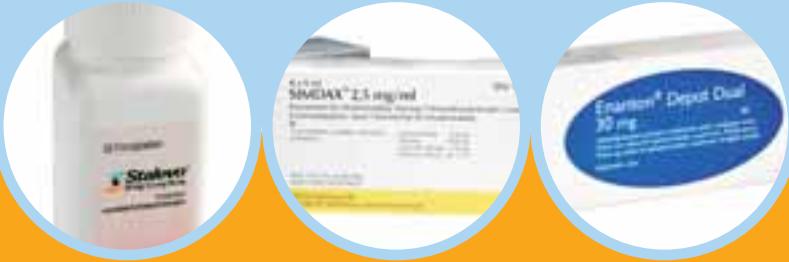
In 1998, Orion launched the COMT enzyme inhibitor entacapone in Europe, and a year later in the United States. Entacapone is a substance that enhances the effect of levodopa, the standard treatment for PD. Orion markets entacapone in Europe under the name Comtess, and in countries where Orion doesn't have its own sales organisation, it is sold under the name Comtan by the partner Novartis. Comtess/Comtan is Orion's first major globally sold drug.

In 2003, further research in entacapone resulted in the launch of Stalevo, an enhanced levodopa treatment containing the basic treatment levodopa and the enzyme inhibitors entacapone and carbidopa in one tablet, in optimised proportions. Favourable long-term clinical experience has established Stalevo as a standard medication for Parkinson's patients requiring levodopa therapy.

In the work with selegiline and entacapone Orion has accumulated globally unique expertise in the treatment of Parkinson's disease.

#### **SPECIALIST DRUGS FOR INTENSIVE CARE AND CARDIOLOGY**

One of the most challenging specialised areas of medical science is patient care in hospital intensive care and cardiac monitoring units. Orion has produced two notable drugs for this challenging field: levosimendan and dexmedetomidine. Orion's first proprietary drugs were the animal sedatives *Domosedan*®, *Domitor*® and their reversal, *Antisedan*®, which are used by veterinarians all over the world. The same alpha<sub>2</sub> receptor research later yielded dexmedetomidine (trade name *Precedex*®), which is used as a sedative for human patients in intensive care. Today, Hospira Inc. markets Precedex in the United States, Japan and several other countries outside Europe. Having reacquired the European rights for dexmedetomidine, Orion set a goal to introduce dexmedetomidine in Europe as well. A major Phase III clinical trial in 1,000 patients is under way for this purpose.



Orion's expertise in the field of cardiology has accumulated through in-house research since the 1980s. Levosimendan, trade name *Simdax*<sup>®</sup>, an intravenously administered hospital drug for acute decompensated heart failure for use in intensive care and cardiac monitoring wards, is available in about 40 countries but lacking marketing authorisation in countries with the largest sales potential. The global marketing and development rights to Simdax, excluding the Nordic countries, are held by Abbott.

#### THE ROLE OF UROLOGY AND ONCOLOGY IS INCREASING

The proprietary products included in Orion's portfolio for urology and oncology are *Fareston*<sup>®</sup> (toremifene) for breast cancer, and a family of hormone replacement therapies for treating menopausal symptoms. The majority of the sales of Fareston are generated in Japan, where it

is marketed by Nippon Kayaku, and in the United States, where the marketing rights are held by GTx, Inc. GTx is also conducting further research in toremifene, for prostate cancer indications.

The hormone replacement therapies comprise a variety of products and treatment options sold under trade names such as *Indivina*<sup>®</sup>, *Divina*<sup>®</sup>, *Divitren*<sup>®</sup>, *Diviseq*<sup>®</sup> and *Divigel*<sup>®</sup>, marketed by several pharmaceutical companies under Orion's license. Divigel, a transdermally administered gel preparation, was launched in 2007 in both Japan and the USA as a product containing the lowest available dose of estradiol.

Orion is actively reconstructing its product portfolio by acquiring marketing rights for patent-protected drugs. Examples in point are the two new collaboration agreements closed in 2007 with the Indian-based company Aurigene and Oasmia of Sweden aiming at new approaches for Orion in the treatment of cancer.

Orion's products have belonged to the daily life in Finnish families for ninety years.



# Specialty Products

Established treatments for a variety of uses

The Specialty Products unit comprises an extensive and diverse range of close to 300 products of generic prescription drugs, hospital medicines and self-care products for primary healthcare. Orion has developed the formulations of most of them in-house and also manufactures the majority of these products in its own plants. One of the most familiar examples for Finns is *Burana*® (ibuprofen), Finland's best-selling painkiller. The *Easyhaler*® range of inhaled asthma medicines is marketed by partners broadly across Europe. Non-medicinal products, such as the *Aqualan*® creams, and the multivitamin *Multivita*® are examples of highly relied non-medicinal Orion products sold by pharmacies and manufactured under the same strict criteria as ordinary medicines although they are not categorised as pharmaceuticals in the legal meaning.

Currently, about 70% of the Specialty Products net sales are generated in Finland, where Orion's solid market position is largely based on its extensive range of basic medicines covering almost all of the most common illnesses. Orion is the largest player in Finland both in terms of the wholesale value and the number of packages sold. In self-care products, Orion has had the greatest

market share for years. In 2007, Orion products accounted for almost a quarter of the total wholesale value of self-care products.

A significant proportion of prescription drugs in Finland fall under the scope of generic substitution. The company aims for an affordable Orion alternative to always be available in pharmacies for a substitutable drug. As a Finnish player, Orion also has a unique competitive advantage: the ability to ensure uninterrupted availability and reliable supply for its entire product range.

As a result of active product development and in-licensing activity Orion is introducing an expanding range of favourably priced preparations for primary care in its European sales territories. In the Scandinavian markets, also self-care products offer good growth opportunities for Orion.

By establishing a broader presence for the Specialty Products division Orion is goal-orientedly building a working pattern that will enable Orion to market future proprietary drugs throughout Europe via its own sales organisations. With a credible presence in the market, Orion becomes an increasingly attractive partner for other pharmaceutical companies.



### Easyhaler®

One example of the Specialty Products division's know-how is the reliable and easy-to-use *Easyhaler®* inhaler technology.

The first Easyhaler was brought to market in 1994, and sales of the renewed and extended product family are boosted by an expanding

network of international partners. Orion has already developed several formulations of respiratory drugs for the Easyhaler.



Pet owners are taking ever better care of their pets' wellbeing.





# Animal Health

One of the leading players in the Nordic countries

Orion is one of the leading players in veterinary medicines in the Nordic countries. The product portfolio marketed by Orion includes both proprietary and generic drugs for livestock, domestic animals and pets. Products of several international manufacturers are represented in the versatile range. Pfizer, the world's largest in veterinary medicines, markets and sells Orion's animal sedatives outside the Nordic countries.

The proprietary drugs *Domosedan*<sup>®</sup>, *Dexdomitor*<sup>®</sup>, *Domitor*<sup>®</sup> and *Antisedan*<sup>®</sup> are major products for the Animal Health business. Domosedan is used for the sedation of large animals, mainly horses, for veterinary examinations and procedures. Domitor is the corresponding product for small animals, such as cats and dogs. Dexdomitor, which is currently being introduced into global markets, is the latest product in the family. Antisedan is an antibody to these sedatives, used for waking up animal patients quickly and safely after procedures.

Other veterinary products include prescription-free parasite drugs for cats and dogs, ketoprofene painkillers for cattle in particular, and the *Aptus*<sup>®</sup> well-being range.

Orion aims to maximise the outputs of human drug development by studying their opportunities in veterinary medicine too.

The Animal Health division accounts for about ten per cent of Orion's net sales. Growth is generated by sales of proprietary drugs as well as by expanding into eastern Europe.



Fermion's production facility in Hanko manufactures active ingredients for Orion's proprietary drugs and for other pharmaceutical companies.



# Fermion

## Active pharmaceutical ingredients

Fermion has a strategically important role in the Orion Group's Pharmaceuticals business, as it primarily manufactures the active ingredients for Orion's proprietary drugs – entacapone, levosimendan, toremifene, detomidine, medetomidine, dexmedetomidine and atipamezole. Fermion also manufactures and sells ingredients to other pharmaceutical companies.

In total, Fermion has high-standard documentations and manufacturing processes for about thirty active pharmaceutical ingredients, such as the cancer drugs methotrexate and azathioprine, as well as the antidepressant trazodone. Six per cent of it's pharmaceutical net sales.

It is strategically important for Orion to have a complete control of the entire supply chain for its proprietary products. Fermion has extensive special know-how in the manufacture of pharmaceutical substances. The company's process technologies and systems meet the strictest standards set by authorities on the production of active pharmaceutical ingredients. In its international customer relations, Fermion's key competitive advantages lie in its cutting-edge technology based on innovations, reliability of delivery, dependability, high quality and cost-effectiveness.

Fermion's production facilities are located in Hanko and Oulu, Finland. The company also has a pilot unit in Espoo, Finland, for testing and developing the production of new active pharmaceutical ingredients.

# Orion Diagnostica

## Point-of-care tests for primary healthcare and hygiene

Orion Diagnostica manufactures *in vitro* diagnostic tests and systems for diagnosing patients in hospitals, health centres and clinics. It is increasingly focusing on point-of-care tests, which physicians and nurses use to diagnose diseases and to monitor the effectiveness of treatment during patient consultations and in small-scale laboratories. Orion Diagnostica's products are marketed globally.

A correct and rapid diagnosis is to every patient's advantage and also benefits all other parties involved in healthcare. Physicians are able to start treating their patients quickly; and the diagnostic method used to evaluate and monitor the patient's condition and required treatment also notably affects the overall efficiency and cost of healthcare.

Diagnostic methods are moving towards easier-to-use, faster and more reliable tests, as well as the combination of diagnostics with suitable medication. The leading brand in Orion Diagnostica's product range is *QuikRead*®, and the CRP test is its most successful application. A blood sample taken from the fingertip is measured for

its C-reactive protein (CRP) content, with a raised value often indicating bacterial infection. The results of the CRP test, combined with the patient's symptoms, help physicians decide whether the patient is suffering from a viral or bacterial infection, and whether or not a course of antibiotics is required.

The *UniQ*™ collagen tests that measure bone metabolism help physicians treat osteoporosis, among others. These tests are extremely sensitive. For example, even if evidence of change is not yet visible in bone density measurements, the ICTP collagen test can reveal metastatic tumours resulting from breast cancer. The PINP test, which measures bone formation, can also be used to monitor treatment of osteoporosis.

Some of Orion's diagnostic tests are used in highly automated hospital laboratories, including those for hormonal, bone, connective tissue, gastroenterological and specific protein assessment. Orion also engages in contract manufacturing of diagnostic products for other companies.

### Examples of point-of-care products

- Turbox*®** an analyser that measures proteins and can be used to assess 18 different proteins from plasma, blood or urine samples.
- Diarlex*®** a test which reveals rota and adeno viruses from faecal samples.
- Uricult*®** a urinary tract infection test which came onto the market 40 years ago as a pioneer and still enjoys stable demand.

### Hygiene tests for a variety of industry sectors

- Hygicult*®** tests are used for monitoring microbial loading in, for example, the food and cosmetics industries and in commercial kitchens.
- Easicult*®** tests are used to measure microbial loading in industrial fluids and liquid fuels in order to optimise use and warehousing times. Easicult users include the paper industry, airlines and oil companies.



**The Hygicult-On test is an easy and reliable method for monitoring hygiene in, for example, kitchens of institutional catering service providers.**



**Researchers Kari Vahervuo (front) and Bert Van Veen are engaged in formulation development at Orion's laboratories for pharmaceutical R&D in Espoo. In the picture they are investigating how to improve the dissolution of a poorly soluble pharmaceutical ingredient.**



# Research and product development

The focus in Orion's pharmaceutical R&D is on early research, i.e. preclinical as well as clinical Phases I and II, whereas the large-scale Phase III trials are preferred to be conducted together with partners selected for further development and marketing.

Orion invests an annual average of about 15% of its pharmaceutical net sales in research and product development, a work field of about 700 people.

Orion's R&D organisation has set a challenging goal for itself: to be the best R&D organisation by 2017. Characteristic of such an organisation is leadership which encourages innovation as well as the search for and application of all available intelligence, an organisational structure optimised to implement the strategy, and a strategy resulting in a balanced product portfolio and enabling the application of new technologies.

## **SCIENTIFIC EXPERTISE AND HIGH TECHNOLOGY ARE ORION'S STRENGTHS**

Scientifically competent researchers make the platform for innovative and productive pharmaceutical research. Orion has the power and agility of a small company but also has all the resources and hands-on experience to conduct projects through all the research phases and to attend to the application and maintenance of marketing authorisations. The management of product life cycles is also a competence area. This means, for example, the

identification of additional indications, or the development of new and more versatile formulations for administering the drug.

The profile of an investigational compound may sometimes prove to be less optimal for the intended purpose. Research will then continue using back-up molecules. Lead molecules and their back-ups are constructed using computer-assisted molecule modelling and structural design. Computer-assisted molecule screening and modelling have accelerated steps and increased efficiency in early research, because they not only reduce the mass screening workload of laboratories but also generate a greater variety of ideas on optimal molecule structures. It is also important that computer models can be continuously fine-tuned on the basis of information gleaned on the target protein and the structural effects of the substances being studied.

The level of technology at all of Orion's research facilities is competitive in global terms. New technologies are deployed if they can yield substantial added value to in-house research.

## **FOCUSED AREAS OF RESEARCH**

Orion's core expertise areas in pharmaceutical research are selected target proteins, enzymes and receptors. One of the particular strengths Orion draws on is the knowledge it has gained on the structure of the target



proteins studied, their cellular mechanisms of action and the behaviour of the compounds in the body. Work focuses on indication areas for which research models that predict efficacy and safety have been developed over the years.

#### COMT enzyme

High-calibre scientific knowledge of the COMT enzyme (catechol-0-methyltransferase) and the role it plays in the treatment of Parkinson's Disease has played a key role in Orion's drive to go international and its growth into a company known for reliable treatments for Parkinson's. On this path, Orion is developing a new COMT inhibitor that is even more efficacious and longer-acting than entacapone.

#### Alpha<sub>2</sub> receptors

Research in adrenergic alpha<sub>2</sub> receptors, which belong to the large family of G protein-coupled receptors, has already yielded four proprietary drugs for Orion. Basic scientific research in this area has proceeded rapidly and the systematic development of new specific compounds acting on alpha<sub>2</sub> receptor subtypes is on the horizon. Orion is actively studying opportunities for the use of alpha<sub>2c</sub> receptors in the treatment of the symptoms of schizophrenia and depression, for instance.

#### Androgen receptor

Research in urological and oncological therapies focuses on hormonal nuclear receptors. In recent years, Orion's researchers have identified many active ingredients affecting the male hormone (androgen) receptor. In

this area, Orion seeks to develop new treatments with testosterone-like favourable effects on muscle mass and bones, for instance, but without the unfavourable effect of enlarging the prostate. Unmet needs in this therapy area also offer potential for new prostate cancer treatments.

#### Diagnostic products

In diagnostics, Orion has strong specialist expertise in the development of easy-to-use and quick methods, especially in point-of-care testing of infectious diseases, hormones, specific proteins and bone metabolism. The transition in the product range to rapid point-of-care tests has strongly steered product development to meet the needs of customers that use those tests, i.e. minor clinics and doctor's offices. The leading product family in this area is the *QuikRead*<sup>®</sup> system, which is under intensive development at Orion. In focus are also tests like the unique *UniQ*<sup>™</sup> collagen tests.

#### SIGNIFICANCE OF NETWORKING AND CO-OPERATION

When companies seek new ideas and research avenues to add to their existing development projects, networking with academic researchers and biotech companies becomes most important. Orion has an active and extensive collaboration with Finnish and foreign research groups. Examples of most recently established partnerships are those with the Indian-based Aurigene, the Swedish Oasmia and the Finnish Medeia, as well as Orion's decision to sponsor the FIMM, the newly established Institute for Molecular Medicine Finland.



**Researcher Markku Kaija places samples in a micronisation device at Orion's R&D laboratory in Espoo.**

## Orion's pharmaceutical innovations

**Detomidine** (Domosedan<sup>®</sup>, a sedative for animals), **medetomidine** (Domitor<sup>®</sup>, a sedative for animals) and **dexmedetomidine** (Precedex<sup>®</sup>, a sedative for human patients in intensive care, and Dexdomitor<sup>®</sup>, a sedative for animals) affect numerous nervous systems via the adrenergic alpha<sub>2</sub> receptors. When the molecules bind to this receptor, they activate it causing a sedated condition in which also stress reactions and pain are alleviated. Atipamezole (Antisedan<sup>®</sup>) is their antibody. When atipamezole binds to the same alpha<sub>2</sub> receptors, it prevents their activation. The blocking of alpha<sub>2</sub> receptors increases nerve cell activity and awakens the patient.

**Entacapone** is Orion's most significant molecule innovation. It is a drug that enhances the effect of levodopa, the basic medication for treating Parkinson's Disease. It works by inhibiting the harmful effects of the COMT enzyme on levodopa. Entacapone acts in the Comtess<sup>®</sup> and Comtan<sup>®</sup> preparations, as well as in Stalevo<sup>®</sup>, which contains levodopa, entacapone and carbidopa in one tablet, the two latter substances enhancing the therapeutic effect of levodopa. Treatment with Stalevo and Comtess/Comtan extends the time when the symptoms are under control, and improves the patient's quality of life more than treatment with conventional levodopa, i.e. without COMT inhibition.

**Levosimendan** is the active ingredient in Simdax<sup>®</sup>, the heart failure drug used intravenously at cardiac monitoring and intensive care wards at hospitals. It is a compound that in the presence of calcium binds to the troponin C protein of the cardiac muscle. Levosimendan sensitises the heart muscle to the calcium contained in the muscle's cells and thus increases heart muscle contractility without raising the heart's oxygen consumption. In addition, it dilates veins by opening their potassium channels, thereby improving blood circulation to vital organs. Both mechanisms improve blood circulation to the body and tissue through the heart. Levosimendan is the active ingredient in Simdax<sup>®</sup>, the heart failure drug used intravenously at cardiac monitoring and intensive care wards at hospitals.

**Toremifene** is an antiestrogen developed by Orion. It is the active ingredient in the breast cancer drug Fareston<sup>®</sup>. Toremifene binds to the estrogen receptors of cancer cells, preventing the body's own estrogen from stimulating cancer cell growth. The American company GTx, Inc. is currently studying toremifene for prostate cancer indications.





Seamless cooperation between many professionals is required in the production of pharmaceuticals.

# Supply Chain

The role of the Supply Chain organisation is to manufacture products and to ensure their deliveries to the customers at the right time as efficiently, economically and reliably as possible. About 950 people work in the supply chain and related quality assurance at Orion's plants in Espoo, Turku and Kuopio, Finland. Each plant specialises in certain types of products. The manufacture of diagnostic products

has been partially integrated into the supply chain of pharmaceuticals.

## **SEAMLESS MANAGEMENT OF THE WHOLE CHAIN IS A MUST**

Large amounts of capital are tied up in the Supply Chain functions. For this reason, it is important to run operations



Rational capacity utilisation is crucial for the cost-effectiveness of the supply chain.



under optimised control, with high cost effectiveness and capacity utilisation, and with rapid turnover of the stocks of materials and finished products. An information system providing complete control – from procurements, forecasts and the inventory status all the way to customer inventories – is an indispensable tool. Correct prediction is important in ensuring that wholesalers have enough products to meet demand.

Orion's production program includes about 300 products. They are sold in about 6,000 versions of packages. For instance, over two billion tablets are produced

annually. In line with its strategy, Orion takes advantage of networking in production as well. It is rational to outsource the manufacturing of some products. For the same reason, Orion serves as a sub-contractor for other pharmaceutical companies. By rational allocation of the capacity we can significantly influence the cost-efficiency of the Supply Chain operations, a key competitive tool. Efficiency also means minimising the lead times of batches and the ability to rapidly switch a production line for another tablet strength or an entirely different product. For instance, the *Stalevo®* and *Comtess®/Comtan®* franchise includes many



tablet strengths and forms, and a great variety of packages for different markets.

The Supply Chain organisation also comprises the procurement function, which handles purchases of materials from external sources. The company seeks cost-efficient sourcing, relying on a few preferred providers for items such as technical and packaging materials. On the other hand, the number of sources for pharmaceutical ingredients is broad, because only a limited selection of substances is available from one supplier.

As Finland's leading pharmaceutical company, Orion has made contingency plans for societal emergencies. To ensure its operational viability under exceptional circumstances, Orion maintains reserve stocks of the most critical active ingredients, other substances required in drug manufacture and packaging materials in excess of its own requirements.



### Only correctly taken medicines help

The product leaflet provides the most elementary information on the drug and its use. The patient can ask his/her attending physician or a pharmacy for more information. It is important to take the drug as prescribed and to store it in the

right conditions. Drugs should not be used after their expiration date. Expired drugs should be taken to a pharmacy for disposal. Doubtful products should also be returned to the pharmacy, which will send it back to the manufacturer.

# The quality of a drug is the outcome of a seamless chain

Orion is committed to developing and producing high-quality pharmaceuticals and diagnostic products that are used for diagnosing, treating and curing diseases, monitoring treatment and maintaining health. Due to its nature the business is subject to stringent supervision. Operations are guided by special legislation, numerous official regulations, comprehensive permits, licenses and reporting procedures as well as regular inspections by the pharmaceutical supervision authorities. Within the EU, the highest regulatory body in the pharmaceutical industry is the EMEA, European Medicines Agency, and its counterpart in the United States is the FDA, Food and Drug Administration. The medicinal authority in Finland is the National Agency for Medicines.

In addition to regulatory provisions, Orion's operations are guided by ethical principles concerning products and healthcare in general, as well as the values of Orion as a working community.

Quality along the entire chain of operations hinges on compliance with good practices based on EU provisions, process efficiency and functionality, the safety and consistent quality of products as well as delivery reliability.

## THE MARKETING AUTHORISATION HOLDER CARRIES THE RESPONSIBILITY

As a drug manufacturer Orion is responsible for ensuring that its products fulfil the requirements of the Medicines Act and boast faultless quality. Manufacture and quality control must comply with the set provisions. Pharmaceutical manufacturers must also use production methods that comply with EU provisions. This applies to outsourced products too. When outsourcing, Orion settles on the responsibilities and technical details of the sub-contractor in specific quality agreements. Orion also verifies the appropriateness of the contract manufacturer's qualifications by making on-the-spot audits.

Each drug is available on the market under a product-specific marketing authorisation granted by a regulatory authority. In order to obtain marketing authorisation, the product must be demonstrated to be medicinally purposeful and safe, and it must fulfil the production and quality requirements set for active ingredients, pharmaceutical preparations and formulations in the official guidebook, the pharmacopoeia. Furthermore, its composition and other information must be appropriately documented and provided.

As the marketing authorisation holder, Orion is responsible for the quality and safety of its products as well as the compliance of its facilities and processes to the regulatory authorities.

## FULL TRACEABILITY

Orion acquires active ingredients from suppliers whose operational quality has been verified. All the materials used in pharmaceutical manufacture and packaging are inspected before being approved for use in production. Pharmaceuticals are manufactured in validated processes in accordance with Good Manufacturing Practices. Each product batch is inspected and verified before market release. These procedures ensure the uncompromised safety and quality of the drugs. All materials and stages of manufacture, quality assurance and distribution can be seamlessly traced on the basis of the batch number on the product package. Orion maintains constant readiness to rapidly recall a product batch from both wholesale and retail distribution. All complaints and quality deviations are logged and examined thoroughly.

Extreme responsibility is required from the manufacturers and marketers. The safety of a drug is constantly monitored throughout the time it is on the market. Consistent follow-up and reporting to the authorities ensure that the benefits outweigh the adverse effects. Orion files all feedback on the quality of its products everywhere they are used, and evaluates this feedback systematically.

# 10

## Building environmental well-being

Environmental aspects are an unseparable part of high-quality manufacture of pharmaceuticals and diagnostic tests. Orion takes environmental impacts into consideration in every stage of product development and manufacture. Also contract manufacturers, vendors and other partners are requested to comply with the same high standards of managing environmental affairs as Orion itself has. The compliance and appropriateness of the operations of partners are ensured by means of quality agreements, audits and other procedures. Orion continuously hones its environmental compliance to reduce the environmental load of its operations.

The company's safety policy also obligates to identify the environmental impacts of the decisions and solutions, to develop operations to preserve the diversity of nature, and to establish procedures in case of accidents.

### EMISSIONS UNDER CONTROL

Orion's plants represent high technology. In its laboratories, manufacturing processes and quality assurance Orion uses up-to-date methods meeting the quality, safety and environmental requirements of pharmaceutical authorities, marketing partners and contract manufacturing customers. The company monitors the environmental impacts of its operations by measuring emissions and keeping track of waste and the volumes of substances and energy consumed. Despite increased production volumes, the company has kept its environmental compliance well under control: methylene chloride emissions have declined, recycling of waste has been stepped up, and relative energy consumption has decreased. Even hazardous waste is converted to energy.

Strict requirements have been set for the conditions and the cleanliness of the production premises. Manufacturing processes are as closed as possible to ensure the physical and microbiological purity of the products. The inflow and outflow air of the production facilities undergoes multi-stage changing and filtering. Volatile organic compounds emitted into the outdoor air are minimal. Emissions from chemical processes are controlled effectively with condensers and scrubbers. Solvent emissions are minimised using modern process technology and upgrading the manufacturing processes so that the need of volatile solvents is kept to a bare minimum.

### CONVERTING WASTE INTO ENERGY

Solvents are the major focus of Orion's emissions control. Solvent emissions result from production phases like filtering, drying, granulation, tablet coating and the washing of process equipment. The most harmful solvent is methylene chloride, which has been successfully phased out in tablet production, but remains indispensable and irreplaceable in some of Fermion's processes. Methylene chloride emissions were, however, brought under effective control when the new solvent gas treatment facilities were taken into use at Fermion's Oulu and Hanko plants in late 2007. These facilities combust the solvent gases into non-hazardous compounds and also generate energy into Fermion's processes. In Hanko, about as little as 0.5 per cent of the solvents consumed evaporate into the air, while the permit allows 5.0 per cent. The corresponding limit at the Oulu plant is 15 per cent.

Orion provides environmental information on its website, [www.orion.fi](http://www.orion.fi).



The year 2007 has been one for environmental investments. Fermion's plants in Hanko and Oulu have received modern facilities where the solvent and exhaust gas emissions are

combusted and converted into energy for use in the production processes. This picture shows the solvent gas treatment facility at Hanko.

Orion offers inspiring and challenging career opportunities for specialists in many fields.





# Orion is a working community of versatile professionals

Orion is a working community with about 3,200 members. Over 2,600 of the employees work at the Group's Finnish locations. A total of about 500 people in 16 countries work for the foreign subsidiaries and representative offices, most of them in marketing. Orion is the largest employer in its field in Finland. The hundreds of job titles of its staff cover the whole field, from research to manufacture, marketing and administration.

The average length of employment at Orion is 11.5 years. Of the personnel, approximately 23% are blue-collar workers and 77% clerical employees. About 93 per cent are in a permanent employment relationship. About one per cent of all employees work part-time.

The pharmaceutical industry offers the chance to work in an international environment and a great variety of challenging career opportunities for experts in different fields. Orion needs a wide range of specialists, ranging from the natural and medicinal sciences to business, mathematics, technology, IT and the humanities. Physicians, chemists, pharmacists, nurses and laboratory technicians have a good educational background for a job at Orion. The pharmaceutical industry trains some of its employees on its own, like sales representatives, for instance.

Orion wants and needs competent employees in order to succeed. The company's success is dependent on its ability to hire, develop, train and motivate professionally skilled personnel. Human resources management aims to ensure the competence, motivation and well-being of employees, the continuous development of the working community and precise resource planning.



Human resources management is based on Orion's values and the equitable and fair treatment of employees. In human resource matters, Orion complies with legislation, collective agreements, work safety regulations and other obligations without compromise.

#### **FAR-SIGHTED DEVELOPMENT**

Orion takes a long-term approach to the development of expertise and the working community. Orion's supervisors have participated in Group-wide coaching on Orion's approach to management for many years. The results of development efforts are tracked annually by means of regular working climate measurements and parameters of leadership and managerial work.

The professional skills of the employees are developed constantly and systematically. The personal needs are revisited in the regular appraisal discussions annually. Orion also has a mentoring programme in which top experts pass on information and experience – "tacit knowledge" – to younger colleagues. Expertise is also developed by means of career planning and purposeful job rotation. Career planning aims to nurture motivated and multi-skilled employees.

#### **ENSURING WELL-BEING AT WORK IN MANY WAYS**

Orion has a versatile toolkit for supporting the occupational well-being of its personnel. A particular life phases programme attends to the occupational fitness of people of all ages in different situations in life. Health checkups are performed by age group to evaluate occupational fitness and the need of measures to maintain it, such as "shape-up" courses that are sponsored by the company. In addition, Orion supports the motional and fitness activities of the personnel in many ways and maintains recreational

facilities for its employees in different regions. Fitness vouchers are in active use. Systematic assessments of the workplace and risks are carried out to continuously develop working conditions.

#### **OCCUPATIONAL SAFETY IS EVERYBODY'S CONCERN**

At Orion, safety issues are led and supervised by a Group-level safety management team. It is responsible for the overall development of safety activities and sets development objectives for the safety committees for the different parts of the Group.

General instructions on safety and exceptional situations are provided in the Safety Guide, which underlines the obligation of all Orion employees to maintain safety and never to consciously violate safety instructions, endanger people's safety or damage property.

#### **INFLUENCING OPPORTUNITIES AND CO-OPERATION**

The management is in regular and uncomplicated dialogue with the personnel. The European Works Council (EWC) convenes each year bringing together the management and personnel representatives over national borders. Management and employee representatives meet at national and local councils numerous times a year. A representative of the employees is a member of the Executive Management Board of the Orion Group.

#### **HUMAN RESOURCES POLICY FOSTERS EQUALITY**

Orion respects human rights. Orion's human resources policy aims to promote gender and generational equality in the working community. A person may never be discriminated against on the basis of his or her age, gender, religion or ethnic background at any time while at Orion.



## Orion Group personnel by country in December 2007

Finland total	2 675
Scandinavia	131
Germany	131
UK and Ireland	59
Other European countries	180
Foreign countries total	501
<b>Orion Group total</b>	<b>3 176</b>



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## Persons in pictures:

- Page 2: Warehouse worker Matti Piira  
Page 3: Graduate student Heidi Silvennoinen, operator Joni Mild  
Page 4: Research Associate Tiina Järvinen, operator Tuula Talasterä  
Page 7: Laboratory Technician Kirsi Haaja, graduate student Heidi Silvennoinen  
Page 8: Business Manager Stiina Ylikangas, Head of Study Management and Medical writing Eeva-Riitta Kultalahti, Group Controller Kari Kantola, Research Scientist Mikko Mäkelä  
Page 11: President and CEO Timo Lappalainen  
Page 17: Product Manager, Psychiatric Products Camilla Nyberg  
Page 28: Operator Kirsi Heinonen  
Page 32: Senior Specialist Kari Vahervuo, Senior Development Manager Bert Van Veen  
Page 33: Research Assistant Lari Saukko, graduate student Heidi Silvennoinen  
Page 34: Research Associate Satu Paalanen  
Page 35: Research Scientist Marko Kaija  
Page 36: Warehouse worker Matti Piira, Warehouse worker Ville Nyberg, Storekeeper Ossi Heikkinen  
Page 37: Packaging Technology Assistant Säde Lindell, granulation process operator Oke Kallio  
Page 38: Laboratory Technician Kirsi Haaja, operator Henriette Piironen  
Page 39: Operator Tuula Talasterä, Export shipper Kivo Pennanen  
Page 40: Laboratory Technician Kirsi Haaja  
Page 44: Research Associate Maria Laaksonen, Research Associate Tiina Järvinen, Warehouse worker Matti Piira, Group Controller Kari Kantola, Research Scientist Mikko Mäkelä  
Page 46: Granulation process operator Oke Kallio, Business Manager, Urology&oncology business Stiina Ylikangas, Head of Study Management and Medical writing Eeva-Riitta Kultalahti, Export shipper Kivo Pennanen  
Page 47: Product Manager, Psychiatric Products Camilla Nyberg, operator Tuula Talasterä, Driver Mauri Kaikkonen

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