

# Annual Report 2010





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Swedish Orphan Biovitrum AB's (publ) 2010 annual report can be downloaded in pdf format from www.sobi.com and the printed version is also available at our headquarters.

Swedish Orphan Biovitrum is a Swedish public limited company subject to Swedish law. Numerical data within parentheses relate to 2009 unless stated otherwise. Millions are expressed as SEKM or SEK million.

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# Sobi in brief

Swedish Orphan Biovitrum (Sobi) is a leading European specialty pharmaceutical company focusing on rare diseases. Key areas are hematological diseases, autoimmune diseases, hereditary metabolic disorders, and therapeutic oncology.

Our product portfolio currently includes about 60 marketed products, as well as a growing number of projects in late stage clinical development. In 2010 Sobi had SEK 1.9 billion in revenues and about 500 employees. The Sobi share (STO:SOBI) is listed on NASDAQ OMX Stockholm.

More information is available at www.sobi.com

### Key figures

	2010	2009 Proforma	Example of
Total revenues, (CER¹)	2,011.4	2,065.6	Förändring -3%
Total revenues, (CER')	2,011.4	2,003.0	-3/0
Total revenues	1,906.7	2,065.6	-8%
Cost of goods and services sold	-685.7	-664.3	3%
Gross profit	1,221.0	1,401.3	-13%
	.,	.,	
Sales and administration expenses	-531.3	-499.7	6%
Research and development expenses	-479.8	-603.1	-20%
Other operating revenues/expenses	162.0	-24.9	
Operating profit/loss before amortiza-			
tions and non recurring items (EBITA)	371.9	273.6	36%
Non-recurring items	-87.7	_	
Amortization	-294.4	-201.6	
Operating profit/loss (EBIT)	-10.2	72.0	
Profit/loss after financial items	-92.4		
Profit/loss for the period	-104.4		
Margins			
Gross margin	64.0%		
EBITA-margin	19.5%		
Per share data (SEK)			
Core earnings per share <sup>2</sup>	1.26	0.84	
Earnings/loss per share after dilution <sup>3</sup>	-0.53	0.32	

- 1) Actuals 2010 converted to the previous year's average exchange rate.
- Core EPS is calculated from P/L for the period excluding amortization of intangible assets and restructuring and other extra ordinary items and calculated on average number of shares.
- 3) Comparison numbers adjusted for new share issue completed in 2010.

#### 2010



The acquisition of Swedish Orphan International Holding AB was completed in January.

Certain previously agreed future milestone payments for Kineret® and Kepivance® were paid in advance to the American company Amgen.

The partnership agreement with the American company Biogen Idec regarding the development projects in hemophilia, rFVIIIFc and rFIXFc, was restructured.

The first patients were enrolled in the rFIXFc registration trial for treatment of hemophilia  ${\sf B}.$ 



A decision was taken to advance Kiobrina® to clinical phase III and the results from the first clinical phase II trial were published.

An agreement was signed with the Dutch company Pharming Group for exclusive commercial rights to Ruconest $^{\text{TM}}$  in 24 EU countries for the treatment of hereditary angioedema (HAE).

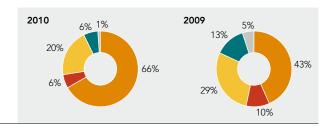
A long-term supplier agreement was signed with the German company Boehringer Ingelheim for commercial production of the active ingredient in Kineret®.

The distribution agreement with Merck Serono for Cyanokit® (Cyanokit is an antidote for treatment of known or suspected cyanide poisoning) was expanded to include Ireland, the UK and the Netherlands, in addition to the Nordic and Baltic countries.

In accordance with the distribution agreement with the French company LFB, Willfact® was launched in Germany.

# Revenues by product segment

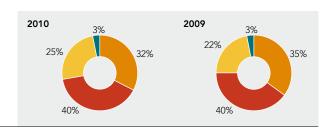
Total revenues	1,906.7	1,297.0
Other		0.1
Licensing and milestone revenues	23.6	62.6
■ Royalty revenues	109.7	165.7
Manufacturing and contract development	388.0	376.5
■ Co-promotion revenues	123.0	127.3
■ Product Sales	1,262.4	564.8
Amounts in SEK million	2010	2009



### Product revenues by region

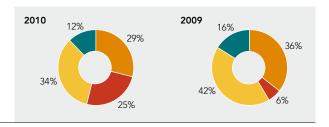
(excluding ReFacto manufacturing-, royalty-, licensingand milstone revenues)

Total	1,385.4	1,460.8
RoW	43.5	43.0
■ North America	340.2	318.2
■ Europe	551.3	587.7
■ Nordic	450.4	511.9
Amounts in SEK million	2010	2009 Proforma



# Avarge number of employees by function

Operations			
■ M&S			
■ FoU			
■ Other			
Total			





The main elements in a declaration of intention to form a strategic business alliance with the Chinese company Dongbao were announced.

The results of phase I/II study of rFIXFc, showing about a three-fold increase in half-life, were presented.

A decision was taken to advance the hemophilia A rFVII-IFc project to phase III. rFVIIIFc was granted orphan drug designation within the EU.

Kineret® was granted orphan drug designation in the US for cryopyrin-associated periodic syndromes (CAPS). CAPS belongs to a family of autoinflammatory diseases.

In September it was announced that distribution agreements with Shire for the products Xagrid®, Fosrenol® and Equasym® will expire in 2011.



The first patient was included in the global registration trial (phase II/III) for rFVIIIFc for treatment of hemophilia A. rFVIIIFc also received orphan drug designation in the IIS

Dongbao granted, through its subsidiary Rechon Life Science Ltd, distribution rights for Iron Sucrose Rechon in Europe to Sobi. Iron Sucrose Rechon is an intravenous formulation of iron, used to treat anemia.

An agreement was reached with the Welsh company Micropharm that entails continued rights primarily in the Nordic countries to distribute ViperaTAb^TM, which is used to treat viper berus bite.

CEO'S COMMENTS:

# An intensive first year



# » By combining Biovitrum with Swedish Orphan we have created a strong platform for profitable growth.«

The merger of Biovitrum and Swedish Orphan, which was completed in January 2010, formed a leading European specialty pharmaceutical company with a focus on rare diseases.

By combining Biovitrum's strength in research and production with Swedish Orphan's international marketing organization and extensive experience of business development, we have created a strong platform for profitable growth.

### Rapid integration

The two operations were rapidly integrated and since May 2010, all functions except production are now gathered in new premises within Karolinska Science Park in Solna.

In 2010 efficiency measures were implemented mainly in the administrative functions, which affected a total of about 50 positions. Efficiency measures were also implemented in both production and distribution. We also introduced a single unified internal system for safety reporting relating to our pharmaceuticals and projects, which also entailed significant cost savings.

Efficiency measures were also implemented on the system and purchasing side, such as purchasing statistics. In line with the growth strategy adopted following the merger, we increased our sales and marketing initiatives during the year. We began to build up a marketing organization in the United States and continued to expand the organization in Europe. In early 2011 we implemented changes and broadened the management team to better reflect the company's focus on international growth. At the same time the number of people working in business development more than doubled.

# New business agreements and expansion of product portfolio

During the year we signed several important business agreements, both to increase our market presence and to expand the product portfolio. An agreement was signed with Pharming Group BV in the Netherlands, enabling Sobi to distribute and sell Ruconest™ beginning in 2011 in 24 EU countries, as well as in Norway, Iceland and Switzerland. Ruconest™ is used by

patients with the rare disease hereditary angioedema (HAE). The product received final marketing approval in Europe in October. Through our partnership with LFB BIOMEDICAMENTS we began to distribute Willfact® in Germany during the second half of 2010. We expect to begin distributing this medication in about ten countries in Europe during the second quarter of 2011.

Willfact® is used to treat von Willebrand's disease, a type of bleeding disorder, and will further strengthen our position in the hemophilia area.

We continue to actively search for partners in the largest countries in Asia. As part of this initiative, in early 2011 we entered into an agreement with the Korean company BL&H CO. LTD for distribution of Orfadin® and Kepivance® in South

Korea. We expect registration of both products to take about one year. License sales will begin in 2011.

With respect to the research portfolio, the hemophilia projects rFVIIIFc and rFIXFc, which we are developing together with Biogen Idec, are proceeding according to plan. We also took a decision in 2010 to advance Kiobrina® into phase III development. Kiobrina® is used to prevent growth retardation in premature infants and is being developed completely by Sobi. The work of further developing Orfadin® and Ammonaps® continued according to plan, as did producing a reformulation of Kineret® and expanding the registration of this medication for additional indications. We are therefore also well on the way to strengthening our future commercial product portfolio.

#### Sales and earnings

We had solid sales growth in the United States, mainly for Orfadin®, while sales in Europe declined year on year. Total revenues fell 8 percent to SEK 1,907 M. In comparable exchange rates (CER) and excluding Tracleer® and milestone revenues, total revenues increased by 2 percent. Earnings were negatively affected by the strong Swedish krona in relation to the dollar and the euro, as well as by delayed product launches in several European countries due to delayed decisions by government agencies relating to registrations and price approvals. Government budget problems with accompanying cost-cutting in several European countries also resulted in mandatory price cuts for medications and caution among wholesalers about building up inventories. Price cuts on orphan drugs were, however, generally lower than for other medications.

Due to these factors our financial performance in 2010 fell short of our expectations from the beginning of the year.

#### **Expectations for 2011**

Great uncertainty remains about developments in the global economy and currencies, as well as the impact on the European pharmaceutical market of the government budget problems in many countries.

Nevertheless, I believe that many of our products will have good volume growth. We will also have a number of product launches. The price cuts for medications carried out in Europe in 2010 will reach full effect in 2011, which together with the expected continued negative impact of the strong Swedish krona will entail lower growth in SEK than the underlying volume

trend. The distribution agreements for Tracleer® and several of Shires products as well as the sale of the rights for Mimpara® will entail a revenue loss of a total of about SEK 90 M compared with 2010. We will continue to pursue our sales and marketing initiatives according to plan through our own organization in both Europe and the US, and also expand our distributor network in the rest of the world. The costs associated with the expansion of the marketing organization as well as the investments in phase III development for Kiobrina® will be offset by the previously announced synergies of about SEK 100 M, which will reach full effect in 2011.

# » During the year we signed several important business agreements, that increases our market presence and expands our product portfolio.«

During the first quarter we also initiated an internal project in which we are reviewing procedures, working methods, and priorities within all areas to achieve additional efficiency gains, including those functions that were not particularly affected during the merger of the two companies.

### Long-term goals remain

We are confident that the products in late stage development phases will successfully reach the market within a few years. As I mentioned earlier, we are also increasing our efforts to enter into more collaborative and licensing agreements, and even to make acquisitions. Our long-term financial target remains: to achieve revenues of about SEK 5 billion and an EBITA margin of at least 30% by 2015.

Kennet Rooth, CEO



# Operations and goals

#### Vision

To become the leading European pharmaceutical company in rare diseases with operations established in the United States and with a presence in the rest of the world.

#### **Business concept**

To develop and provide specialty pharmaceuticals and services to patients with rare diseases. The medications can be in-licensed, acquired or developed in-house. Revenues come from product sales, production, royalties and co-promotion.

#### Goals

To assist patients who suffer from rare diseases and have significant medical needs.

#### Financial targets

about SEK 5 billion and an EBITA margin of at least 30% by 2015.

#### Strategy

# Sobi will achieve profitable growth through:

Full leverage of the current product portfolio

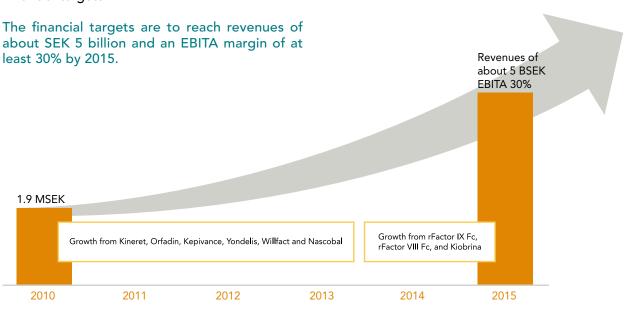
- Existing commercial products
- Ongoing development projects

#### Expansion of the product portfolio

- Through further in-licensing and distribution agreements of commercial products.
- Acquisition of commercial products or products in late development phase.
- Further develop existing products and develop new products based on the company's unique expertise in proteinbased drugs.

#### Continued geographic expansion

- Continued expansion of the organization in Europe and the
- Establish collaboration with more partners in Asia and the rest of the world.









#### Lack of treatment for rare diseases

The lack of satisfactory treatment for many rare diseases results in an increased need for niche drugs.

There are about 7,000 uncommon diseases and the number of people afflicted ranges between 27 and 36 million in the EU alone and about 25 million in the US. These diseases are often life-threatening or cause chronic disability and therefore have a severe impact on patients and their families. Therefore these patients require specialist care. Less common diseases are largely neglected because of inadequate diagnostics and insufficient research. Too many diseases still lack satisfactory treatment.

Even though these patient groups are relatively small and prescriptions are limited in quantity, niche drugs have a significant market potential. Due to the significant medical need and relatively low number of patients per disease, development of these medications does not require as extensive resources as medications that focus on the large common diseases.

#### **Operations**

Operations include all areas of applied research and development, production, distribution, marketing and customer support. The company has years of experience of research and drug development, mainly within protein-based drugs. The sales organization is extensive in Europe with its own marketing companies in 11 countries as well as offices in nine other countries. Sobi is also well-represented through partners in the Middle East, Israel, Australia and New Zealand. An organization is being established in North America.

#### New organization

Sobi was formed when Biovitrum AB acquired Swedish Orphan international AB. The acquisition was announced in November 2009 and completed in January 2010.

The acquisition brought Biovitrum a European marketing organization and its product portfolio expanded by about fifty products.

Both operations were successfully integrated during the year. To achieve synergies and benefits of scale efficiency measures were implemented, particularly in the administrative functions. The marketing organization was divided into the regions Northern Europe, Central Europe, Western Europe, Central/Eastern Europe and the US.

The respective distribution networks for Biovitrum and Swedish Orphan International were integrated to streamline and simplify distribution of products to customers.

#### Production

Sobi's own production takes place in two facilities, one in Stockholm and one in Umeå. External contract manufacturers are also used for certain products.

Sobi is the global producer of the active ingredient in Pfizer's drug ReFacto AF®/Xyntha®, a protein used to treat hemophilia. Production takes place in the Stockholm facility. An upgrade was carried out in 2010, including replacement of the culture control system, which will provide greater delivery reliability. During the year ReFacto protein was delivered according to plan and we also produced test sessions that completed an upscaled purification process, a

change that in the long-term will lead to increased production capacity.

The Umeå facility focuses on production of Multiferon®.

The process to transfer production of Kineret® from the US to new contract manufacturers in Europe was initiated in 2010, with completion expected in 2011. The change is planned to be reported to the regulatory authority in autumn 2011, with approval expected in 2012.

### The product portfolio

After the merger with Swedish Orphan the commercial product portfolio consists of about 60 products.

The largest products in terms of sales are ReFactoAF®/Xyntha® for the treatment of hemophilia A, Kineret® for rheumatoid arthritis, Orfadin® for hereditary tyrosinemia type 1, Kepivance® for wounds in the oral cavity from chemo and radiation therapy. Ammonaps® for defects in the urea cycle, Yondelis® as a second-line treatment for soft tissue sarcoma and platinum-sensitive ovarian cancer.

For more information please see the table below. More product information is available at www.sobi.com.

#### Project portfolio

Research includes a number of recombinant protein projects in hemophilia, prevention of growth retardation in premature infants, autoimmune diseases, hereditary metabolic disorders and cancer supportive care. We augment the inflow of new projects from our own research through strategic acquisitions, collaboration and alliances.

The project portfolio includes several projects in late stage clinical development, along with several preclinical projects and projects intended to improve currently available commercial products. In 2010 regulatory authorities approved applications for orphan drug designation for:

- rFVIIIFc for hemophilia A by the EU Commission and the U.S.
   Food and drug Administration (FDA)
- Kineret® for the indication cryopyrin-associated periodic syndromes (CAPS) by the U.S. FDA

The two hemophilia projects (rFVIIIFc and rFIXFc), which are conducted jointly with Biogen Idec, made important advances during the year as both projects have started treating patients in their respective phase III programs.

#### Revenue development by key product

Therapy areas	Amounts in SEK million	Indication	Partner	2010	Proforma 2009	Change
hematological diseases	Refacto®	Hemophilia A	Pfizer	587.1	631.9	-7%
	of which Manufacturing revenues			388.0	376.5	3%
	of which Co-promotion			89.4	89.7	0%
	of which Royalty			109.7	165.7	-34%
	Willfact®	von Willebrands disease	LFB	13.1	1.2	992%
Autoimmune diseases	Kineret®	Rheumatoid arthritis		422.3	440.8	-4%
Hereditary metabolic disorders	Orfadin <sup>®</sup>	Hereditary tyrosinemia type 1		321.8	310.0	4%
	Ammonaps®	Defects in the urea cycle	Ocyclyd	69.1	69.9	-1%
Therapeutic oncology	Yondelis®	Second-hand treatment of advanced soft- tissue platinum-sensitive ovarian cancer	Pharmamar	40.6	43.9	-8%
	Kepivance	Wounds in the oral cavity from chemo and radiation therapy		94.8	109.9	-14%
	Other product revenues			328.4	328.4	
	Total revenues continued products			1,877.2	1,936.0	-3%
	Tracleer	Distribution rights have been returned to Actelion during 2010	Actelion	5.9	66.9	-91%
	Other revenues			23.6	62.6	-62%
	Total revenues			1,906.7	2,065.5	-8%

### Development pipeline

Indication	Product/Project	Partner	Phase I	Phase II	Phase III	Reg Phase
Hemophilia A	rFVIIIFc	BiogenIdec				
Hemophilia B	rFIXFc	BiogenIdec				
Prevent growth retardation in premature infants	Kiobrina®					
CAPS	Kineret®					
Pernicious anemia	Nascobal®	Strativa				

#### Factor IX Fc (rFIXFc) for hemophilia B

rFIXFc is a recombinant manufactured coagulation factor designed to replace the protein that hemophilia B patients lack, but to last longer than today's commercially available Factor IX products. The product is being developed in cooperation with Biogen Idec. The global registration trial, known as B-LONG, began in early 2010. The study is designed to determine the safety, efficacy and pharmacokinetics of long-acting rFIXFc, for both prophylaxis and acute treatment. In 2010 data were presented from the first clinical trial with FIXFc, an open phase I/Ila safety and pharmacokinetics study, in which patients with hemophilia B were treated with incremental doses. The study showed that rFIXFc was well-tolerated with about a three-fold increase in half-life compared with historic data for currently available treatments.

#### Factor VIII Fc (rFVIIIFc) for hemophilia A

rFVIIIFc, like FIXFc, is a recombinant coagulation factor under development in cooperation with Biogen Idec, to replace the protein that patients with hemophilia A lack. Even here, the goal is to obtain a product that lasts longer than commercially available factor VIII products.

In 2010 a decision was taken to advance to phase III and in early December the first patient was treated in a global registration trial. The study, called A-LONG, is a phase II multicenter study to evaluate the safety, pharmacokinetic profile and efficacy of rFVIIIFc in previously treated hemophilia A patients, in both preventive and acute treatment.

In December rFVIIIFc was granted or phan drug designation by the FDA in the United States.

# **Kiobrina®** for prevention of growth retardation in premature infants

Kiobrina® is a recombinant produced bile salt-stimulated lipase (BSSL) developed by Sobi to prevent growth retardation in premature infants who receive pasteurized breast milk or infant formula. BSSL is one of the most important lipase enzymes in premature infants. BSSL is found in fresh breast milk, where it improves breakdown and absorption of essential fatty acids, such as long polyunsaturated fatty acids, which is of great importance for the development of the brain.

In 2010 the second clinical phase II trial concluded with favorable results and Sobi took the decision to advance to phase III.

Kineret® for treatment of other autoinflammatory diseases Kineret® is currently approved for treatment of rheumatoid arthritis. The potential for label expansion by documentation of available data on Kineret® for certain orphan indications is being explored. For example, the FDA granted Kineret® orphan drug designation for the treatment of the rare disease cryopyrin-associated periodic syndromes (CAPS).

#### Nascobal® for pernicious anemia

Nascobal® is vitamin  $B_{12}$  in the form of a nasal spray for patients with pernicious anemia (a serious type of anemia), which is marketed in the United States by Strativa Pharmaceuticals. The rights to register and market Nascobal® in Europe were acquired through an agreement between Swedish Orphan and Strativa before the formation of Sobi. A smaller clinical trial began in late 2010 to meet requirements for registration in Europe. These studies will be completed in the first half of 2011.



### **Partners**

Sobi has a long, successful history of collaboration with partners in all phases of the product life cycle, from drug discovery and development to production and commercialization. Today Sobi's partners include both large and small commercial enterprises as well as universities.

# Important commercial events— new and changed cooperation agreements

# Additions to product portfolio

#### Ruconest™

In April 2010 Sobi and the Dutch company Pharming signed an agreement for the exclusive commercial rights to Ruconest™ in 24 EU countries. On June 24, 2010, the medication received positive statements from CHMP, paving the way for a central EU approval in autumn 2010. On October 28, 2010, Ruconest™ received European market approval in the 27 EU countries plus Norway, Iceland and Liechtenstein. Ruconest™ is intended for use by adults with the rare disorder hereditary angioedema (HAE).

#### Removab®

In late January 2011, Sobi signed a seven year distribution agreement with Fresenius Biotech to distribute Removab® in Sweden, Denmark, Norway, Finland, Iceland, Poland, Czech Republic, Slovak Republic, Slovenia, Romania, Bulgaria, Hungary, Estonia, Latvia and Lithuania. Removab® was granted marketing authorization by the European Commission in April 2009 for the treatment of malignant ascites associated with cancer and has been launched in Germany, Austria and France so far. Removab® is an innovative product that holds great value to cancer patients with an accumulation of fluid in the abdomen. Moreover, Removab® fits in well with Sobi's portfolio of cancer products, along with Yondelis®, which is distributed in approximately the same territories.

#### Dongbao

The main elements in a declaration of intention to form a strategic business alliance with the Chinese company Dongbao were announced on July 6.

On November 3 Dongbao, through its subsidiary Rechon Life Science Ltd, granted Sobi the distribution rights to Iron Sucrose Rechon in Europe. Under the agreement, Sobi will pay to Rechon a regulatory approval milestone. Sobi will pay a transfer price and royalties on net sales to Rechon Life Science Ltd. Iron Sucrose Rechon is an intravenous formulation of iron, used to treat anemia. It is in registration phase with Sweden as the reference country.

#### Geographic expansion

BL&H Co. Ltd

In January 2011, Sobi and South Korean company BL&H Co. Ltd. signed a distribution agreement for the products Orfadin® and Kepivance® in South Korea, yet another step in the geographic expansion of Sobi's products. Under the agreement BL&H will be responsible for registration and distribution of the products in South Korea. Since the South Korean Food and Drug Administration registration process is adapted to products already approved by the FDA or EMA, registration is expected approximately one year from application. Sales on a named patient basis may be initiated already during 2011.

#### Extended agreements

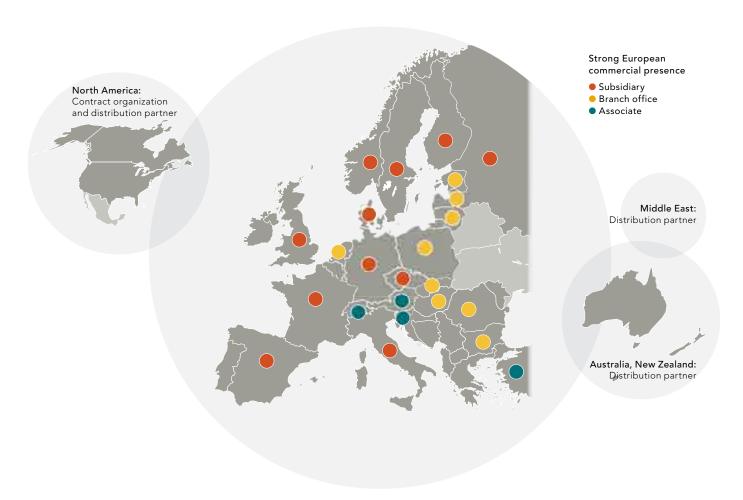
#### LFB BIOMEDICAMENTS (LFB)

In January 2010 Sobi signed an addendum to its distribution agreement with the French company LFB according to which Sobi distributes the products Willfact®, Hemoleven®, IvHebex® and Betafact® in 13 countries in Europe. The extension lengthens the term of the agreement through 2014. In March Willfact® was approved for treatment of the coagulation disorder von Willebrand's disease and the medication was launched in Germany in April.

#### Amended agreements

#### Biogen Idec

The partnership agreement with Biogen Idec regarding the rFVIIIFc and rFIXFc development projects in hemophilia was updated. Under the changed agreement, Biogen Idec accepts full responsibility for development and costs for the rFVIIIFc-and rFIXFc programs, and receives the production rights. In addition to existing commercial rights in North America, Biogen Idec will also be responsible for promotion within those areas of the rest of the world that were previously divided between the companies. Swedish Orphan Biovitrum's commercial rights remain unchanged in Europe, Russia, Turkey, North Africa and Middle East. The cross-royalty rate was reduced for both companies. The royalty rate from Sobi will be higher until that Sobi's share of Biogen Idec's development costs are covered. For more information please see Note 35 on page 84.



#### Merck Serono

In early April 2010 Sobi signed an expansion of its distribution agreement with Merck Serono for Cyanokit®, which is used to treat confirmed or suspected cyanide poisoning. The distribution agreement was expanded to include Ireland, the UK and the Netherlands, in addition to the Nordic and Baltic countries.

#### Micropharm

In late 2010 Sobi and MicroPharm Ltd. signed an agreement under which Sobi will continue to distribute, mainly in the Nordic markets, ViperaTAb $^{\mathsf{TM}}$ , for treatment of viper berus bite.

# Shire

Shire is starting its own sales organization in the Nordic region, which means that Sobi will no longer have marketing, distribution and medical support for the products Xagrid®, Fosrenol® and Equasym® when the agreement with Shire expires in 2011.

#### Symphogen

Development rights for Sym001 were returned to Symphogen for strategic reasons. The company decided to terminate this collaboration in order to fully focus on other development programs.

#### Amgen

Sobi sold the sales rights for Mimpara® back to Amgen for strategic business reasons and received an undisclosed payment from Amgen for these rights.

# The Sobi share

Since June 24, 2010, the share has been listed under the new company name, Swedish Orphan Biovitrum AB (formerly Biovitrum AB) and the ticker SOBI (formerly BVT).

The Biovitrum share was listed on NASDAQ OMX Stockholm's list for Mid Cap companies on September 15, 2006.

### Share performance and turnover

The price¹ of the Sobi share increased during the year by 45.7 percent, from SEK 27.80 per share at the beginning of the year to SEK 40.50 at the year-end. The benchmark index rose 0.5%. The highest trading price during the year was SEK 47 (April 6, 2010) and the lowest price was SEK 27.80 (January 15, 2010). The last price paid was SEK 40.50. Market capitalization was SEK 8.6 billion at the end of 2010.

#### **Shareholders**

At year-end Sobi had 8,661 (5,562) shareholders. Investor AB was the largest shareholder with 40.2 percent of capital and 40.5 percent of votes at year-end. Together, the 15 largest shareholders accounted for 78.5 percent of capital and 79.2 percent of votes.

#### Largest shareholders as at December 30, 2010\*

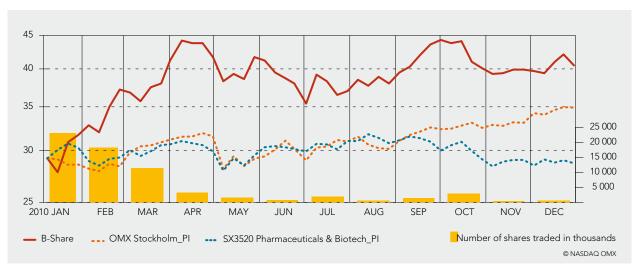
The table below shows the largest shareholders as at December 30, 2010. The total number of shares on December 30, 2010, was 214,249 813.

#### Shareholders

	Number of Shares	Share capital %	Share votes
Investor AB	86,075,322	40.2%	40.5%
Omnibus Account W FD:OM80	19,468,748	9.1%	9.2%
MPM Funds	14,195,424	6.6%	6.7%
Livförsäkringsbolaget SKANDIA	8,465,139	4.0%	4.0%
SEB Private Bank S.A., NQI	7,353,377	3.4%	3.5%
Handelsbanken Fonder inkl XACT	6,516,204	3.0%	3.1%
Nordea Bank Nore Nominee	4,504,422	2.1%	2.1%
Orkla ASA	4,475,933	2.1%	2.1%
Swedbank Robur Fonder	4,256,928	2.0%	2.0%
ABN AMRO Nordic Ventures	2,728,551	1.3%	1.3%
Apoteket AB´s Pensionsstiftelse	2,600,000	1.2%	1.2%
Andra AP-Fonden	2,144,202	1.0%	1.0%
JPM Chase NA	2,039,040	1.0%	1.0%
SEB Investment Management	1,774,236	0.8%	0.8%
AMF – Försäkringar och Fonder	1,562,800	0.7%	0.7%
Sweden Oprhan Biovitrum AB (C-shares, 1/10 vote per share)	1,552,949	0.7%	0.1%
Biovitrum Treasury AB (C-shares, 1/10 vote per share)	515,585	0.2%	0.0%
Other	44,020,943	20.5%	20.7%
Total	214,249,813	100.0%	100.0%

#### The Sobi share, price and trading volume during 20101

<sup>\*</sup>Source: Euroclear Sweden AB



<sup>&</sup>lt;sup>1)</sup> Adjusted for the new share issue completed in January 2010.

# Development in share capital and number

		Number of shares	Total share capital SEK
December 2009		50,911,901	27,935,503
January 2010	Issue of shares in connection with acqusition of Swedish Orphan	159,129,238	87,313,411
May 2010	Issue of shares	2,373,300	1,301,495
August 2010	Issue of shares	282,425	155,693
Oktober 2010	Issue of shares in connection with share based incentive program 2010	1,552,949	852,098
December 2010		214,249,813	117,558,199

### Share capital

Sobi's share capital at year-end was SEK 117,558,199 shared between 214,249,813 shares with a par value of around SEK 0.55. Issued shares break down as 212,181,279 ordinary shares and 2,068,534 C shares. The ordinary shares carry one vote per share and the C shares carry 1/10 vote per shares. All C shares are treasury shares. In conjunction with Share Program 2008, Share Program 2009 and Share Program 2010, the company issued C shares and at year-end the company has 2,068,534 C shares. C shares only give entitlement to a fixed annual dividend equal to 10 percent of the company's distributable profits, calculated on the quota value of the share. All shares entail equal rights to the company's assets and any surplus in the event of liquidation.

#### Acquisition of treasury shares

In 2010 Sobi acquired 1,552,949 treasury shares of share class C. The purchase price for the shares was SEK 852,098, which represents a share value of SEK 0.55. These shares represent 1.0 percent of the total number of shares in the company.

The long-term share program ("Share Program 2010") is the reason for the acquisition of the shares.

# Analysts who follows Sobi

ABG Sundal Collier, Stockholm	Erik Hultgård
Carnegie, Stockholm	Kristofer Liljeberg-Svensson, Camilla Oxhamre och Marcus Bellander
Danske Bank	Mattias Häggblom, Martin Parkhøi, Thomas Bowers
SEB/Skandinaviska Enskilda Banken, Stockholm	Gustaf Vahlne
Nordea, Stockholm	Patrik Ling
Nomura Code Securities Limited, London	Samir Devani
Morgan Stanley Research Europe	Liav Abraham, Andrew Baum, Peter Verdult och Simon Mather
Swedbank	Susanna Karlsson Li, Johan Unnerus
E. Öhman J:or Fondkommission AB	Yilmaz Mahshid

# Responsibility for sustainable development

We are driven by a common ambition to build and expand our company, whose success is based on our ability to solve medical problems and help people achieve a better quality of life. We care about patients with rare diseases, their relatives, healthcare providers and healthcare payers. These diseases are often life-threatening or cause chronic disability and therefore have a severe impact on patients and their families. Treating patients with rare diseases and enabling them to work and earn a living is therefore important, not just for the involved individuals, but for society at large. By advocating sustainable development of our products and our operations we can ensure that our contribution to society can proceed and be broadened in pace with our growth.

#### Dialogue with the rest of the world

Our actions, products and services concern and affect people. Our decisions and actions are therefore based on ethical standards and a sense of responsibility consistent with the company's core values. In our dialog with patients, employees, decision-makers, industry organizations and other stakeholders we gain understanding for the questions about and expectations for our operations and how we can work to meet these expectations. The dialog with stakeholders serves as the foundation for those areas that we are proactively developing and improving from a sustainability perspective.

### Workplace and employees

#### Common values

A healthy workplace where our employees have the opportunity to grow and work together to advance our business is essential to our success. Our professional conduct and our behavior in relation to each other, our patients and our investors can be summarized in our values commitment, innovation and focus on results. These values give us direction and a sense of community that drive us forward in our work with sustainable development.

→ Commitment We are driven by a common ambition to build and expand our company, whose success is based on our ability to solve medical problems and help people achieve a better quality of life. We care about patients with rare diseases, their relatives, healthcare providers and healthcare payers. We also care about each other and our partners, and we work closely with supervisory and other regulatory authorities. We are open and communicative.

- → Innovation We are not afraid to think outside the box and have the courage to try new paths. We provide novel treatments and solutions and we offer services beyond medicine. We find pathways to optimize the return on our investments. We value an open dialog and nurture diversity in experience, expertise and personalities.
- → Focus on results We will deliver our product candidates and new high-quality orphan drugs to those patients who need them. Based on this philosophy we will strive to achieve common goals where results and performance are encouraged and success is recognized.

#### Average number of employees

Group	2010	of which men	2009	of which men
Sweden	415	40%	403	41%
Denmark	12	17%	1	_
Finland	10	60%	2	100%
Norway	11	48%	2	100%
United Kingdom	8	73%	25	57%
France	9	33%	_	_
Germany	13	57%	_	_
Italy	8	43%	_	-
Spain	6	17%	_	_
Russia/Balticum	5	21%	_	_
Central Eastern Europe	11	38%	_	
Total	508	40%	433	42%

#### Salaries and benefits

We will ensure that we hold the right core competencies. Good terms of employment are a prerequisite if we are to be able to recruit and retain qualified colleagues. All employees will have individual goals as part of the effort to achieve operational objectives and as part of their personal development. Competitive salaries and benefits are a prerequisite for us to be able to retain and recruit personnel.

#### Occupational health and safety

The physical and psychosocial work environment is of great importance for creating job satisfaction and motivation. We have a system to follow up any incidents that might occur, including regular monitoring and proposals for corrective measures to improve safety.

#### Health and wellness

We take a preventive approach to health and wellness by offering wellness programs to all employees. In 2010 sick leave within

the parent company was 1.9 percent of regular working hours.

#### Diversity and equal opportunity

We are an international company with operations in the Nordic region and Europe. In Sweden we are located in Stockholm and Umeå; 18 percent of employees work outside Sweden. As at December 31 we were 508 employees.

#### Safety and fire prevention

Sobi's safety policy aims to protect personnel, operations and property against undesirable events such as threats, theft, unlawful intrusion and other criminal actions. The company's policies and procedures for safety and fire protection are described and accessible to all employees on our Intranet. Sobi also pursues active Loss Control, particularly within preventive fire protection and emergency planning. Evacuation exercises are held at least once a year in all buildings where Sobi conducts operations. As a key component in its systematic fire protection campaign the company also carries out internal controls twice a year. In all, 20 percent of Sobi's employees completed Defibrillation/CPR training (use of defibrillator). Defibrillators are accessible at all Sobi operations in Sweden for situations that require emergency care.

#### Product liability

#### Patient safety

Sobi continually analyzes and balances the risks and benefits of its products on the market and under development. During clinical trials patient safety is always in focus and human rights are respected at all times. Our employees are therefore tasked with ensuring compliance with both internal and external rules with respect to any clinical trials that Sobi sponsors.

#### Handling of adverse event reports

We have marketing authorization for a number of products in a number of markets and therefore have responsibility for gathering and processing safety information as well as reporting side effects to regulatory authorities under international rules and guidelines. This responsibility includes detection, assessment, understanding and prevention of adverse drug reactions and other drug related problems. The Drug Safety unit is tasked with capturing and analyzing signals to benefit the well-being and safety of patients. It is therefore crucial that Sobi has an efficient system and network for collection, marketing and communication of adverse effects. We learn about adverse drug events from sources such as patients, medical personnel, regulatory

authorities, product quality issues, scientific publications, business partners, and drug information and marketing functions. All employees are responsible for reporting any adverse effects of Sobi products that come to their attention.

#### Animal experiments

Sobi endeavors to reduce the number of tests conducted on animals, but an important part of Sobi's R&D involves testing the effect of successful compounds on laboratory animals, which is also a safety requirement by law. We therefore follow the three Rs – Replacement, Reduction and Refinement – in animal experiments. This means that we design animal experiments to ensure that we use the most appropriate laboratory animal model and can reduce the number of animals needed to obtain the necessary information. Nevertheless, drug development uses a large number of methods that are not based on laboratory animals. Our aspiration is to continue to develop in vitro methods to replace or reduce the number of laboratory animals.

# Safe production of pharmaceutical proteins

In our Stockholm facility we produce the active ingredient for ReFacto AF® to meet the global need and in our Umeå facility we produce the pharmaceutical product Multiferon®

Other production is contracted out to external manufacturers. External production is handled by agreement to ensure supply and quality. The European (EMA) and American (FDA) drug regulatory authorities, as well as other authorities, regularly inspect the production facilities.

#### Safe purchasing procedures

Raw materials, other material, equipment and other services are purchased as stated in our procurement policy. The policy must ensure that all procurement and purchasing take place professionally and competitively, in accordance with Sobi's rules and other policies.

#### Role in the community

#### Customer contacts

In addition to the ethical norms of our industry, Sobi also applies its values in all contacts with different types of customers. We strive to be sensitive, accountable and problem solving-oriented, while being clear and honest in everything we do.

#### Clinical trials

Drug development is governed by the needs of patients, the healthcare system and society. It is therefore vital for us to have







good contacts with patients, patient organizations and regulatory authorities. As a key component in our social commitment, we participate in the debate about the long-term prospects for clinical research and help to influence public opinion. Discussions with doctors, patients and patient organizations help us gain a greater insight into the problems that individuals, large patient groups and society perceive to be important to correct. Sobi's project portfolio mainly consists of projects in clinical development.

How Sobi purchases and carries out its clinical trials is regulated in Standard Operating Procedures (SOP), which are formulated together with and maintained by of our own Quality Assurance department (QA).

Information for patients, patient organizations and relatives Learning that a child has a chronic or serious disease is overwhelming for both the child and the child's family. In addition, the care is often complicated. Let's use hemophilia as an illustrative example. Parents who learn that their son has hemophilia often have a great thirst for knowledge. Thanks to more effective and safer treatments, people with hemophilia today live longer. Sobi has initiated an extensive investment in education and information materials, for medical staff, patients and relatives. This is an example of how we help to improve patient care and simultaneously satisfy a need for information which may vary over time and from person to person.

#### Education for the healthcare team

Together with Swedish expert groups, we have produced several extensive training programs for healthcare providers who

treat patients with Sobi's products and equivalent alternatives. Several of the training programs are now certified by public health services. Such initiatives bring Sobi closer to the patients so we can listen to their daily needs.

#### External involvement and networking

We have a long-term strategy for the continued development of new drugs. A complete list of the patient organizations we support is available on our website www.sobi.com under the Patients & Public and Patient organizations tab.

Sobi is a member of European Biopharmaceutical Enterprises (EBE). EBE is an organization that represents biopharmaceutical firms in Europe and supports innovation and new opportunities within biotechnology. EBE also provides expertise during development of new regulatory requirements, provisions and standards relevant to biopharmaceuticals.

We also support the networks that contribute to the continued development of pharmaceuticals in Sweden. Sweden's Biotechnology Industry Organization, Sweden BIO, is a trade association tasked with successfully establishing and developing internationally competitive biotech companies in Sweden. Sobi was a founding member and has played an active role in the organization since its inception. Sobi also belongs to the Swedish Association of the Pharmaceutical Industry (LIF). LIF's task is to create good conditions for research and development of drugs in Sweden.

#### Responsibility for a better environment

Proactive environmental management is a natural part of our operations and is integrated with our occupational safety and

quality management initiatives. The company works according to an environmental management system based on the international standard ISO 14001, but is not certified. Sobi's management has adopted an environmental policy to further emphasize the importance of environmental management. The environmental policy is available on Sobi's web site at www.sobi. com/about us/corporate responsibility/environment.

We strive to fully comply with all environment-related laws and regulations. Our computerized management system links current legislation and rules to internal control documents and procedures. Sobi's production facilities in Stockholm and Umeå are licensed for hazardous operations in compliance with the Swedish Environmental Code, with wastewater management conditions. Compliance with the terms of the permit is reported annually in environmental reports prepared for the local licensing authorities.

Legislation is also on the agenda at Sobi's environment days, which are held once each quarter with representatives from the entire organization. The representatives (14 in 2010) summarize action plans for environmental management in cooperation with the responsible line managers, safety representatives and other employees. Systematic risk assessments, safety inspections, questionnaires, environment meetings, internal audits and other studies comprise the basis when preparing environmental management goals and plans, which are usually handled at the department level. Awareness of environmental issues among all personnel is crucial for successful environmental management. As of December 31, 2010, 72 percent of all employees in Sweden had completed a general environmental training program. The company offers continuing education and relevant environmental training is included as an item in the annual action plans. In 2010 the internal control documents/procedures for environmental management, waste management, chemical management, incident reporting and dangerous goods were revised. The company is working on adaptation to comply with REACH and CLP regulations and has reviewed procedures for chemical handling and the flow of MSDSs.

# New environmentally friendly premises

In 2010 all operations in the Stockholm area, except for production of ReFacto®, moved to new premises within Karolinska Institutet's Sciences Park in Solna. Akademiska Hus is a leading Swedish property management company in terms of energy efficiency and climate optimization in buildings.

The environment was taken into account when choosing building materials and production methods. The heating system, including radiators and floor heating, is hydronic. All chemical-

based building materials were environmentally assessed; for example, only water-based paints were used.

#### Energy and resource consumption

Our operations with offices, laboratories and production facilities require a large amount of energy. In 2010 we intensified our efforts to reduce our energy and resource consumption and their environmental impact. Our total energy consumption in 2010 was 25 GWh and water consumption was 165,000 m3. The total amount of waste decreased in 2010 compared with 2009; please see the table Waste 2006 – 2010. Air emissions primarily come from travel, where flights account for emissions of 770 tons of carbon dioxide. The figures reported refer to the Swedish companies. We are working on improving our systems to be able to gather data from our subsidiaries and generally reduce our costs and thus even our environmental impact with respect to energy and resource consumption.

#### Waste disposal 2008-2010



#### \*Included in recycling, %

	2008	2009	2010
Combustible	48.3	53	42.6
Office stationary	9.3	10	9.3
Corrugated cardboard	6.5	10.8	11

# IT and IS contribute to environmental system

Our functions Information Technology (IT) and Information Systems (IS) are responsible for controlling how IT and IS are managed within Sobi and for ensuring that the IT/IS strategy is consistent with the business strategy. Selection of services, solutions and systems are continually adapted and reviewed to achieve optimal quality and cost efficiency. IT and IS are regulated by a number of established policies and environmental concerns are an important share of the daily work.



# Operational risk management

The company is constantly surrounded by uncertainties and events that positively or negatively affect its business objectives and milestones. Favorable events are opportunities for the company that help us to achieve the objectives and generate value. Events that have a negative impact comprise risks, and processes for identifying, addressing and managing these risks is part of the company's daily work.

Our risk assessment is based on identification and assessment of events that can influence our opportunities to achieve the company's goals and events with a negative impact on our work. These risks are assessed based on the probability that they will occur and the consequences they entail if they should occur. Based on this platform we determine how to manage risks: Accept, Monitor, Reduce or Eliminate. An action plan is approved for each risk.

Sobi works to continually improve its risk management procedures by following the guidance established by COSO – ERM (Committee of Sponsoring Organizations of the Treadway Commission – Enterprise Risk Management Integrated Framework).

This framework is the basis for Sobi's Risk Management Policy, which aims to support activities to identify events which would negatively affect the company's potential for reaching its goals. Implementation of uniform procedures and continuous improvement of processes is an ongoing project.

The overall risk management structure consists of eight interrelated components that follow the structure of the company's organization and the link to its objectives:

- 1. Internal environment
- 2. Goal setting
- 3. Incident identification
- 4. Risk Assessment
- 5. Risk measures
- Control activities
- 7. Information and communication
- 8. Monitoring, including follow-up and evaluation.

This methodology makes it possible to focus on the total picture of the company's risk management with its objectives, components and the various elements and relationships of the organization.

Operational risk management is an ongoing process that affects all levels of the organization. Sobi's strategic objectives are defined in the annual operational objectives. The departments and projects base their goals on these annual operational objectives and their various risk aspects for responsible line managers and project managers.

Few industries are as regulated and monitored as the pharmaceutical industry. Sobi's risk management procedures therefore also include monitoring to ensure that the company not only complies with business objectives, but also meets all reporting and legal compliance goals.

Risk management is classified under the legal department and the general counsel appoints a risk management officer who reports to the CEO and the audit committee quarterly.

Sobi has revised its emergency preparedness policy with updated areas of responsibility, action plans and crisis communications for the new organization. Emergency preparedness is an important part of the company's efforts to be optimally prepared to handle any negative events that may occur. The crisis management group meets regularly for planning and exercises.

# Directors' report

(Refers to both the Group and parent company, as applicable)

# General information on operations

Swedish Orphan Biovitrum (Sobi) is a Swedish-based pharmaceutical company with an international market presence. The product portfolio consists of some 60 orphan and specialty pharmaceuticals. Swedish Orphan Biovitrum has an emerging late stage clinical development orphan and specialty pharmaceutical pipeline. Important areas for the company are hemophilia, inflammation/autoimmune diseases, fat malabsorption, cancer and inherited metabolic disorders.

Swedish Orphan Biovitrum's mission is to provide valuable pharmaceuticals to patients with rare diseases. The company's business objective is to be a profitable pharmaceutical company.

The Company had sales of SEK 1.9 billion in 2010, with 508 employees on December 31, 2010.

Swedish Orphan Biovitrum develops its portfolio of specialist- and niche pharmaceuticals in-house or together with partners in order to generate future revenues.

# In 2010 the company generated revenues through:

- Production of the active pharmaceutical substance for ReFacto®, royalties from Pfizer's global sales of ReFacto® and co-promotion revenues from the sale of ReFacto® in the Nordic region.
- Product sales with Europe and North America as the primary markets.

#### Important events in 2010

#### Summary

- Operating profit before restructuring and other one-off costs totaled SEK 77.5 M (16.2).
- Net revenues amounted to SEK 1,906.7 M (1,297.0) and the profit/loss for the year before restructuring and other nonrecurring costs was SEK -16.7 M (32.4). Profit/loss for the year was SEK - 104.4 M (32.4), equivalent to earnings per share<sup>1</sup> of SEK -0.53 (SEK 0.33).
- Cash flow from operations amounted to SEK -215.1 M (58.9).
   Cash and cash equivalents and short-term investments as of December 31 amounted to SEK 38.5 M (306.6).
- Net revenues fell 7.7% to SEK 1,906.7 M (pro forma 2,065.6).
   Sales, excluding Tracleer®, rose 2% at constant exchange rate (CER).
- Operating income (EBITA) surged 36% to SEK 371.9 M (273.6)
- Net profit for the period totaled SEK -104.4 M (32.4), which corresponds with earnings per share after dilution of SEK -0.53 (0.32).

- An international hemophilia B (rFIXFc) registration trial (phase II) began in January.
- A decision was taken to advance Kiobrina® to clinical phase III.
- International hemophilia A (rFVIIIFc) registration trial (phase II/III) began.
- rFVIIIFc received orphan drug designation from the FDA in the United States.
- Development rights for Sym001 returned to Symphogen for strategic reasons.
- On April 15 Swedish Orphan Biovitrum signed an agreement with Pharming regarding the exclusive commercial right to Ruconest™ in 24 EU countries.
- On November 5 Swedish Orphan Biovitrum and Amgen announced that by mutual agreement, Swedish Orphan Biovitrum would sell back all co-promotion rights in the Nordic countries for Mimpara (cinacalcet) to Amgen for strategic business reasons. Swedish Orphan Biovitrum received payment from Amgen for these rights.
- In late 2010 Swedish Orphan Biovitrum and Micropharm agreed that Swedish Orphan Biovitrum will continue to distribute, mainly in the Nordic markets, ViperaTAb™ for treatment of viper berus bite.

#### Swedish Orphan Biovitrum AB (publ) created

**Acquisition:** Biovitrum AB (publ) completed the acquisition of Swedish Orphan International Holding AB on January 14, 2010. The acquisition was financed through a preferential new share issue, an issue in kind and bank loans.

Name change: On May 6 the company changed its name to Swedish Orphan Biovitrum AB (publ) and on June 24 the company changed the short name of the share to SOBI. (The company's share has been listed on NASDAQ OMX Stockholm since September 15, 2006.)

#### **New CEO**

On November 25, 2010, the company announced that CEO Martin Nicklasson would leave the company and Kennet Rooth succeeds him as acting CEO from January 1, 2011 until a new CEO is recruited.

<sup>1)</sup> Earnings per share have been adjusted for the bonus issue component of the new share issue completed in January 2010

# Business events – new and amended cooperation agreements during the year

#### Amgen

Some previously agreed future milestone payments for achieved sales levels for the products Kineret® and Kepivance® were paid in advance to Amgen. Sobi sold the sales rights for Mimpara® back to Amgen for strategic business reasons. Swedish Orphan Biovitrum received payment from Amgen for these rights.

# Boehringer Ingelheim

Sobi and Boehringer Ingelheim signed a long-term supplier agreement for commercial production of the active pharmaceutical substance in Kineret<sup>®</sup>.

#### Biogen Idec

The partnership agreement with Biogen Idec regarding rFVIIIFc and rFIXFc was updated. Under the amended agreement, Biogen Idec accepts full responsibility for development and costs for the rFVIIIFc- and rFIXFc programs, and receives the production rights. In addition to existing commercial rights in North America, Biogen Idec will also be responsible for promotion within those areas of the rest of the world that were previously divided between the companies. Sobi's commercial rights are unchanged in Europe, Russia, Turkey, Northern Africa and the Middle East. The cross-royalty rate was reduced for both companies. The royalty rate will be higher from Sobi until Sobi's share of Biogen Idec's costs have been covered.

#### Dongbac

On July 6, a Letter of Intent to form a strategic Commercial Alliance with Chinese pharmaceutical company Dongbao was announced

On November 3 Dongbao, through its subsidiary Rechon Life Science Ltd, granted Sobi the distribution rights to Iron Sucrose Rechon in Europe. Under the agreement, Sobi will pay to Rechon a regulatory approval milestone. Sobi will pay a transfer price and royalties on net sales to Rechon Life Science Ltd. Iron Sucrose Rechon is an intravenous formulation of iron, used to treat anemia. It is in registration phase with Sweden as the reference country.

#### Merck Serono

On April 1, Sobi expanded its distribution agreement with Merck Serono for the distribution of Cyanokit®, used for treatment of confirmed or suspected cyanide poisoning.

#### Micropharm

In late 2010 Sobi and MicroPharm Ltd. signed an agreement under which Sobi will continue to distribute, mainly in the Nordic markets, ViperaTAb<sup>TM</sup>, for treatment of viper berus bite.

#### LFB

In January Sobi signed an extension to its distribution agreement with LFB under which the company distributes the products Willfact®, Hemoleven®, IvHebex® and Betafact® in 13 countries in Europe. The extension lengthens the term of the agreement through 2014. In March Willfact® was approved for treatment of the coagulation disorder von Willebrand's disease and the medication was launched in Germany in April.

#### Pharming

Sobi and Pharming signed an agreement for exclusive commercial rights to Ruconest™ in 24 EU countries. On June 24 the medication received positive statements from CHMP, paving the way for a central EU approval in early autumn 2010. On October 28, 2010, Ruconest™ received European market approval in the 27 EU countries plus Norway, Iceland and Liechtenstein.

#### Shire

Shire is starting its own sales organization in the Nordic region, which means that Sobi will no longer have marketing, distribution and medical support for the products Xagrid®, Fosrenol® and Equasym® when the agreement with Shire expires in 2011.

#### Symphogen

Development rights for Sym001 were returned to Symphogen for strategic reasons. The company decided to terminate this collaboration in order to fully focus on other development programs.

# Continued successes in our clinical project portfolio The rFIXFc and rFVIIIFc hemophilia projects progressing according to plan

An international hemophilia B (rFIXFc) registration trial (phase II/III) was initiated in January in cooperation with Biogen Idec. The study is designed to analyze the safety, pharmacokinetics and efficacy of the companies' long-acting recombinant factor IX Fc fusion protein (rFIXFc) in hemophilia B patients. The study, called the B-LONG study, will evaluate the efficacy of rFIXFc in the prevention and acute treatment of a number of previously treated patients with severe hemophilia B.

The results from the phase I/II study of rFIXFc were presented on July 11 at the World Federation of Hemophilia Congress in Buenos Aires, Argentina. The results showed a three-fold increase in half-life.

In December 2010, Sobi and Biogen Idec announced that the first patient was treated with the companies' long-lasting recombinant factor VIII Fc-fusion protein (rFVIIIFc) in a global registration trial. The study, called A-LONG, is a, phase II/III, multicenter study designed to evaluate the safety, pharmacokinetic profile and efficacy of rFVIIIFc in previously treated hemophilia A patients.

During the year rFVIIIFc received orphan drug status from the FDA in the United States and from the EU Commission for the EU. rFIXFc already has orphan drug status in both the EU and the US.

#### Kiobrina®

Sobi decided to advance Kiobrina® to clinical phase III and the results from the first clinical phase II trial were published. Kiobrina® also received a "positive opinion" from PDCO/EMH for its "Pediatric Investigational plan," which means that a phase III trial can be initiated as planned during H1 2011.

### Marketing and sales

#### Product revenues

Amounts in SEK million	2010	2009	Pro forma 2009
ReFacto®	587.1	631.9	631.9
of which manufacturing rev- enues	388.0	376.5	376.5
of which co-promotion	89.4	89.7	89.7
of which royalty	109.7	165.7	165.7
Kineret®	422.3	440.8	440.8
Orfadin <sup>®</sup>	321.8	-	310.0
Kepivance®	94.8	109.9	109.9
Ammonaps®	69.1	_	69.9
Yondelis®	40.6	-	43.9
Willfact®	13.1	-	1.2
Other product revenues	328.4	51.8	328.4
Total remaining products	1,877.2	1,234.4	1,936.0
Tracleer	5.9	-	66.9
Other revenues	23.6	62.6	62.6
Total revenues	1,906.7	1,297.0	2,065.6

The company expanded its marketing and sales organization in connection with the acquisition of Swedish Orphan by establishing sales and marketing capacity in the U.S. and reinforcements in Europe. The merger entails new opportunities for existing products through a broader geographic market and the companies' established marketing organizations.

Sobi strengthened its expertise and capacity with respect to the products Kineret® and Kepivance® in 2010. Sales of Kineret®

in local currency rose 3% year on year, while equivalent sales of Kepivance® dropped 7%. The two products from Swedish Orphan with the highest sales, Orfadin® and Ammonaps®, had corresponding increases of 13% and 9%, respectively.

#### Co-promotion revenues

Total	123.0	127.3
Kepivance®	_	0.0
Kineret®	_	0.2
Mimpara <sup>®</sup>	22.7	26.2
BeneFIX®	10.9	11.2
ReFacto <sup>®</sup>	89.4	89.7
Amounts in SEK million	2010	2009

The transition to ReFacto AF $^{\otimes}$ , which was launched in the Nordic region in 2009, has been successful. Co-promotion revenues from ReFacto in local currency increased by 5% in 2010.

During the year Swedish Orphan Biovitrum sold all copromotion rights regarding Mimpara® to Amgen. Net sales through November 5, 2010, amounted to SEK 22.7 M (26.2, full year 2009).

Co-promotion revenues for BeneFix $^{\circ}$  continued to grow during the year and amounted in local currency to SEK 10.9 M (11.2).

For product information please see www.sobi.com

#### Manufacturing and contract development

Total	388,0	376,5
Contract development	0,5	14,1
of which validation batches	_	_
ReFacto®	387,5	362,5
Amounts in SEK million	2010	2009

Swedish Orphan Biovitrum is the only global manufacturer of the active ingredient for ReFacto AF® (sold under the name Xyntha® in the United States). The production process is completely free of any human or animal components which, compared with earlier processes, results in higher yield while excluding foreign proteins.

To meet increased market demand, the production facilities are being extensively updated to further increase process capacity.

Manufacturing revenues for ReFacto® rose 3% in 2010 in both SEK and local currency. Volumes will continue to vary from one quarter to the next as a result of Pfizer's production planning.

As a result of the decision to use expertise within protein-based drugs for in-house projects/products, contract development revenues fell during the year to SEK 0.5 M (14.1).

#### Product development

Sobi's R&D portfolio includes both developing new protein-

based drugs for patients with rare diseases and projects for continued development of our existing products. The portfolio currently consists of three phase III projects, one product that will be registered on the European market and several projects in preclinical phase. Sobi's projects span therapy areas such as hemophilia, treatment of premature infants and inflammation.

Sobi's R&D costs in 2010 amounted to SEK 479.8 M (569.4). During the year outlicensing and milestone revenues were SEK 23.6 M (62.6). In early 2010 we renegotiated our collaboration agreement with Biogen Idec, under which research costs for FIXFc and FVIIIFc will be deducted from future profits when the products reach the market.

#### Development project

#### Factor IX Fc (rFIXFc) for hemophilia B

rFIXFc is a recombinant clotting factor designed to replace the protein that hemophilia B patients lack, but to last longer than today's commercially available Factor IX products. The product is being developed in cooperation with Biogen Idec. The global registration trial, known as the B-LONG study, began in early 2010. The study is designed to analyze the safety, efficacy and pharmacokinetics of long-acting rFIXFc in both preventive and acute treatment.

During the year data were presented from the first clinical trial with FIXFc, an open phase I/IIa, safety and pharmacokinetics study carried out with increasing doses in hemophilia B-patients. The study showed that rFIXFc was well-tolerated with about a three-fold increase in half-life compared with historic data for currently available treatments.

### Factor VIII Fc (rFVIIIFc) for hemophilia A

rFVIIIFc, like FIXFc, is a recombinant coagulation factor under development in cooperation with Biogen Idec, to replace the protein that patients with hemophilia A lack. Here too the goal is a product with a longer effect than the commercial available factor VIII products. During the year the companies decided to advance to phase III and in early December the first patient was treated in a global registration trial. The study, called A-LONG, is a phase II/III multicenter study to evaluate the safety, pharmacokinetic profile and efficacy of rFVIIIFc in previously treated hemophilia A patients, in both preventive and acute treatment.

In December rFVIIIFc was granted orphan drug designation by the FDA in the United States.

# Kiobrina™ for prevention of growth retardation

in preterm infants

Kiobrina® is a recombinant human bile-salt-stimulated lipase (rhBSSL) developed by Sobi to prevent growth retardation in preterm infants who receive pasteurized breast milk and/ or formula. BSSL (bile-salt-stimulated lipase) is one of the most important lipases for premature infants, present in fresh

mother's milk, improving digestion and absorption of essential fatty acids, such as LCPUFAs (long-chain poly-unsaturated fatty acids), critical for the developing brain.

In 2010 the second clinical phase II trial ended with positive results and Sobi took the decision to advance to phase III.

#### Nascobal® for pernicious anemia

Nascobal is vitamin B<sub>12</sub> in the form of a nasal spray for patients with pernicious anemia (a serious type of anemia), which is marketed in the United States by Strativa Pharmaceuticals. The rights to register and market Nascobal® were acquired through an agreement between Swedish Orphan and Strativa before the formation of Sobi. A small clinical trial in healthy volunteers has begun at the end of the year, 2010, prior to the European registration.

#### Kineret® for treatment of other rare diseases

Kineret® is currently approved for treatment of rheumatoid arthritis. The potential for label expansion by documentation of available data on Kineret for certain orphan indications is being explored. For example, the FDA granted Kineret® orphan drug designation for the treatment of the rare disease Cryopyrinassociated periodic syndromes (CAPS).

#### Other

For strategic reasons, Sobi returned all rights to develop Sym001 to its partner Symphogen. Sym001 is under development for the treatment of immune thrombocytopenic purpura (ITP) and for prophylaxis of hemolytic disease in newborns, known as anti RhD prophylaxis (ADP).

During the year, development of Exinalda for treatment fat malabsorption, which is caused by pancreas insufficiency in cystic fibrosis patients, was discontinued as the project is no longer viewed as being commercially viable due to the high production costs.

#### Operational risks

#### Sales of ReFacto® and ReFactoAF®/Xyntha®

Sales of ReFacto® and ReFacto AF®/Xyntha® account for almost one third of revenue for Swedish Orphan Biovitrum. After acquiring the pharmaceuticals Kepivance® and Stemgen® and the exclusive license for Kineret as well as the acquisition of Swedish Orphan, the percentage of sales of the company's total revenue decreased from 72 percent in 2008 to 48 percent in 2009, and to 31 percent in 2010.

Under the company's agreement with Pfizer, which expires on December 31, 2015, Swedish Orphan Biovitrum receives revenue for both contract development and manufacture of the pharmaceutical ingredients ReFacto® and ReFacto AF®/ Xyntha® and for co-promotion from sales of ReFacto® and ReFacto AF®/Xyntha® in the Nordic region, as well as royalties from

Pfizer's global sales of ReFacto® and ReFacto AF®/Xyntha®. In 2010 the combined revenues relating to ReFacto® amounted to around 31 percent of the company's total revenues, compared with 48 percent in 2009 and 72 percent in 2008. Any material decrease in the revenues that the company receives from ReFacto® and ReFacto AF®/Xyntha®, could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position. This is regardless of whether it is due to reduced demand, increased competition, a deterioration in Swedish Orphan Biovitrum's capacity to develop the necessary quantities of pharmaceutical ingredient or to successfully market ReFacto® and ReFacto AF®/Xyntha®, changes in the company's agreement with Pfizer or for other reasons such as changed rules on government medicine subsidies for preventive treatments or a reduction in the spread of hemophilia

#### Product sales

Product sales account for about two-thirds of Swedish Orphan Biovitrum's revenue, 66.7 percent, of which Kineret®, Kepivance®, Orfadin® and Ammonaps® account for 73 percent. Even though the acquisition of Swedish Orphan has reduced dependence on individual products, each material decrease in revenue for the company from these products would have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

Revenues could decrease due to reduced demand, increased competition, a deterioration in Swedish Orphan Biovitrum's capacity to provide the necessary quantities of pharmaceutical ingredient or to successfully market the products or for other reasons such as changed rules on state medicine subsidies or stock shortages.

A majority of net sales for the acquired business, Swedish Orphan, is obtained from contracted products and there is no guarantee that present agreements for these products can be maintained, which could have a negative effect on Swedish Orphan Biovitrum's business, results and financial position. Moreover distribution products can be sensitive to the parallel distribution with lower net prices or loss of Sobi sales as a consequence.

The acquired business relies on certain partners for a considerable part of its net sales. For example, the business is dependent on partners for supply of the products.

# Increased globalization of operations

The company considerably expanded its operations geographically in connection with acquisition of Swedish Orphan. Even though the merged organizations have established local distribution and sales channels, future changes and further expansion will be associated with uncertainty and place large demands on resources and organization. Should it prove that the company does not have an adequate organization or suf-

ficient resources for its increased globalization, or that the costs associated with globalization exceed the company's estimates, this could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

Increased globalization may also result in the company carrying on business in countries that typically have longer payment periods than its home market. Increased delays in payment could therefore also be a consequence of increased globalization and could have a material negative effect on Biovitrum's business, results and financial position.

Moreover, increased globalization has made the company more dependent on contract partners for distribution, sales and manufacture. If such agreements are not renewed on similar terms or are terminated prematurely, this could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### Future profit trend

Swedish Orphan Biovitrum receives significant revenues from Pfizer for ReFacto® and ReFacto AF®/Xyntha® and from product sales as well as from co-promotion or exclusive distribution agreements for the Nordic market. Although the company expects to continue to receive such revenues in the future, there are no guarantees that the revenues will be sufficient to make Swedish Orphan Biovitrum profitable in view of the company's research and development costs, and other costs. If these revenues cease or decrease this could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### **Production facilities**

Swedish Orphan Biovitrum is dependent on the production facility in Stockholm for the manufacture of ReFacto® and ReFacto AF®/Xyntha® as well as the production facility in Umeå for the manufacture of Multiferon® being maintained and offering a high level of availability. If the facilities or the equipment were seriously damaged or destroyed, or if the facilities had to be closed for some reason, or if the company were unable to replace or repair damaged equipment quickly and cost-effectively, Swedish Orphan Biovitrum could lose revenue as a result of reduced production capacity, which could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position. Although Swedish Orphan Biovitrum has insurance for damage to property and loss of production for an amount deemed sufficient by the company, it is not certain that the company could recoup these amounts in full or that amounts recouped would be sufficient to compensate for the losses suffered and lost revenue.

#### Extensive quality requirements and controls

Swedish Orphan Biovitrum manufactures recombinant protein

pharmaceuticals. In addition, the company cooperates with pharmaceutical companies and companies in the biotech sector as regards the manufacture of pharmaceuticals developed by Swedish Orphan Biovitrum. The manufacture of recombinant protein pharmaceuticals requires precise and high-quality manufacturing processes and controls, which means that the company must ensure that all manufacturing processes and methods and all equipment meet the requirements in force in respect of what is known as Good Manufacturing Practice (GMP requirements). Moreover, Swedish Orphan Biovitrum must perform extensive audits of its distributors, contract laboratories and suppliers that are covered by these requirements. GMP requirements control all aspects of the manufacture of pharmaceuticals, including quality control and quality assurance, manufacturing processes and procedures as well as documentation. The meeting of these standards demands that Swedish Orphan Biovitrum and its distributors, contract laboratories and suppliers achieve and maintain high quality manufacturing processes and controls that are sufficient to guarantee that the products meet current specifications and other requirements. Swedish Orphan Biovitrum's production facilities may be inspected at any time by the authorities and by the company's customers. Should such an inspection reveal deficiencies, Swedish Orphan Biovitrum could be forced to take measures, stop production or close the facility, which would disrupt manufacturing processes and have a negative impact on revenues. Should any of the company's cooperation partners fail to meet the standards/qualityrequirements in force, the company could not license in pharmaceutical projects or other products from that partner. Moreover, failure by Swedish Orphan Biovitrum or its subcontractors to achieve and maintain manufacturing standards that meet GMP requirements could result in manufacturing defects, which might lead to patients being injured or dying or in products being recalled, in delays or shortcomings in product tests or deliveries, high costs or other problems that could seriously damage Swedish Orphan Biovitrum's business, results and financial position.

### Manufacture of pharmaceutical ingredients

Some of Swedish Orphan Biovitrum's candidate drugs in preclinical or clinical phases are based on recombinant technologies. The manufacture of proteins for use in pharmaceuticals in accordance with current regulations is complex, time-consuming and expensive. The company could face a variety of problems, including production yield, quality control and guarantees, availability of qualified personnel, supply of raw materials, adequate training of existing personnel, the business not being run in accordance with FDA or other applicable regulations, production costs and the development of advanced production technology and process control. If the company would fail

to operate its production facilities in an efficient manner, not obtain regulatory permits, not be able to produce sufficient volumes in time or in any other way run into any of the problems mentioned in the preceding paragraph, this could obstruct or lead to delays in the launch of the company's candidate drugs, which could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

# Risks relating to research and development Risks inherent in pharmaceutical development and the commercialization of products

Developing a new drug up to and including its launch is both a capital-intensive and a risky process. The probability of getting to market increases as the project moves forward in the development chain, while the costs increase at a growing pace in the later clinical phases of development. If Swedish Orphan Biovitrum cannot develop its existing or future project portfolio to later development phases, if developed candidate drugs cannot be manufactured at reasonable cost, if any of the development programs were to be delayed or if Swedish Orphan Biovitrum were unable to successfully commercialize any candidate drugs this could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

# Safety and efficacy criteria in conjunction with project development

Before the launch of any of Swedish Orphan Biovitrum's candidate drugs is initiated the company and its cooperation partners must show that the candidate drug meets the stringent standards for safety and efficacy expected by the authorities in the countries in which Swedish Orphan Biovitrum plans to market the drug. Swedish Orphan Biovitrum has not yet received such authorization from the FDA, EMA or any other authority for any of the candidate drugs in the product portfolio. The regulatory approval process usually requires extensive preclinical and clinical data, is extremely expensive, and takes many years.

The FDA, EMA and other authorities may delay, restrict or refuse authorization for a number of reasons, including that the candidate drug is perhaps not safe or effective, that the manufacturing processes or facilities that the company has chosen perhaps do not meet requirements in force or that changes in the authorities' authorization policies or the introduction of new rules may require additional work to be carried out. Even if the company's candidate drugs meet the requirements of safety and efficacy in clinical trials, the authorities may take a different view to Swedish Orphan Biovitrum as regards the interpretation of data from preclinical studies and clinical trials and therefore refuse authorization. No guarantees can be given that Swedish Orphan Biovitrum will be granted marketing authorization for any of its existing or future candidate drugs. If Swedish Orphan

Biovitrum does not succeed in obtaining marketing authorization for its existing or future candidate drugs, they will not be able to be marketed and sold. Authorities may also authorize a candidate drug for fewer indications than applied for or make the authorization conditional upon the performance of aftermarket studies. Delayed or limited permits, or failure to obtain permits, may prevent Swedish Orphan Biovitrum from achieving sufficient revenues from these candidate drugs and have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### Clinical trials

Swedish Orphan Biovitrum currently has a number of projects in clinical development and several projects in preclinical development. Before the company can be authorized to launch any of its candidate drugs it must be shown that they are safe and effective through sufficient well-controlled preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required varies depending on the candidate drug, indications, preclinical and clinical results and the rules that apply to the specific candidate drug. The company cannot predict with certainty when clinical trials in progress will be concluded, if they ever are, or when planned clinical trials will be initiated or concluded. Preclinical and clinical development is a long drawn-out and expensive process that is affected by many factors, including those beyond the company's control, such as slower than expected patient recruitment and scheduling difficulties relating to staff and the clinical institutions that are to take part in the clinical trials. It is also difficult to exactly predict the costs associated with clinical trials, and the actual costs of implementing a clinical trial may exceed the budgeted costs. As a consequence, the results and the total costs of Swedish Orphan Biovitrum's preclinical and clinical development projects are in themselves uncertain.

During clinical development it may emerge that the candidate drugs are not sufficiently effective or they may prove to have undesirable or unintended side effects, toxicities or other properties that may disrupt, delay or stop clinical development and prevent or limit the commercial application of the candidate drugs. Such results could lead to the company, its cooperation partners or the competent authorities for clinical trials suspending or cancelling clinical trials at any time.

Swedish Orphan Biovitrum cannot guarantee that any of the candidate drugs in the project portfolio will be developed into drugs that are safe and effective for use in humans or that these drugs will receive the necessary authorization for commercialization. Any deficiencies or delays in the implementation of clinical trials will reduce or delay Swedish Orphan Biovitrum's capacity to generate revenues from the commercialization of its candidate drugs and to maintain and supplement the project portfolio, which could have a material nega-

tive effect on Swedish Orphan Biovitrum's business, results and financial position.

# Successes in early clinical trials are not necessarily indicative of the results in later clinical trial

The results of Swedish Orphan Biovitrum's clinical trials in early stages are based on a limited number of patients and may be revised or nullified by authorities after further review or by clinical results at later stages. Historically speaking, the results of preclinical studies and early clinical trials in the industry have often not been indicative of the results obtained in later clinical trials. A number of new candidate drugs have shown promising results in clinical trials, but have later not succeeded in demonstrating the safety and efficacy required in order to obtain the necessary authorization. No guarantees can therefore be given that the information gathered from the preclinical studies and clinical trials of the company's candidate drugs will be sufficient to obtain authorization from the FDA, EMA or any other authority.

Delayed or limited permits, or failure to obtain permits, could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

# Commercial success and market acceptance for Swedish Orphan Biovitrum's products

Even if the pharmaceuticals in Swedish Orphan Biovitrum's product portfolio were to receive marketing authorization, it is not certain that any of these products would gain price approval and reimbursement within the national health care systems, acceptance in the market among physicians, patients, procurement organizations and the medical world. The degree of market acceptance for each of the company's candidate drugs depends on a number of factors, including the following:

- the ability to produce acceptable proof of safety and efficacy
- relative convenience and simple administration,
- the incidence and degree of any negative side effects,
- the availability of alternative treatments,
- price and cost effectiveness, and
- the effectiveness of Swedish Orphan Biovitrum's development partners' or licensees' sales and marketing strategy.

Swedish Orphan Biovitrum's success is further dependent on the products developed by the company being covered by and entitled to payment through private or state payment systems within the healthcare sector. Legislation and regulatory proposals in various European countries and in the US cover measures that could restrict or prevent payment for treatment with certain drugs. In certain cases such legislation has also resulted in the pricing of drugs being subject to increased state price controls or mandatory price cuts, which can create price differences between countries and increased parallel

distribution and reduced margins. Most countries require that products undergo time-consuming and demanding reviews in order to be able to be covered by the state payment systems and the time required for this examination may vary and it can lead to delayed product launches. The use of drugs may also be affected by guidelines, recommendations and studies published by authorities and organizations.

If Swedish Orphan Biovitrum's drugs, despite being authorized, do not gain market acceptance or are not included in private insurance systems, state payment systems within the healthcare sector or become subject to legislation on medical treatment or pricing, or receive negative attention through guidelines, recommendations or studies published, this could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### Cooperation with external parties

Part of Swedish Orphan Biovitrum's strategy is to enter into various cooperation agreements, such as agreements concerning joint development and licensing, with pharmaceutical and biotech companies for the development and launch of certain of Swedish Orphan Biovitrum's substances. The success of such partnerships will largely depend on the work of Swedish Orphan Biovitrum's partners or licensees, since these still have considerable right of determination over the work and resources that will be put into the projects. Swedish Orphan Biovitrum's cooperation partners or licensees may reprioritize matters internally, take a different view of the results of clinical trials, find themselves in a financial crisis, have production problems or suffer staffing problems. Such factors may, individually or together, have a negative effect on their willingness or ability to develop Swedish Orphan Biovitrum's substances or to otherwise cooperate with the Swedish Orphan Biovitrum. Moreover, many of the company's development partners and licensees are also competitors and it cannot be guaranteed that they will not have interests that conflict with Swedish Orphan Biovitrum's own interests. Neither can it be guaranteed that Swedish Orphan Biovitrum will succeed in the future in entering into cooperation and/or licensing agreements on terms acceptable to Swedish Orphan Biovitrum. Poor cooperation with partners and the inability to enter into or renew agreements could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

# Applications for authorization for licensed-in or acquired candidate drugs

Many of the candidate drugs in Swedish Orphan Biovitrum's product portfolio are based on substances or technologies developed by other pharmaceutical or biotech companies that the company has licensed in or acquired by other means. Many of the preclinical studies and clinical trials carried out for these

candidate drugs were carried out by companies before Swedish Orphan Biovitrum obtained a license or acquired the candidate drug. Problems with the studies/trials performed before such licensing or such acquisition could cause the company's applications to the authorities to be delayed or rejected, and even if the earlier studies/trials are acceptable to the authorities Swedish Orphan Biovitrum may need to devote more time and work to analyzing and presenting the results of the studies/trials. The costs of such work may be significant. Problems with earlier studies/trials may also require Swedish Orphan Biovitrum to redo some or all of these studies/trials, which could result in unforeseen costs or delays. Delayed or limited permits, or failure to obtain permits, could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### Strengthening of the product portfolio

An important component of Swedish Orphan Biovitrum's strategy is to develop a balanced product portfolio by, in addition to its internal research program, licensing in or otherwise acquiring the rights to potential new drugs. Licensing in and acquisitions of pharmaceutical products is a competitive component and the company may not be able to obtain a license for or acquire further suitable candidate drugs or products from third parties. A number of more established companies also have a strategy of licensing in or acquiring products within the areas that the company focuses on. Such companies may have a competitive advantage over Swedish Orphan Biovitrum due to their size, financial position or greater capacity for clinical development and commercialization. If the company is unable to obtain rights for new drugs from third parties on terms acceptable to the company this could mean that Swedish Orphan Biovitrum is unable to create a balanced product portfolio, which could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

## Need for additional financing

Swedish Orphan Biovitrum will need significant funds to carry on research and development of the company's potential products. Swedish Orphan Biovitrum may need to seek further external financing in the future and may do so through public or private financing. It may prove that further financing is not available at all or is not available on terms acceptable to Swedish Orphan Biovitrum.

Moreover, Swedish Orphan Biovitrum may need additional capital to finance future licensing in and acquisitions. It cannot be guaranteed that such financing will be obtainable in time or obtained on acceptable terms. If additional capital cannot be raised in time, the company may be forced to substantially limit its plans for in-licensing, acquisitions or research and development, which could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

# Conflicts may arise between Swedish Orphan Biovitrum and its cooperation partners

From time to time conflicts or differences of opinion arise between the company and its cooperation partners or counterparties regarding the interpretation of clinical data, the achievement of milestone payments, the interpretation of financial compensation for or the rights of ownership of patents and similar rights developed in cooperation. Any such conflict or difference of opinion could delay, prevent or otherwise hinder the development or commercialization of the company's candidate drugs, which could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

# Other business-related risk Competition

The market for specialist pharmaceuticals is characterized by significant competition and rapid technology development. Swedish Orphan Biovitrum's competitors include international pharmaceutical, biotech and specialist pharmaceutical companies. Some competitors have significantly greater financial, technical and human resources. Swedish Orphan Biovitrum's competitors may have greater manufacturing, distribution, sales and marketing capabilities than the company. Moreover, there is always a risk that the company's product concepts are exposed to competition from similar products or to entirely new product concepts which prove to be superior. By allying itself with external research groups in the forefront of medical development, the company achieves increased opportunities for gaining access to target proteins that can be developed for long-term competitive medical treatment options. To further strengthen its own position, strong patent protection is a priority. The above described competition could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### Parallel imports and pirated products

It cannot be ruled out that differences in drug prices in the markets in which Swedish Orphan Biovitrum is active could lead to an increase in parallel imports, which means that Swedish Orphan Biovitrum's products are purchased less expensively in certain markets and then compete with Swedish Orphan Biovitrum's sales in other markets. Swedish Orphan Biovitrum thus cannot guarantee that the company's products will not be imported in parallel. Moreover, the supply of prescription drugs has come to face an increasing challenge from the fact that the distribution channels are vulnerable to illegal pirating and the supply of pirated products in an increased number of markets as well as on the Internet. With the increased demand for cheap pharmaceutical products, primarily in developing countries,

pirated products have become an increasing problem. Swedish Orphan Biovitrum cannot guarantee that the company's products will not be at risk of attempted pirating, which could expose Swedish Orphan Biovitrum's patients to serious health risks. Pirated products do not meet the requirements of safety, but could be mistaken for the company's original products. Negative events caused by this could cause material financial losses due to damage to Swedish Orphan Biovitrum's reputation. Parallel imports and pirating could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### Dependence on key personnel

Swedish Orphan Biovitrum's success is dependent on key personnel in the company's executive management team. In view of these persons' knowledge within the pharmaceutical and biotech industry in general, and within the company in particular, the loss of one or more of these persons could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

The company's future development also depends in part on its continued ability to recruit and retain skilled personnel with the necessary expertise to run the business. If Swedish Orphan Biovitrum cannot continue to attract and retain such skilled personnel on terms acceptable to the company, Swedish Orphan Biovitrum could find it difficult to maintain or develop the business, which could have a material negative effect on the company's business results and financial position.

#### Acquisitions

Swedish Orphan Biovitrum completed the acquisition of Swedish Orphan in January 2010. The acquisition involves the integration of previously independent operations, Biovitrum and Swedish Orphan. Delays or difficulties that arise in connection with this integration could have a negative effect on the new group Swedish Orphan Biovitrum's business after the acquisition. One of the factors that the company has taken into consideration in connection with the acquisition is the opportunities for synergy effects. There are no guarantees that expected synergy effects, e.g. in the form of lower operating expenses and future costs or the utilization of Swedish Orphan's established infrastructure for sales and marketing in Europe, will be achieved or that additional integration costs will not be required in order to achieve synergy effects why it cannot be guaranteed that future financial targets are achieved. Failed, delayed or more costly integration of the two companies' businesses could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

The value of and consideration for Swedish Orphan were established using commonly used valuation methods and assumptions. The valuations may deviate from the businesses'

future fair value and there is therefore no guarantee that the consideration that Swedish Orphan Biovitrum pays for Swedish Orphan will not exceed Swedish Orphan's future fair value.

It cannot be guaranteed that Multiferon® will be a commercial success or will be authorized for its intended purpose in all markets. Prior to the acquisition, Swedish Orphan launched Multiferon® in two Nordic countries. In 2010 Swedish Orphan Biovitrum launched Multiferon® in a number of other European countries where the product has been authorized for two indications: (i) treatment of high-risk malignant melanoma and (ii) secondary treatment of patients who are intolerant to or do not respond to treatment with recombinant alfainterferon, irrespective of the underlying disease. The market's acceptance of the product depends on, among other things, whether it can demonstrate clinical efficacy and safety, whether it is cost-effective, whether the administration is smooth and simple, and whether it has any advantages over alternative treatment methods.

In the future the company may acquire further businesses or products that supplement or strengthen its current business or project portfolio. Future acquisitions of businesses or products could entail many operational and financial risks, which could have a material negative effect on the company's business, results and financial position, including the following:

- acquired drugs may not be successfully developed and successfully developed drugs may not achieve market acceptance,
- exposure to unknown commitments,
- higher costs than expected for acquisition and integration,
- difficulties and costs of integrating the operations and personnel of acquired companies with Swedish Orphan Biovitrum's operations and personnel,
- a deterioration in relations with key suppliers or customers of acquired companies due to changes in the corporate management and ownership,
- inability to retain key personnel of acquired companies, and
- significantly increased debt or increased dilution for existing shareholders as a result of payment in the company's own shares

#### Product liability

Although Swedish Orphan Biovitrum is not aware of any significant product liability claims against the company, the manufacture and sale of pharmaceutical products involves a significant risk of such claims. Although the company considers its product liability insurance to be adequate, no guarantees can be given that the insurance will cover future claims on the company. Moreover there could be a need to increase the insurance cover, which could lead to a material increase in costs or that a satisfying insurance cover could not be received. Product liability claims could result in significant costs for legal proceedings and damages, and a successful claim on the company

beyond the available insurance cover, or a claim that results in significant negative publicity, could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### Handling of environmentally harmful materials

The company's research and development involves the controlled use of biological and hazardous materials and waste. The company is subject to laws and regulations controlling the use, manufacture, storage, handling and disposal of such materials and waste products. Although Swedish Orphan Biovitrum considers its safety routines for the handling and disposal of such materials to meet the prescribed standards, it cannot entirely eliminate the risk of accidental contamination or personal injury due to such material. Should an accident occur, the company could be held liable for damages or be punished by fines, which could have a material negative effect on the company's business, results and financial position. Moreover, Swedish Orphan Biovitrum may incur significant costs in order to comply with future environmental legislation and regulations.

#### Exchange rate fluctuations

The company's business is also subject to exchange rate risks. The majority of its expenses are incurred in SEK (Swedish kronor), while a significant proportion of its revenues accrue in other currencies. As a result of the international expansion that the company has undergone, a reduction in the exchange rate of US dollars and the euro in particular, or other foreign currencies in which revenue is earned relative to SEK could have a material negative effect on Swedish Orphan Biovitrum's results and financial position.

To hedge future foreign exchange flows, the company has adopted the following policy on currency hedging.

- Based on forecasts, natural hedging (offset/netting of incoming and outgoing currency flows) should be applied as far as possible.
- Swedish Orphan Biovitrum will hedge the net foreign currency exposure as follows:

Currency flow	Expected maturity	Hedge ratio	Minimum amount
Known/Secure	-	80-100%	SEK 1 million
Unknown/Not secure	< 1 år	< 50%	SEK 1 million

# Complex regulatory requirements for Swedish Orphan Biovitrum's business

The regulatory requirements concerning the manufacture, testing and marketing of the company's candidate drugs and products are complex and may change over time. Changes to rules applicable to pharmaceuticals and biological products could increase Swedish Orphan Biovitrum's costs, limit

opportunities for process development and manufacturing or hinder development of the company's candidate drugs and have negative effects on Swedish Orphan Biovitrum's ability to generate revenue.

# The industry in which Swedish Orphan Biovitrum operates is to an increasing extent affected by price pressure

The increased cost of medical treatment and healthcare in many countries leads to governments and other payers becoming more aware of the costs, which in turn leads to Swedish Orphan Biovitrum and the healthcare industry in general operating under strong price pressure. In most of the markets where Swedish Orphan Biovitrum is active, governments apply a certain control over the prices of drugs. The exercise of this control and its effects vary from country to country and different methods are applied on both supply and demand to control the costs of drugs. The introduction of new or extended measures for cost control of drugs could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

# The company's IT systems could suffer a crash, collapse or breach of security

Swedish Orphan Biovitrum is dependent on a number of IT systems in its business. In order to be able to resume normal operations and alleviate any losses, the company has back-up processes and contingency plans for the recovery of lost data in the event of the collapse of an IT system. Nonetheless, the business could be disrupted, resulting in delays in manufacturing, product distribution, etc., which could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### Tax disputes, other tax risks and legal disputes

Swedish Orphan Biovitrum is subject to different tax exposures due to a number of considerable restructurings and other transactions which the company has conducted or been party to, including restructurings for the purpose of disposal of operations and real property. The company has subsidiaries and considerable sales in many countries outside Sweden, meaning that the company is exposed to complex regulations within the tax area, inside as well as outside Sweden.

Particularly rules regarding social security contribution and other taxes in relation to incentive programs could be subject to different interpretations. Swedish Orphan has previously had incentive programs under which Swedish Orphan's employees were given the opportunity to acquire shares in Swedish Orphan. These incentive programs contained certain temporary transfer restrictions for the acquired shares. The risk of the tax authority taking the position that all of the increase in the value of the shares, while they are subject to transfer restric-

tions, should be considered to be salary and not capital gains, cannot be ruled out.

In April 2008 the Tax Agency filed a request with the county administrative court in the county of Stockholm for the company to be taxed for an amount of SEK 234 M based on the application of the Swedish Tax Avoidance Act regarding a disposal of real property through a limited partnership (kommanditbolag). The company has disputed the claim. Furthermore, on October 9, 2009 the Tax Agency submitted a new writ in which, based on two rulings by the Supreme Court on May 29, 2009, it presented new grounds for why the rules based on the Tax Avoidance Act regarding underpriced transfers should not be applied. Swedish Orphan Biovitrum believes that the Tax Agency should not win its case based on these new grounds either. The property, Paradiset 14, was transferred in 2004 to a company that was essentially a foreign-owned limited partnership company called Nya Paradiset KB and subsequently the shares in Nya Paradiset KB were sold to an external party at market price. The property was transferred to Nya Paradiset KB based on the rules regarding so-called underpriced transfers for a payment equivalent to the property's written-down value. The Tax Agency in a writ submitted to the county administrative court dated April 17, 2008 – based on the Tax Avoidance Act - has asked that the rules regarding underpriced transferred be disregarded. According to the Tax Agency, this means that as a result of the transfer of the property to Nya Paradiset KB Swedish Orphan Biovitrum should be taxed for a capital gain of SEK 234.5 M. In Swedish Orphan Biovitrum's opinion it is entirely clear that the company has not acted contrary to the purpose of the legislation in the manner claimed by the Tax Authority in the above-mentioned writ. On March 3, 2011, the administrative court announced that they uphold the Tax Agency's request, explaining that Swedish Orphan Biovitrum AB under the tax law will be charged an amount of 232.2 million as revenue in the 2005 tax year. The Company intends to appeal.

In the event that the company should lose these disputes, the company's losses carried forward can subsequently be reduced with considerable amounts. The Group's losses carried forward from previous years amount to a significant sum. However, some of the losses carried forward are blocked for utilization through group contributions during a certain number of years. Further, losses carried forward in acquired group companies amounting to approximately SEK 76 M can have been, or may be definitely lost if a certain agreed additional purchase price does not fall due. Also in general, losses carried forward in the Group may, wholly or in part, be lost through changes in ownership. In cases where tax penalties and VAT are levied these cannot be offset against losses carried forward.

The sellers of pharmaceutical company Arexis, which was aquired in August 2005, have made a claim against Swedish Orphan Biovitrum in the amount of approx SEK 325 M. The

sellers of Arexis claim that Swedish Orphan Biovitrum has not performed its obligations under the share purchase agreement entered into at the time of acquisition. Swedish Orphan Biovitrum have contested all claims presented by the sellers. The sellers have recently requested arbitration regarding parts of the above mentioned claim as well as, regarding the other parts, an expert determination provided for in the agreement.

# Risks relating to intangible assets Biotechnology, patent risks and intellectual property rights

Swedish Orphan Biovitrum's success will largely depend on the company's or its licensor's ability to obtain protection in the US, the EU and other countries for the intellectual property rights inherent in the products that the company develops, manufactures, markets and sells. The patent situation within the area of biotechnology and pharmaceuticals is generally highly uncertain and involves complex legal and scientific issues. In these circumstances it is difficult for the patent authorities to correctly assess inventions that are the subject of patent applications in relation to prior art. It is not certain that either the company or its licensor will be able to obtain patents for its products or its technology. Even if a patent is granted, it may be contested, declared void or circumvented, which would both limit the company's ability to prevent competitors from marketing similar products and reduce the period during which the company enjoys patent protection for its products. Furthermore, it is not certain that the company's and its licensor's patent will provide adequate protection from competitors with similar products or technology. Since patent applications in the US and many foreign jurisdictions are not generally published until 18 months after they have been submitted, or in certain cases not at all, and since the publication of discoveries in the scientific literature often takes place long after the discoveries were actually made, neither Swedish Orphan Biovitrum nor its licensor can be certain that it was first to make the inventions in patents issued or in patent applications in progress, or whether it was the first to apply for protection of the inventions described in the patent applications.

There is thus no guarantee that products and processes that are covered by a patent granted will not come under attack or be contested by competitors or that patents granted do not infringe competitors' patents.

In the event for example that a third party has applied for a patent covering the same product or technology as Swedish Orphan Biovitrum's, the company could be forced to take part in proceedings to decide who holds the rights to the patent. The costs of such proceedings may be significant. Moreover, the company could lose such proceedings and thus the right to the patent. The inability to receive and retain a satisfying

protection for intangible assets, which are included in the products that the company develop, manufacture, market and sell, could have a material effect on the company's business, result and financial position.

Within Swedish Orphan there are 12 officially designated and/or approved orphan drugs. Orfadin® is patent protected up to and including 2017 and has market exclusivity as an orphan drug in Europe until February 2015, with a possible prolongation of two years through a pediatric investigation plan. Orfadin® is patent protected in the United States through 2013. Issued patents for the production process for Multiferon® within the EU and the US expires between 2010 and 2019. Restrictions on these patent could have a material negative effect on the company's business, results and financial position.

#### Infringement of the intellectual property rights of others

The technologies that Swedish Orphan Biovitrum uses in its research, or which are included in target products or candidate drugs that the company endeavors to develop and commercialize, may infringe patents or patent applications owned or controlled by others. A third party could take action against the company or its cooperation partners, which could force the company to pay significant damages. If an action in respect of patent infringement were to be brought against Swedish Orphan Biovitrum or its cooperation partners, it/they could be forced to cease or defer research, development, manufacturing or sales of the product or candidate drug that is the subject of the action. Consequently, the company or its cooperation partners could choose to seek, or be forced to seek, a license from the third party and thus in all likelihood be forced to pay license fees and royalties. It is not certain that these licenses will be available on acceptable terms or even available at all. Even if Swedish Orphan Biovitrum or its cooperation partners were able to obtain a license, the rights could be non-exclusive, which would provide the company's competitors with access to the same intellectual property rights. Finally, the company could be prevented from commercializing a product, or forced to cease some aspect of its business, due to claims relating to patent infringement, which could considerably damage the business.

Extensive legal disputes and other proceedings in respect of patents and other intellectual property rights have occurred in the pharmaceutical and biotech sector. In addition to a claim of infringement against the company, it could become party to other patent proceedings and other disputes, including what are known as interference proceedings as notified by the United States Patent and Trademark Office and recovery proceedings in the European Patent Agency in respect of intellectual property rights to the company's projects, products and technologies. Swedish Orphan Biovitrum is currently a party in two objection proceedings at the European Patent Agency concerning certain third party patents. No guarantees can be given that the

results of such proceedings will be in Swedish Orphan Biovitrum's favor. Even if the ruling is in Swedish Orphan Biovitrum's favor, the costs incurred by Swedish Orphan Biovitrum could be significant. Certain of the company's competitors are better able to bear the costs of such legal proceedings and disputes than the company due to their significantly greater financial resources. Uncertainty as a result of the fact that patent legal proceedings and other proceedings have been instigated and are being continued could have a negative effect on Swedish Orphan Biovitrum's competitiveness. Patent legal proceedings and other proceedings could also take up a great deal of management time. For the above mentioned reasons, potential infringement of third party intellectual property could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

#### Technology licenses

Swedish Orphan Biovitrum is party to a number of technology licenses that are important for the business and the company is expected to be able to obtain further licenses in the future. The company has entered into license agreements with Amgen, Pfizer, Syntonix/Biogen Idec and a number of other cooperation partners. These licenses impose certain obligations on Swedish Orphan Biovitrum as regards commercialization, milestone payments, royalty income, insurance and other aspects. If the company fails to discharge these obligations, the licensor is entitled to terminate the license, as a result of which the company would be unable to market the products covered by the license concerned. Notice of termination by licenses could have a material negative effect on Swedish Orphan Biovitrum's business, result and financial position.

#### Trade secrets and know-how

In addition to patented products and technologies, the company uses its own technology, own processes and own knowhow that are not protected by patents. The company endeavors to protect such information, including through confidentiality agreements with employees, consultants and cooperation partners. It is not certain that such agreements will provide protection from leaks of confidential information or that the agreements will provide sufficient compensation if breached. Moreover, the company's trade secrets may otherwise become known or may be developed independently by competitors.

If Swedish Orphan Biovitrum's own internal information and know-how cannot be protected for some reason, this could have a material negative effect on Swedish Orphan Biovitrum's business, results and financial position.

# Employees/co-workers

#### Values and culture

Swedish Orphan Biovitrum combines advanced research with commercial results. Our operations place high demands on our employees and on our innovative and high-performance corporate culture. Our values – commitment, innovation, and focus on results – are important premises for achieving our objectives. These values are expressed in our leadership and are reflected in processes such as employee performance evaluations. We use a specific method for management by objectives and follow-up called the performance management process. Supervisors and employees set annual individual goals together based on the general goals of the company. For employees to remain committed, they must understand the company's mission and objectives and how their own performance contributes to these. At the end of the year, efforts are evaluated and performances are rated.

#### Skills development and innovation

Swedish Orphan Biovitrum is a knowledge-intensive company. Skills development is pivotal to improving our project portfolio so we can strengthen the production process and launch products. Employee skills development is linked to individual goals, which are based on operational and project needs. Many employees make a positive contribution to the operation through active participation in academic networks, with advantages such as access to new research findings.

#### Salaries and benefits

Good employment terms are a prerequisite if Swedish Orphan Biovitrum is to recruit and retain qualified employees. Swedish Orphan Biovitrum therefore offers competitive salaries and benefits. The company applies the principle that salaries should be individual and differential, and they are determined by local salary criteria.

#### Diversity and equal opportunity

The average number of employees in 2010 was 508 (433), with a good balance between men and women.

For us, it stands to reason that everyone is offered the same opportunities and is treated equally, regardless of age, gender, religion, sexual orientation, disability or ethnic affiliation. We also strive to be a company where working life and private life can coexist within the framework of our operations.

#### Health and wellness

Swedish Orphan Biovitrum aims for a work environment that promotes health and well-being, and sickness absences in 2010 was just below two percent. Employees are offered an annual fitness allowance to use for various wellness activities.

#### Occupational health and safety

Swedish Orphan Biovitrum strives to fully comply with all environment-related laws and regulations. Environmental initiatives are integrated into our work environment and quality assurance efforts. Our combined work environment and environmental policy emphasizes the significance of the work environment. The environmental policy is available on Swedish Orphan Biovitrum's website: www.sobi.com. Formal work environment responsibility is delegated down the line. Each restricted area has an environmental group coordinator who helps the people in charge create a good work environment. They work with managers, safety officers, and other employees to compile environmental action plans. Risk inventories and safety inspections focusing on ergonomics, chemicals, genetically modified microorganisms, electrical safety and radiation protection are performed regularly in restricted areas. No workplace accidents were reported to the Swedish Work Environment Authority in 2010.

#### Respect for rules in the labor market

Swedish Orphan Biovitrum complies with and respects labor market regulations and agreements signed by parties in the labor market. We have a constructive partnership with trade unions and employer organizations and relations are good.

#### Remuneration for senior executives

Board proposal for guidelines for remuneration to senior executives

The board of directors proposes that the Annual General Meeting resolve to approve the board of directors' proposal regarding guidelines for remuneration for the management as set forth below which shall apply until the Annual General Meeting 2012. In this context, the management refers to the chief executive officer of Swedish Orphan Biovitrum and the executives who, from time to time, report to the chief executive officer and who are also members of senior management, as well as members of the board of directors to the extent they enter into employment or consulting agreements.

#### Motives

Swedish Orphan Biovitrum shall offer remuneration in line with market conditions to enable the company to recruit and retain qualified personnel. The remuneration to the management may consist of fixed salary, variable salary, pension and other customary benefits. Long-term incentive programs may be offered in addition to the above and will then be submitted to the Annual General Meeting for approval. The remuneration is mainly based on position, performance and the achievements of the company and the individual in relation to objectives determined in advance.

#### Fixed salary

The fixed salary for the chief executive officer and the other members of the management shall be in line with market conditions and mirror the demands and responsibility that the position entails. The fixed salary for the chief executive officer and other members of the management is reviewed once a year, as per January 1.

To the extent a member of the board of directors carries out work for the company or for another group company, in addition to the board work, consulting fees and/or other remuneration for such work may be payable.

#### Variable salary

The variable salary for the chief executive officer and the other members of the management shall be based on the company's fulfillment of objectives determined in advance. These objectives are determined for the promotion of the long-term development, value creation and financial growth of the company/ group and shall be designed in a way that does not encourage excessive risk-taking. The variable salary may not amount to more than 50 per cent of the fixed salary for the chief executive officer and not more than 30 – 50 per cent of the fixed salary for the other members of the management.

#### Long-term incentive programs

Long-term incentive programs may constitute a complement to the fixed salary and the variable salary. The program participants are nominated based on competence, performance and to retain key employees with the company. The outcome is dependent on the fulfillment of certain predetermined performance requirements. The aim of long-term incentive programs shall be to create long-term commitment to Swedish Orphan Biovitrum, to offer participants the opportunity to take part in Swedish Orphan Biovitrum's long-term success and value creation and to create possibilities to attract and retain members of the management and key employees. For more information about Swedish Orphan Biovitrum's current incentive programs, see Swedish Orphan Biovitrum's annual report 2010, note 14.

#### Other remuneration and terms of employment

The pension benefits for the chief executive officer and the other members of the management shall preferably consist of premium based pension plans, but may also be defined-benefit pursuant to collective agreements.

The employment agreements with the members of the management may be terminated with a reciprocal notice period of up to six months. Upon termination by the company a severance payment is paid corresponding to maximum 18 monthly salaries. Fixed salary during a period of notice and severance pay, including possible compensation for restraint on competition/non-competition and non-solicitation, are together not

to exceed an amount equivalent to the individual's fixed salary for two years. Upon a material change in the business, the employee is provided, under certain circumstances, with the possibility to terminate the employment with a right to severance payment in accordance with the above corresponding to maximum 12 monthly salaries. The chief executive officer shall be entitled to severance payment corresponding to 18 monthly salaries in case of termination of employment due to a change of control of the company meaning that more than 50 per cent of the shares in the company are owned by one shareholder. However, the total severance payment for all members of the management may not exceed the existing salary for the remaining months up to the age of 65.

#### Deviation from the guidelines

The board of directors may resolve to deviate from the guidelines if the board of directors, in an individual case, is of the opinion that there are special circumstances justifying that.

#### Deviations from the previously adopted guidelines

The Board have, supported by the 2010 annual meeting adopted guidelines, deviated from the guidelines in force regarding consulting agreements with a member of the board. The discrepancy consist of an employment contract concluded with the chairman of the board.

#### Information on past decisions on remuneration that is not due for payment at the Annual General Meeting review of draft guidelines

Decided executive compensation falls within the guidelines.

#### Remuneration policy 2010

Guidelines regarding compensation and other terms of employment, within Swedish Orphan Biovitrum, decided at the Annual General Meeting in 2010 can be found in Note 14 – employees, human resources, remuneration to the Board.

#### Share and option programs

Swedish Orphan Biovitrum currently has two active option programs and three share programs. The programs are described in more detail in Note 14.

#### Employee option program 2006/2011

In May 2006, 150,000 warrants were issued to be used in an option program for certain key individuals. Each warrant entitles the holder to subscribe for 3.78 shares.<sup>2</sup> The issue price per share based on these options is SEK 58.21<sup>2</sup> and the warrants expire on May 31, 2011. When allocated, the options entitle holders to earn an equal number of warrants, earning one-third of the total allocated warrants per year during the first three

years. Options and their subsequent warrants are allocated free of charge (without payment).

In 2010, no options were surrendered and no options were issued. The number of outstanding options at year-end amounted to 15,000.

#### Employee option program 2007/2012

The 2007 Annual General Meeting resolved to initiate an employee option program for 2007/2012. As part of the plan, employee options may be issued with the right to acquire up to 567,000 shares in the company. Each employee option may be exercised through April 1, 2012, to acquire 1.89 shares in Swedish Orphan Biovitrum at an exercise price of SEK 58.21² per share. The right to acquire new shares under the employee option program will be exercisable with one-third of the total amount of employee options allocated from the date falling one year from the allocation date (the "anniversary date") and an additional one-third from each of the two subsequent anniversary dates, provided that the holder as of these dates is still employed by the company and has not been given notice of termination of employment.

A total of 300,000 employee options in this program were allocated and at year-end the number outstanding was 300,000.

#### Share Program 2008

The Annual General Meeting in 2008 resolved to approve a performance-based, long-term share program in 2008. Share program 2008 covers management and key individuals in Swedish Orphan Biovitrum, and may involve a total maximum allocation of 422,280 shares² in Swedish Orphan Biovitrum AB (publ). The number of shares, to be received by program participants, will be based on the development of the Swedish Orphan Biovitrum share over a three-year assessment period. The program was implemented in late 2008, and the performance period is from November 26, 2008 to November 25, 2011.

#### Share Program 2009

The 2009 Annual General Meeting resolved to approve a performance-based, long-term 2009 share program. Share program 2009 covers management and key individuals in Swedish Orphan Biovitrum, and may involve a total maximum allocation of 322,148 shares² in Swedish Orphan Biovitrum AB (publ). The number of shares, to be received by program participants, will be based on the development of the Swedish Orphan Biovitrum share over a three-year assessment period. The program was implemented in 2009, and the performance period extends from June 10, 2009 to June 9, 2012.

#### Share Program 2010

The 2010 Annual General Meeting resolved to approve a performance-based, long-term share program. Share Program

2) Adjusted for the new share issue completed in January 2010

2010 is essentially the same as the share programs from earlier years, except that in Share Program 2010 participants are required to invest in Swedish Orphan Biovitrum shares and hold these shares throughout the three-year vesting period. The program covers management and key individuals, who receive the opportunity for allocation of ordinary shares in Swedish Orphan Biovitrum on condition that involved employees invest in Swedish Orphan Biovitrum shares and on condition that involved employees remain employed throughout the vesting period. Provided that the abovementioned requirements are met, involved employees may receive Swedish Orphan Biovitrum shares free of charge equivalent to the number of shares the employee invested in under the Share Program 2010 ("Matching shares") as well as additional Swedish Orphan Biovitrum shares depending on whether targets set by the board of directors for value creation are met ("Performance shares"). Share Program 2010 was implemented in late 2010 and the performance period is from December 13, 2010, to December 12, 2013, and may entail a maximum total allocation of 510,547 shares in Swedish Orphan Biovitrum.

#### Changes in the company's ownership structure

The CEO and six of the senior executives in 2010 have a clause in their employment agreements entitling them to certain rights in the event of a considerable change in the company, such as the company being transferred to a new dominating shareholder. The CEO, Martin Nicklasson, will, in such a case, be entitled to terminate his employment with six months' notice and to receive severance pay equivalent to eighteen monthly salaries. The six members of corporate management who have such a provision written into their agreements have the corresponding right to terminate their employment with up to 12 months of pay.

#### **Environmental information**

Swedish Orphan Biovitrum works according to an environmental management system based on the international standard ISO 14001, but is not certified. The system also covers Swedish health and safety rules. The environmental management system is integrated in the operation with formal responsibility for environmental issues delegated in the line. Sobi's management has adopted an environmental policy to further emphasize the importance of environmental management. The policy is available on the Swedish Orphan Biovitrum website www.sobi.com. Sobi's computerized management system links current legislation and rules to internal control documents and procedures. In 2010 the internal control documents/procedures for environmental management, waste management, chemical management, incident reporting and dangerous goods were revised. Adaptation to comply with REACH and CLP regulations has been part of this initiative. Risk inventories, safety inspections

and action plans for 2010 were carried out or established at the departmental level.

Swedish Orphan Biovitrum's production facilities in Stockholm and Umeå are licensed for hazardous operations in compliance with the Swedish Environmental Code, with wastewater management conditions. Compliance with the terms of the permit is reported annually in environmental reports prepared for local licensing authorities. In 2010 no violations of the conditions were reported. Notifiable operations, under the same rules, are carried out at Solna.

In 2010 Swedish Orphan Biovitrum had a permit from the Swedish Environment Authority for handling of thioacetamide. Sobi previously reported to the Swedish Environment Authority the use of infectious agents in risk group 2 as well as contained use of genetically modified microorganisms (GMM), with an annual update. In 2010 a new application was submitted for the contained use of GMM for the operation that moved to Karolinska Institutet Science Park. The company also has an import permit for animal by-products from the Board of Agriculture and a permit to handle flammable goods. Swedish Orphan Biovitrum is associated with REPA. In 2010 Swedish Orphan Biovitrum had to pay an environmental sanction charge because the 2008 control report for a refrigerant plant arrived three days late.

Adaptation to current regulations has not yet affected Swedish Orphan Biovitrum's competitiveness or operations negatively, but the company cannot predict the effects of future regulations.

#### Revenues and profit Four years overview

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Amounts in SEK million	2010	2009	2008	2007	2006
Total revenues	1,906.7	1,297.0	1,140.6	1,256.4	1,201.1
Adjusted profit/loss for the period	-16.7	32.4	60.4	79.0	92.7
Cost of goods and services sold	-685.7	-375.7	-264.7	-348.8	-293.8
Research and development expenses	-479.9	-569.4	-670.6	-694.3	-650.4
Operating profit/loss	-10.3	16.2	-386.2	55.1	54.6
Financial items – net	-82.2	16.3	20.2	23.9	39.6
Profit/loss for the period	-104.5	32.4	-335.4	79.0	92.7
Earnings/loss per share <sup>1</sup> , SEK	-0.53	0.33	-3.67	0.87	1.01
Earnings/loss per share <sup>1</sup> , SEK	-0.53	0.32	-3.67	0.85	0.93
Number of shares	212,181	50,396	49,815	45,623	45,623
Equity ratio	61.4%	48.2%	49.8%	74.6%	66.5%

<sup>1)</sup> Earnings per share have been adjusted for the bonus issue component of the new share issue, which was concluded in January 2010.

#### Operating revenues

Operating revenues for 2010 totaled SEK 1,906.7 M, compared with SEK 1,297.0 M for 2009, with the following breakdown:

Total revenues	1,906.7	1,297.0
Other	-	0.1
Licensing and milestone revenues	23.6	62.6
Royalty revenues	109.7	165.7
Manufacturing and contract development	388.0	376.5
Co-promotion revenues	123.0	127.3
Product Sales	1,262.4	564.8
Amounts in SEK million	2010	2009

#### ReFacto®

Revenues from ReFacto® fell to SEK 587.1 M in 2010 compared with SEK 617.8 M in 2009. Total manufacturing revenues for the full year were SEK 388 M (362.5). Royalty revenues for the sale of ReFacto® fell to SEK 109.7 M (165.7). Co-promotion revenues declined marginally to SEK 89.4 M (89.7).

For the twelve-month period total ReFacto® revenues were 6% lower in CER year on year, mainly due to lower royalties for ReFacto AF/Xyntha® compared with ReFacto®. In 2010 Swedish Orphan Biovitrum completed the transition to ReFacto AF/Xyntha®.

#### Kineret®

Global sales of Kineret® declined to SEK 422.3 M in 2010 compared with SEK 440.8 M in 2009.

Sales in Europe were affected by mandatory price cuts and discounts imposed by public authorities in several countries. As a result of expected lower prices, inventory cutbacks at the distributor and wholesaler level have become noticeable, which had a negative impact on sales.

Despite these factors, global full-year sales of Kineret® increased 3% (CER) mainly because North American sales were 12% (CER) higher than in 2009. A relaunch in Europe is in progress to boost sales of Kineret®, with the full effect first expected in 2011.

#### Orfadin®

Global sales of Orfadin® rose to SEK 321.8 M in 2010 compared with SEK 310 M in 2009.

For the twelve-month period sales of Orfadin® increased 30% (CER) in the United States and 12% (CER) in Europe. Mandatory price cuts or discounts only had a minimal impact on the price of Orfadin® in Europe.

#### Kepivance®

Global sales of Kepivance® declined to SEK 94.8 M in 2010 compared with SEK 109.9 M in 2009.

The year-on-year decline is largely due to a decision by the European regulatory authority EMA to restrict an approved

indication, along with mandatory discounts or price cuts imposed by certain national regulatory authorities.

Continued good demand in North America increased sales by 3% in CER for the year.

#### Yondelis®

Global sales of Yondelis® fell to SEK 40.6 M in 2010 compared with 43.9 SEK M under 2009.

The launch of a second indication in the field of ovarian cancer is underway.

#### Ammonaps®

Global sales decreased marginally to SEK 69.1 M in 2010 compared with SEK 69.9 M in 2009. This decline can largely be explained by negative currency effects, price pressure and a shortage of goods from the manufacturer in late 2010. On a twelve-month basis product sales grew 9% (CER) compared with 2009.

#### Willfact®

Sales of Willfact® in 2010 totaled SEK 13.1 M. Willfact® is currently sold in Germany, where the drug is approved, as well as on a named patient basis in other countries. Sales are expected to increase further during 2011 since marketing approval was recently obtained in the Nordic and Baltic countries as well as other parts of Central and Eastern Europe.

#### Expenses

The cost of goods and services sold increased as a result of the acquisition of Swedish Orphan and the increase in product sales as a percentage of total revenue. Gross margin declined in 2010 due to lower licensing and milestone payments and lower royalty revenues as a result of the transition to Refacto AF®, as well as a changed product mix and increased expenses for the Tech Transfer project relating to Kineret®. Gross margin excluding licensing and milestone payments totaled 63.5% (69.6%).

Research and development expenses decreased by 16 percent in 2010 compared with 2009, and amounted to SEK 479.9 M (569.4). This reduction was due to the restructured cooperation agreement with Biogen Idec for the rFIXFc and rFVIIIFc projects, as well as the sale of the subsidiary CBT.

Selling and administrative expenses increased during the year. The European subsidiaries expanded their services in conjunction with the integration of the products Kineret® and Kepivance® into their existing product portfolios, and continued simultaneous investments in other key products. In the United States recruitment of local marketing staff continued in 2010, reaching closes to planned capacity by the end of the year. To some extent the cost increases were offset by positive currency effects in Europe and the US.

#### Profit/loss

Operating income (EBITA) was SEK 371.9 M (273.6). The operating profit/loss for 2010 was SEK -10.2 M (16.3). Excluding restructuring and non-recurring costs the operating profit/loss was SEK 77.5 M (16.3). Net financial income in 2010 was SEK -82.2 M (16.3).

The profit/loss for 2010 was SEK -104.4 M (32.4).

#### Financial position

Cash and cash equivalents and short-term investments as of December 31, 2010 amounted to SEK 38.5 M (306.6). Of this amount, SEK 38.5 M (129.6) were bank balances and SEK 0 M (128.6) investments in securities with a term of less than three months from the date of acquisition. These short-term investments are classified as cash and cash equivalents. Besides cash and cash equivalents, in 2009 the company had other short-term investments with a term of more than three months amounting to SEK 48.4.

Cash flow from operations was SEK -215.1 M (58.9).

#### Investments

The Group's investments in fixed assets in 2010 amounted to SEK 1,934.1 M (346.5), of which SEK 1,811.3 M relates to intangible assets largely associated with the acquisition of Swedish Orphan. Depreciation and write-downs amounted to SEK 355.1 M (109.7).

#### Taxes

The Group has accumulated a loss carry-forward, most of which has not been recognized as an asset. Consequently the company's tax rate deviates from the Swedish tax rate. Swedish Orphan Biovitrum's tax expense was SEK 12 M (0). Tax expense for the year was SEK 38.5 M (0) and the company reversed a deferred tax liability of SEK 26.5 M (0 SEK M).

#### Parent company

The parent company reported revenues for full year 2010 of SEK 1,185.9 M (1,297.0), operating profit/loss of SEK -17.1 M (36.4) and net profit/loss of SEK -104.7 M (70.4). Cash, cash equivalents, and short-term investments at December 31, 2010 amounted to SEK 9.1 M (December 31, 2009: 306.4).

Shareholders' equity in Swedish Orphan Biovitrum (publ) as of December 31, 2010 amounted to SEK 4,375.9 M (December 31, 2009: 1,326.1).

#### Outlook

Due to considerable uncertainty relating to global macroeconomic trends, currency uncertainty, current budget problems in most European countries in 2011, and the impact of these factors on the pharmaceutical market especially in Europe, no guidance will be provided for the coming year. The company expects a favorable volume growth, but price cuts for pharmaceuticals in Europe in 2010 will have full impact during 2011, and the strong Swedish krona in relation to the US dollar and the euro is expected to reduce the growth in SEK compared to the underlying volume increase.

Seven product launches (Ruconest®, Willfact®, Promixin®, Yondelis®, Multiferon®, Kineret® and Removab®), product development activities, and the successes in the late project portfolio (rFVIIIFc, rFIXFc and Kiobrina®) lay a strong foundation for profitable growth. In accordance with previous plans, we are continuing our increased marketing and sales efforts by expansion of the subsidiaries in Europe, the strengthening presence in the US and the expansion of the distributor network for our products in rest of the world.

We are confident that the products in late stage development phases, rFVIIIFc, rFIXFc and Kiobrina®, will reach the market within a few years. We also have increased our business development activities in order to conclude further cooperation and licensing agreements as well as making acquisitions. To increase profitability, an internal project has been initiated aiming at eliminating unnecessary costs by reviewing working procedures, routines and prioritizations.

In the light of these facts, our long-term business objective is to achieve revenues of SEK 5 B and an EBITA margin of 30% by 2015.

#### Events after the closing date

- On January 11, 2011, Swedish Orphan Biovitrum and BL&H Co Ltd entered into a distribution agreement for the products Orfadin® and Kepivance® in South Korea, yet another step in the geographic expansion of Sobi's products. Under the agreement BL&H will be responsible for registration and distribution of the products in South Korea. Since the South Korean Food and Drug Administration registration process is adapted to products already approved by the FDA or EMA, registration is expected approximately one year from application. Sales on a named patient basis may be initiated already during 2011.
- On January 27, 2011, Sobi announced that a distribution agreement with Fresenius Biotech had been signed to distribute Removab® in the Nordic countries, Poland, Czech Republic, Slovak Republic, Slovenia, Romania, Bulgaria, Hungary, Estonia, Latvia and Lithuania over seven years. Removab® was granted marketing authorization by the European Commission in April 2009 for the treatment of malignant ascites associated with cancer and has been launched in Germany, Austria and France so far. Removab® is an innovative product that holds great value to patients with high medical needs. Moreover, Removab® is a perfect fit with our cancer product portfolio such as Yondelis® which is distributed in similar territories.

- On February 22, 2011, Sobi announced changes to its management team and a strengthening of its Business Development function. The changes illustrates Sobi's commitment to a growth strategy built both on products coming from its own late stage pipeline as well as aggressively pursuing partnerships with other pharmaceutical and biotech companies, distribution agreements, in-licensing activities and acquisitions. In addition, the broadening of the Executive Management Team is a reflexion of Sobi's international focus. Many of the team members have vast international experience.
- On March 3, 2011, the administrative court announced that they uphold the Tax Agency's request, explaining that Swedish Orphan Biovitrum AB under the tax law will be charged an amount of 232.2 million as revenue in the 2005 tax year. The Company intends to appeal.

#### Changes in shareholders' equity

Consolidated shareholders' equity as of December 31, 2010, was SEK 4,342.4 M, compared with SEK 1,352.8 M on December 31, 2009.

During the year 159,129 238 shares were issued in connection with acquisition of Swedish Orphan. In addition, 2,373,300 shares were issued when debt instruments were converted, 282,425 shares were issued in connection with a milestone payment, and 1,552,949 C-shares issued in connection with the implementation of Share Program 2010.

#### Shareholders

At year-end, Swedish Orphan Biovitrum had a total of 8,661 (5,562) shareholders. Investor AB was the largest shareholder with 40.2 percent of capital and 40.5 percent of votes at year-end. The 15 biggest shareholders together controlled 78.5 percent of the capital and 79.2 percent of the votes.

Share holder	Number of Shares	Share capital %	Share votes %
Investor AB	86,075,332	40.2%	40.5%
Omnibus Account W FD: OM80	19,468,748	9.1%	9.2%
MPM Funds	14,195,424	6.6%	6.7%
Livförsäkringsbolaget Skandia	8,465,139	4.0%	4.0%
SEB Private Bank S.A., NQI	7,353,377	3.4%	3.5%
Handelsbanken Fonder inkl XACT	6,516,204	3.0%	3.1%
Nordea Bank Norge Nominee	4,504,422	2.1%	2.1%
Orkla ASA	4,475,933	2.1%	2.1%
Swedbank Robur Fonder	4,256,928	2.0%	2.0%
ABN AMRO Nordic Ventures	2,728,551	1.3%	1.3%
Apoteket AB's Pensionsstiftelse	2,600,000	1.2%	1.2%
Andra AP-Fonden	2,144,202	1.0%	1.0%
JPM Chase NA	2,039,040	1.0%	1.0%
SEB Investment Management	1,774,236	0.8%	0.8%
AMF – Försäkringar och Fonder	1,562,800	0.7%	0.7%
Swedish Orphan Biovitrum AB (C-shares, 1/10 vote per share)	1,552,949	0.7%	0.1%
Biovitrum Treasury (C-shares, 1/10 vote per share)	515,585	0.2%	0.0%
Other	44,020,943	20.5%	20.7%
Total	214,249,813	100.0%	100.0%

#### Share capital

Swedish Orphan Biovitrum's share capital at year-end was SEK 117,558,199 shared between 214,249,813 shares with a par value of around SEK 0.55. The issued shares break down as 212,181 279 ordinary shares and 2,068,534 C shares. The ordinary shares carry one vote per share and the C shares carry 1/10 vote per share. All C shares are treasury shares.

In connection with Share Program 2008, Share Program 2009 and Share Program 2010 the company issued C shares and the company has 2,068,534 C shares at year-end.

C-shares only give entitlement to an annual dividend equal to 10 per cent of the company's distributable profits, calculated on the quota value of the share. All shares entail equal rights to the company's assets and any surplus in the event of liquidation.

#### The company's treasury shares

In 2010 Swedish Orphan Biovitrum acquired 1,552,949 treasury shares of share class C. The purchase price for the shares was SEK 852,098 which represents a share value of 0.55 SEK. These shares represent 1.0 percent of the total number of shares in the company.

The long-term share program ("Share Program 2010") is the reason for the acquisition of the shares.

Below is a summary of developments in the company relating to share capital and number of shares.

#### Swedish Orphan Biovitrum share

Swedish Orphan Biovitrum's share price rose 45.7 per cent during the year, from SEK 27.80 per share at the beginning of the year to SEK 40.50 at the end of the year. Market capitalization was SEK 8.6 billion at the end of 2010. The Swedish Orphan Biovitrum share is included in the OMX Nordic Exchange's Stockholm Pharma Biotech & Life Science Index, which during the same period increased by 0.5 percent. The highest trading price during the year was SEK 47 (April 6, 2010) and the lowest price was SEK 27.80 (January 15, 2010).

#### Development in share capital and number

		Change number of	Change share	Total share capital	Total number of
		shares	capital	(SEK)	shares
Jan 2001	Founding of company	=	=	10,000,000	10,000,000
May 2001	Bonus issue	1,880,000	1,880,000	11,880,000	11,880,000
July 2001	Issue of shares	11,880,000	11,880,000	23,760,000	23,760,000
Apr 2006	Redemption of shares	-4,514,400	-4,514,400	19,245,600	19,245,600
Apr 2006	Bonus issue	2,405,700	4,514,400	23,760,000	21,651,300
Aug 2006	Split 2:1	21,651,300	=	23,760,000	43,302,600
Sep-Dec 2006	Issue of shares in connection with warrant programs	2,320,100	1,273,032	25,033,032	45,622,700
Jun 2008	Issue of shares in connection with additional purchase price related to Arexis	142,422	78,147	25,111,179	45,765,122
Sep 2008	Issue of shares in connection with warrant programs	250,502	137,450	25,248,628	46,015,624
Sep 2008	Issue of shares in connection with share based incentive pro- gram 2008	284,000	159,237	25,407,865	46,299,624
Nov 2008	Issue of shares in connection with warrant programs	30,642	16,786	25,424,651	46,330,266
Dec 2008	Issue of shares in connection with purchase price related to Amgen products	3,768,516	2,064,393	27,489,044	50,098,782
May/Jun 2009	Issue of shares in connection with warrant programs	581,534	319,086	27,808,130	50,680,316
Sep 2009	Issue of shares in connection with share based incentive program 2009	231,585	127,372	27,935,502	50,911,901
Jan 2010	Issue of shares in connection with acqusition of Swedish Orphan	159,129,238	87,313,411	115,248,913	210,041,139
May 2010	Issue of shares	2,373,300	1,301,495	116,550,408	212,414,439
Aug 2010	Issue of shares	282,425	155,693	116,706,101	212,696,864
Oct 2010	Issue of shares in connection with share based incentive program 2010	1,552,949	852,098	117,558,199	214,249,813
	Shares being held by Biovitrum				2,068,534





#### Corporate Governance Report 2010

Swedish Orphan Biovitrum AB (publ), referred below to as "Swedish Orphan Biovitrum," is a Swedish public limited liability company with registered office in Stockholm, listed on the NASDAQ OMX Stockholm AB. In addition to the rules laid down by law or regulation, the company applies Swedish Code of Corporate Governance. The company does not deviate from the code. This corporate governance report refers to the 2010 financial year. This report comprises a part of the formal Annual Report and has been reviewed by the company's auditors.

Swedish Orphan Biovitrum's Articles of Association and more information as to how Swedish Orphan Biovitrum is managed are available at www.sobi.com under the heading: Om oss/ About us

#### **Annual General Meeting**

The company does not apply any special arrangements relating to the function of the annual meeting of shareholders, either due to provisions in the Articles of Association or, as far as is known to the Company, shareholder agreements. The Articles of Association stipulate that the Annual General Meeting be held in Stockholm. Swedish Orphan Biovitrum has not found that the composition of the body of shareholders motivates any particular measures for shareholders being able to follow the Annual General Meeting remotely.

#### Annual General Meeting 2010

At the Annual General Meeting April 27, 2010, the following directors were elected until the Annual General Meeting 2011: Bo Jesper Hansen, who was also elected to serve as Chairman, Hans Glemstedt, Adine Grate Axén, Lennart Johansson, Wenche Rolfsen, Michael Steinmetz and Hans Wigzell. The

Meeting also passed resolutions regarding among other things fees for the Chairman and for directors elected at the Annual General Meeting, see page 45, Board remuneration.

The Meeting also adopted a resolution on a new performance-based, long-term share program 2010 as well as a decision on a directed issue of series C shares. Finally, the Board was authorized to repurchase the issued series C shares. All resolutions were unanimously adopted.

The minutes from the 2010 Annual General Meeting are available on the company's website, www.sobi.com.

#### Shareholders, share capital, the share and voting rights

At year-end, Swedish Orphan Biovitrum had a total of 8,661 shareholders. At that time Investor AB held 40.2 percent of capital and 40.5 percent of votes and the 15 largest shareholders together accounted for 78.5 the percent of capital and 79.2 percent of the votes. No shareholder other than Investor AB has a direct or indirect shareholding in the company that represents at least one tenth of the voting rights for all shares in the company. The company's Articles of Association contain no restrictions on how many votes each shareholder may cast at a general meeting.

The company's Articles of Association do not have any specific provisions regarding the appointment and dismissal of directors, or about amending the articles.

At present, the Board intends to use any future profits for Swedish Orphan Biovitrum to finance the continued development and expansion of operations, for which reason the Board does not intend to propose any dividend within the foreseeable future. For more information about the company's share capital, see page 40, Share capital.

#### Nomination Committee

The Nomination Committee's duties include making recommendations to the Annual General Meeting regarding the Chairman of the General Meeting, the number of directors elected by General Meetings, the Chairman of the Board of Directors and other directors; making recommendations to the Annual General Meeting concerning compensation to the Chairman and other directors, and concerning potential compensation for committee assignments; and, whenever applicable, making recommendations for auditors, alternate auditors, and auditors' fees.

In accordance with the criteria stipulated by the Annual General Meeting held April 27, 2010, the Nomination Committee shall consist of four persons, three of whom shall represent the three largest owners of the company in the week preceding publication of the company's Interim Report for the third quarter. The fourth person shall, in accordance with the same resolution, be the Chairman of the Board of Directors. The members of the Committee are to be announced no later than six months before the Annual General Meeting. After contacts with the company's largest shareholders in accordance with the regulations for the Nomination Committee, the Nomination Committee, which shall prepare proposals for the 2011 Annual General Meeting, consists of:

- Petra Hedengran, representing Investor (Chairman of the Nomination Committee)
- Roger Johanson, representing Skandia Liv
- Åsa Nisell, representing Swedbank Robur Fonder AB
- Bo Jesper Hansen, in his capacity as Chairman of the Board of Swedish Orphan Biovitrum AB (publ)

The Nomination Committee held three meetings prior to the 2011 Annual General Meeting.

#### **Board of Directors**

#### Duties of the Board of Directors

The task of the Board of Directors according to the Swedish Companies Act is to be responsible for the Group's organization and management, and to ensure that bookkeeping, management of funds and financial conditions in general, are satisfactory. The Board shall make decisions regarding general goals, strategies, financial structure, policies, the appointment of the CEO and remuneration to management, acquisitions, sales and major capital expenditures. The Board approves and adopts the Annual Report and Interim Reports, and is responsible for proposing dividend, if any, to the Annual General Meeting.

In addition, the Board shall evaluate the work done by the CEO and management, and ensure that effective systems and

procedures are in place for the follow-up and supervision of operations and the financial position of the company in relation to established goals. The basis for these tasks is the formal work plan for the Board, which the Board has adopted, and the instructions to the CEO, and the principles for the division of work between the CEO, the Chairman of the Board, the Board of Directors and various committees that the Board has established. The formal work plan of the Board and the instructions to the CEO are revised and updated once a year.

#### Number of meetings

The Board meets at least five times a year, usually in connection with the Annual General Meeting and with the publication of the Interim Reports and full-year financial statements. Additional meetings or telephone conferences are scheduled as necessary. During at least one of the Board Meetings per year, the Board carries out an in-depth strategic review of operations. The Board has planned five meetings and three telephone conferences for 2011.

#### Committees

Within the Board there are committees for auditing, compensation and benefits and scientific matters. These have been established to streamline the work for the Board by preparing certain issues before the Board takes them up for review. The members of the committees are appointed by the inaugural Board Meeting, and working instructions for the committees are included in the Board's formal rules of procedure.

At the Board Meetings, ongoing matters are discussed concerning the follow-up of general operational goals, financial updating and updating of the product and R&D portfolio, and other activities and reports from the committees. In addition to these matters, a large part of the Board's time is spent on matters concerning capital expenditures, acquisitions, and licensing in and licensing out of drug projects and products.

#### Chairman of the Board

The Chairman of the Board of Directors' duties, apart from leading the Board in its work, include following the development of the company and ensuring that important matters in addition to those already on the agenda are brought up for discussion as necessary. The Chairman shall also ensure that constructive and active discussion is held prior to important decisions, and that the various members of the Board and their competencies are, in this regard, brought to expression in a fruitful way, and can be used properly. The Chairman shall consult with the CEO regarding strategic matters, participate in important external contacts and represent the company with regard to ownership matters. The Chairman is also responsible for ensuring that the work of the Board is regularly evaluated and that new directors receive adequate training. As can

	Dependent/ Independent	Attendance Board Meetings	Attendance Comp & Ben Committee	Attendance Finance & Audit Committee	Shareholding <sup>1)</sup>
Håkan Åström, chairman up to April 26	•	7/20	1/6	2/8	
Bo Jesper Hansen, vice chairman, chairman from April 27	•	17/20	5/6	n/a	7,115,077
Hans Glemstedt	•	18/20	6/6	6/8	6,000
Adine Grate Axén from April 27	•	13/20	n/a	5/8	
Lennart Johansson from April 27	•	13/20	n/a	6/8	10,000
Mats-Olof Ljungkvist up to April 26	•	7/20	n/a	2/8	
Wenche Rolfsen	•	20/20	n/a	n/a	33,400
Peter Sellei up to April 26	•	5/20	n/a	1/8	
Michael Steinmetz	•	19/20	5/6	n/a	
Hans Wigzell	•	18/20	n/a	n/a	180,000
Catarina Larsson, union representative	•	20/20	n/a	n/a	600
Bo-Gunnar Rosenbrand, union representative	•	19/20	n/a	n/a	1,050

- 1) As per December 30th, 2011
- Member to be regarded as independent both to the company and its management
- Member to be regarded as independent both to principal share holders
- Member to be regarded as independent both to the company, its management and to principal share holders
- Appointed by the trade unions

#### **Board of Directors**

#### Bo Jesper Hansen

Chairman

Born 1958. MD with a Ph.D. from Copenhagen University. Board member as of January 2010. Chairman of Sobi's Compensation & Benefit Committee. Board member of Gambro AB, MipSalus, TopoTarget A/S and Zymenex A/S. Has previously held various executive positions in Swedish Orphan International AB since 1993, CEO 1998-2010. Founder of Scandinavian Medical Research, through which he worked as medical advisor for Synthelabo, Yamanouchi and Pfizer.

Shares: 7,115,077 Warrants: 0

#### Adine Grate Axén

Born 1961. MBA from Stockholm School of Economics. Harvard AMP. Board member since 2010. Member of Sobi's Financial & Audit Committee. Chairman of the Listing Committee of Nasdaq OMX Stockholm. Board member of EDB Business Partners (member and chairman of the Audit committee) and Swedavia, advisor and working board member of 3 Scandinavia. Member of the Commission for the sale of shares in companies with state ownership until this was closed in 2010. 1994 – 2007 various senior management positions within Investor AB and member of the management group 1999 – 2007.

Shares: 0

#### Hans Glemstedt

Born 1962. M.Sc. Business Administration and Economics. Board member since 2009. Member of Sobi's Financial & Audit Committee as well as the Compensation & Benefits Committee. Member of Investor AB's investment organization since 2006. Board member of Aleris AB. Previously Senior Consultant at McKinsey during 9 years. More than 10 years of private equity and venture capital investment experience.

Shares: 6,000 Warrants: 0

#### Lennart Johansson

Born 1955. MBA from Stockholm School of Economics. Board member since 2010. Chairman of Sobi's Financial & Audit Committee. Member of the management team and head of the Operating Investment group at Investor AB. Board member in Mölnlycke AB and Gambro AB. Previously CEO in b-business partners och Emerging Technologies AB.

Shares: 10,000 Warrants: 0

#### Wenche Rolfsen

Born 1952. Pharm. Dr. Professor Pharmaceutical Faculty, Uppsala University. Board member since 2004. member of Sobi's Scientific Committee. Board member of Aprea (Chairman), Denator (Chairman), Artimplant, Moberg Derma, Industrifonden, Aker Biomarine AS, Norway and Axis Shield, United Kingdom. Has previously held various senior management positions at former PharmaciaUpjohn, has been CEO at Quintiles AB and Vice President Quintiles Europe, Explorative Clinical Research.

Shares: 33,400 Warrants: 0

#### Michael Steinmetz

Born 1947. Ph.D. Board member since 2001. Chairman of Sobi's Scientific Committee and member of the Compensation & Benefits Committee. Managing Director Clarus Ventures LLC. Board member of Allozyne (Chairman), Heptares, MacroGenics, Oxford Immunotec, TaiGen, Tetra-Logic and Virdante. Previously GeneralPartner MPM Capitals Funds Bio Ventures I, II and III.

Shares: 0 Warrants: 0

#### Hans Wigzell

Born 1938. Med Dr. h.c., Ph. D. Professor Immunology. Board member since 2004. Member of Sobi's Scientific Committee Member of the Royal Swedish Academy of Sciences and the Royal Swedish Academy of Engineering Sciences. Board Member of the Karolinska Development AB (Chairman), RaySearch AB, Rhenman and Partner Asset Management (Chairman), Intercell AG, HuMabs AG and AVI Biopharma. President of Karolinska Institutet 1995-2003.

Shares: 180,000 Warrants: 0

#### Catarina Larsson

Union Representative

Born 1952. Laboratory engineer. Board member since 2001. Representative of Federation of Salaried Employees in Industry and Services.

Shares: 600 Warrants: 0

#### Bo Gunnar Rosenbrand

Union Representative

Born 1963. Laboratory engineer. Deputy board member 2001 – 2005. Board member since 2006. Representative of Federation of Salaried Employees in Industry and Services.

Shares: 1,050 Warrants: 0 be seen in Note 5 of the Annual Report, the Chairman of the Board is employed by the company as executive Chairman. The Chairman's duties are, in addition to those he has according to Swedish Companies' Act and Swedish Code of Corporate Governance respectively, to represent the Company in contacts with partners and other stakeholders in the pharmaceutical field as well as actively participate in negotiations about acquisitions and business agreements. For more information, see Note 5 of the Annual Report 2010.

#### Composition of the Board of Directors

During financial year 2010, the Board of Directors has consisted of seven directors elected at the Annual General Meeting held on April 27, 2010, as well as two employee representatives, and two deputies, appointed by the trade union organizations. Three members of the Board of Directors, including the employee representatives, are women.

Swedish Orphan Biovitrum is a specialty pharmaceutical company with a focus primarily on marketing, development, and production of medications to treat rare diseases. The portfolio contains about 60 marketed products, as well as a growing number of products in late stage clinical development. For the company it is crucial that the Board of Directors has extensive and deep experience of marketing and research in the pharmaceutical industry, as well as financial qualifications.

At the time of publication of this report, the following directors are independent in relation to the company and its corporate management, as well as in relation to the company's principal shareholders:

Adine Grate Axén Hans Wigzell Wenche Rolfsen

A specification of remuneration to the board, resolved upon the Annual Genral Meeting on April 27, 2010, can be found in note 14 of the 2010 Annual Report.

#### The work of the Board of Directors during 2010

The Board of Directors held its first meeting on April 27, 2010, and met 20 times during 2010. The Secretary of the Board of Directors has been Swedish Orphan Biovitrum's General Counsel, Fredrik Berg. Other employees at Swedish Orphan Biovitrum participated at Board Meetings to present reports. During the year the Board addressed issues relating to development of the project portfolio, suggestions for potential acquisitions and collaborations, and the future strategy of the company. The Board also took decisions about changes in the company's management. The number of Board Meetings during the year was affected by issues such as the acquisition of Swedish Orphan International and a number of cases involving commercial agreements.

#### Board remuneration

The Annual General Meeting held April 27, 2010 resolved that for the period of time up until the next Annual General Meeting, a Board remuneration of SEK 1,755,000 shall be paid of which SEK 250,000 shall be paid to each director elected by the Annual General Meeting with the exception of the Chairman of the Board, who will not receive any remuneration for work on the Board. For work on the Audit Committee, a fee of SEK 75,000 will be paid to the Chairman of the committee and SEK 40,000 each to each other committee member. For work on the Scientific Committee a fee will be paid amounting to SEK 50,000 to the Chairman of the committee and SEK 25,000 to each other committee member. No fee will be paid for work on the Compensation and Benefits Committee.

#### The Compensation and Benefits Committee

Swedish Orphan Biovitrum's Compensation and Benefits Committee has consisted of three directors: Bo Jesper Hansen (Chairman), Hans Glemstedt and Michael Steinmetz. Hans Glemstedt and Michael Steinmetz are independent in relation to the management The company's Human Resources Director, Maria Berggren, is Secretary of the Committee, but not a member. The Compensation and Benefits Committee's duties are to propose guidelines and principles for the company's remuneration programs. This responsibility includes oversight and proposals for remuneration to senior executives and proposals for long-term incentive programs, pension plans and other issues relating to remuneration to the company's employees. The Compensation and Benefits Committee convened six times during the year with all three members present and once with two members present. At these meetings, the Committee discussed and followed up annual salary revision and bonuses for the CEO and senior executives, and made proposals for guidelines, nominations, and allocation in the long-term incentive program. Proposals for guidelines for remuneration to the CEO and senior management will be presented to the Annual General Meeting in April 2011, for the approval of the shareholders.

A specification of salaries and remuneration to the CEO and senior executives can be found in note 14 of the 2010 Annual Report.

#### **Audit Committee**

Swedish Orphan Biovitrum's Audit Committee has consisted of three directors who are independent in relation to the management: Lennart Johansson (Chairman), Adine Grate Axén, and Hans Glemstedt. The company's CFO, Lars Sandström, is Secretary of the Committee, but is not a member. The Committee's main duties are to handle the company's accounting, financial, reporting and audit matters, as well as matters relating to internal control in the company. The responsibilities of the

Committee include an annual discussion of the proposals from the auditors regarding the scope and methods of the audit, examining in advance proposed changes in auditing principles and adjustments of accounting documents that affect the financial reporting, consulting with the management and the auditor regarding conformity to laws and regulations involving financial matters, and annually examining remuneration to the company's auditors. The Committee convened seven times during the year with all three members present and one time with two members present. At these meetings, the Committee primarily discussed the auditors' presentations and the company's Interim Reports. The company's elected auditors also attended four of the meetings during the year. Discussion topics at these meetings included the auditors' planning of the audit, their observations and review of the company and compensation to the auditors. For more information on compensation to the company's auditors, see Note 15 of the 2010 Annual Report.

#### Scientific Committee

Swedish Orphan Biovitrum's Scientific Committee has consisted of three directors, all of whom are independent in relation to the management: Michael Steinmetz (Chairman), Wenche Rolfsen and Hans Wigzell. The Committee's tasks include advising on scientific matters, evaluating the company's research strategies, and following up and reporting to the Board regarding scientific trends and new areas of research. The Committee's tasks om 2010 have also included advising on acquisitions and licensing in of new research projects. The Committee convened two times during the year with all three members present.

#### Management Team

Each year, the Board of Directors establishes the distribution of work between the Board of Directors, the Chairman of the Board, and the CEO. The operative management is based on the decision-making procedure that the Board of Directors has established for Swedish Orphan Biovitrum. The decisionmaking procedure stipulates which matters require approval or confirmation by the Board of Directors. This is subsequently reflected in the organization and management model that forms the basis of the company's management and operation. At Board Meetings, the CEO and, when necessary, the Chief Financial Officer, General Counsel and other senior executives in Swedish Orphan Biovitrum's Management Team also present information on matters that require the attention of the Board of Directors. The company has a functional organization and the Management Team consists of the heads of the most important functions, who meet once or twice a month.

Swedish Orphan Biovitrum's Management Team has consisted of nine members, but at year-end the Management Team consisted of eight members. The Management Team comprises a broad composition of people with deep and extensive expe-

rience in R&D, as well as the production and sale of pharmaceuticals. In addition, the members of the Management Team have the requisite background in finance and accounting, law, human resources and communications.

On November 25 it was announced that Martin Nicklasson would leave the post of CEO of the company and that Kennet Rooth serve as CEO until a permanent replacement is appointed. Martin Nicklasson left his post on December 31

#### Chief Executive Officer (acting)

#### Kennet Rooth

Born 1955. Studies in chemistry and biology at Stockholm University and leadership training at INSEAD-CEDEP. 2005 – 2010 Country Manager for Sweden and subsequently Director International Marketing & Sales for Swedish Orphan International. 1989 – 2005 various positions at Bristol-Myers Squibb, including Executive Director, Country Manager, Business Unit Manager and product manager.

Shares: 188 118 Warrants: 0

For a more extensive presentation of Swedish Orphan Biovitrum's Management Team, see www.sobi.com/about us/senior management as well as page 90 of Swedish Orphan Biovitrum's 2010 Annual Report.

#### Remuneration to senior management

In order to attract and keep competent employees, Swedish Orphan Biovitrum has established long-term incentive programs. The CEO and senior management, all chief officers and a number of other key persons receive a fixed salary and a variable salary. The variable salary, which shall be in accordance with a system adopted by the Board of Directors, is based on both overall company goals and individual goals. The principles for remuneration to senior management are established by the Compensation and Benefits Committee. The variable salary may amount to a maximum of 30 – 50 percent of an individual's annual salary. For more information please see note 14 of Swedish Orphan Biovitrum's 2010 Annual Report.

# System for internal control and risk management with respect to financial reporting for the 2010 financial year *Introduction*

The Board is responsible for internal control in accordance with the Swedish Companies Act and the Swedish Code of Corporate Governance. Below the Board presents the most important features of the system for internal control and risk management as regards financial reporting. During 2010, efforts to streamline and develop the processes in the accounting department have continued. The internal control environment at Swedish Orphan Biovitrum follows the established framework, Internal Control – Integrated Framework "COSO," which consists of the following five components: Control Environment, Risk

Assessment, Control Activities, Information and Communication, and Follow-up.

The objectives of risk management within the Group are to:

- provide support in the strategic decision-making process for the Board of Directors and management
- improve the operational decision-making process
- increase risk awareness throughout the organization
- improve control over the company's risk exposure

#### Control Environment

The control environment constitutes the basis of the Swedish Orphan Biovitrum Group and the company's internal controls. The control environment mainly comprises the culture on the basis of which the Board and company management communicate and work.



This culture includes values, management philosophy, procedures and policies. The following is a more detailed description of the constituent elements. The basis of the internal control of the financial reporting is comprised by the control environment, which includes organization, decision-making processes, authority and responsibilities that are documented and communicated in governing documents such as internal policies, guidelines, manuals and codes.

All of the guidelines for Swedish Orphan Biovitrum's activities can be found on the company's intranet. The content includes the following:

- The Group's business concept, vision, mission, strategies, goals and values.
- Organizational structure and descriptions of positions.
- Administrative processes, guidelines and instructions such as authorities, authorization instructions, risk management, purchasing and investment policy, workplace health and safety, accounting and reporting instructions, and more.
- Information about the company's values, expertise issues and the regulatory environment in which the company is active.

#### Risk assessment

Effective risk assessment unites Swedish Orphan Biovitrum's business opportunities and results with the requirements of shareholders and other interested parties for stable, long-term value growth and control. Structured risk assessment or risk management make it possible to identify the important risks that affect the internal controls with regard to financial reporting and to identify where these risks are, i.e., at what level in the company. Risk management is intended in part to minimize the number of risk factors within financial reporting, and in part to ensure that the opportunities available within the company are used in the best possible way. Risk management further aims to manage risks during the development and production of pharmaceuticals, and with regard to biotechnology and patent risks. Risk assessment subsequently results in a number of control goals, which supports the fulfillment of the basic requirements of financial reporting.

#### Proposed appropriation of profit

The following funds are at the disposal of the Annual General Meeting:

Total	SEK 3,458,079,130
Profit/loss for the year	SEK -104,745,903
Retained earnings	SEK 32,312,316
Share premium reserve	SEK 3,530,512,717

The Board of Directors and the Chief Executive Officer propose that the funds at their disposal, SEK 3,458,079,130, be carried forward.

# Group's statement of comprehensive income

Note	2010	2009
1-4	2010	2007
6-7	1,906,741	1,296,973
8	-685,720	-375,740
	1,221,021	921,233
15	-825,605	-302,901
	-479,925	-569,422
	-87,745	-
10	234,108	43,262
11	-72,123	-75,998
9, 12, 14, 16, 19, 31	-10,269	16,174
17	-4,731	28,603
18	-77,439	-12,340
	-82,170	16,263
	-92,439	32,437
20	-12,012	_
	-104,451	32,437
	-1,754	-4,097
	-106,205	28,340
	-0.53	0.33
	-0.53	0.32
	212,181,279	50,396,316
	198,741,374	50,142,990
	315,000	335,000
	212,804,979	50,766,316
	199,371,494	50,793,547
	6-7 8 15 10 11 9, 12, 14, 16, 19, 31 17 18	1-4 6-7 1,906,741 8 -685,720 1,221,021  15 -825,605 -479,925 -87,745 10 234,108 11 -72,123 9, 12, 14, 16, 19, 31 -10,269  17 -4,731 18 -77,439 -82,170  -92,439 20 -12,012 -104,451  -1,754 -106,205  -0.53 -0.53 -0.53  212,181,279 198,741,374 315,000 212,804,979

<sup>&</sup>lt;sup>1</sup> In correspondence with Revised IAS 1 all changes in equity that do not arise from transactions with owners should be reported in statement of comprehensive income. Translation differences does entirely concern equity in foreign subsidiary.

<sup>&</sup>lt;sup>2</sup> For calculation, see disclosure "Changes in Equity" Earnings per share have been adjusted for the bonus issue component of the new share issue which was concluded in January 2010.

# Group balance sheet

SEK thousands	Note	2010-12-31	2009-12-31
ASSETS	1-4		
Fixed assets			
Intangible fixed assets	21	5,224,294	1,159,144
Tangible fixed assets	22	251,446	251,963
Financial fixed assets	24	10,033	102,707
Deferred income tax assets	25	11,800	11,800
Total fixed assets		5,497,573	1,525,614
Current assets Inventories	26	1.070.424	F70 200
		1,070,434	578,398
Accounts receivable, trade	27, 30	322,618	105,203
Other receivables	27	63,564	33,109
Prepaid expenses and accrued income	28	76,892	256,567
Short-term investments	29, 30	20.440	48,359
Liquid funds	29, 30	38,469	258,280
Total current assets		1,571,977	1,279,916
TOTAL ASSETS		7,069,550	2,805,530
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital		117,559	27,936
Other capital contribution		4,267,494	1,261,336
Other reserves		-29,487	-27,733
Retained Earnings		93,010	62,916
Net result		-106,205	28,340
Shareholders' equity referring to the owners of the parent company		4,342,371	1,352,795
HARMATIES			
LIABILITIES			
Long-term liabilities	05	750,000	40.000
Deferred income tax liabilities	25	759,209	48,200
Other liabilities	32	1,022,452	290,348
Provisions for other liabilities and charges	33	188,380	365,645
Total long-term liabilities		1,970,041	704,193
Short-term liabilities			
Liabilities to credit institutions	32	164,286	50,000
Accounts payable		289,367	243,899
Current tax liabilities		46,212	568
Other liabilities		52,204	136,770
Accrued expenses and prepaid revenues	34	196,632	310,221
Other provisions	33	8,437	7,084
Total short-term liabilities		757,138	748,542
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		7,069,550	2,805,530

## Group statement of changes in equity

SEK thousands	Share capital	Other capital contribution	Other reserves	Profit/loss carried forward	Total share-holders' equity
Shareholders' equity, January 1 2009	27,489	1,222,312	-23,636	58,819	1,284,984
Comprehensive income					
Net profit/loss for the year				32,437	32,437
Comprehensive income				32,437	32,437
Other comprehensive income					
Translation differences			-4,097		-4,097
Other comprehensive income		_	-4,097	_	-4,097
Sum comprehensive income		_	-4,097	32,437	28,340
Transactions with shareholders'					
Sharebased compensation		5,186			5,186
Redemption of shares		-153			-153
Issue of shares	447	33,991			34,438
Sum transactions with shareholders'	447	39,024	_	_	39,471
Shareholders' equity, January 1 2010	27,936	1,261,336	-27,733	91,256	1,352,795
Changes in accounting principles <sup>1</sup>		-58,753			-58,753
Adjusted shareholders' equity,					
January 1 2010	27,936	1,202,583	-27,733	91,256	1,294,042
Comprehensive income					
Net profit/loss for the year				-104,451	-104,451
Comprehensive income				-104,451	-104,451
Other comprehensive income					
Translation differences			-1,754		-1,754
Other comprehensive income			-1,754		-1,754
Sum comprehensive income			-1,754	-104,451	-106,205
Transactions with shareholders'					
Sharebased compensation		8,511			8,511
Redemption of shares		-852			-852
Issue of shares	89,623	3,057,252			3,146,875
Sum transactions with shareholders'	89,623	3,064,911	_	_	3,154,534
Shareholders' equity, Dec 31 2010	117.559	4,267,494	-29,487	-13,195	4,342,371
	117,559				

<sup>&</sup>lt;sup>1</sup>As a consequeuence of adopting new accounting principles, IFRS 3, as from January 1, 2010, prepaid expenses related to acquisition in progress as per December 31, 2009, has been charged to equity as an adjustment of opening balances.

Swedish Orphan Biovitrum's share capital at year-end was SEK 117,558,199 shared between 214,249,813 shares with a par value of around SEK 0.55. The issued shares break down as 212,181 279 ordinary shares and 2,068,534 C shares. The ordinary shares carry one vote per share and the C shares carry 1/10 vote per share. All C shares are treasury shares.

In connection with Share Program 2008, Share Program 2009 and Share Program 2010 the company issued C shares and the company has 2,068,534 C shares at year-end.

In 2010 Swedish Orphan Biovitrum acquired 1,552,949 treasury shares of share class C. The purchase price for the shares was SEK 852,098 which represents a share value of 0.55 SEK. The par value of the shares as of December 31, 2010 was SEK 0.55. These shares represent 1.0 percent of the total number of shares in the company.

The long-term share program ("Share Program 2010") is the reason for the acquisition of the shares.

#### Earnings per share

Earnings per share before dilution is calculated by comparing the part of the profit that belongs to the shareholders of the parent company, divided with an average of outstanding ordinary shares during the period, with exclusion of redempted shares .

	2010	2009
Net profit/loss referable to share- holders of the Parent company	-104,451	32,437
Average number outstanding ordinary shares (thousands) <sup>1</sup>	198,741	50,143
Earnings per share before dilution <sup>2</sup> (SEK per share)	-0.53	0.33

The average number of outstanding ordinary shares have been adjusted with all potential ordinary shares, in order to calculate the earnings per share after dilution.

	2010	2009
Net profit/loss referable to share- holders of the Parent company	-104,451	32,437
Average number outstanding ordinary shares for calculation of earnings per share after dilution (thousands) <sup>1</sup>	199,371	50,794
Earnings per share after dilution <sup>2</sup> (SEK per share)	-0.53	0.32

<sup>&</sup>lt;sup>1)</sup>The difference between 198,741 and 199,371 consist of outstanding warrants.

<sup>&</sup>lt;sup>2</sup> Earnings per share have been adjusted for the bonus issue component of the new share issue completed in January 2010.

## Group cash flow statement

SEK thousands	2010	2009
Occupios		
Operations Profit/loss for the year	-104,451	32,437
Adjustment for items not affecting cash flow	354,148	16,408
Cash flow from operations before change in working capital	249,697	48,845
Cash flow from operations before change in working capital	249,097	40,045
Change in working capital		
Decrease(+) / Increase(-) in inventories	-399,275	9,265
Decrease(+) / Increase(-) in operating receivables	245,722	-147,028
Increase(+) / Decrease (-) in operating liabilities	-311,252	147,803
Cash flow from operations	-215,108	58,885
Investment activities		
Investment in operation <sup>1</sup>	-1,811,293	-60,809
Divestment of operation	_	22,714
Investment in intangible fixed assets	-80,692	-62,666
Investment in tangible fixed assets	-42,109	-96,049
Divestment tangible fixed assets	1,389	2,104
Divestment of financial fixed assets	-	-1,868
Divestment of short term financial assets	48,359	157,474
Cash flow from investment activities	-1,884,346	-39,100
Financing activities		
Loans – Raising	1,211,023	_
Issue of shares	1,415,003	34,438
Redemption of shares	-852	-153
Repayment of bank loan	-743,426	-50,000
Cash flow from financing activities	1,881,748	-15,715
Net change in liquid funds	-217,706	4,070
Liquid funds at beginning of year	258,280	254,228
Exchange rate differences in liquid funds	-2,105	-18
Liquid funds at end of year <sup>2</sup>	38,469	258,280

<sup>1)</sup> Investment in operation during 2010 is mainly related to the acquisition of Swedish Orphan, during 2009 investment in operation relates to prepaid expenses of acquisition in progress.

<sup>2)</sup> Not included in liquid funds is short term investments to a value of SEK 0 M (48.4) as per December 31, 2010.

### Supplementary data to the Cash Flow Statement – Group

SEK thousands	2010	2009
Interest paid and received	2.212	7 000
Interest received	2,212	7,809
Interest paid	34,328	11,538
Adjustments for items not affecting cash flow		
Amortization/depreciation and write down of assets	355,524	109,664
Write-down of financial asset	20,073	-
Unrealised exchange rate differences	-932	-6,765
Capital gain/loss from divestment of tangible fixed assets	6,207	-2,095
Capital gain/loss from divestment of financial fixed assets	_	21,540
Revaluation of present value of long-term liability	2,200	-12,260
Allocation of costs for options	8,513	5,144
Revaluation of financial fixed assets	_	4,663
Pensions	13,367	-5,598
Deferred tax	-26,491	-
Restructring costs	-18,760	-97,885
Other items	-5,553	-
	354,148	16,408
Acquisition of subsidiaries and other busi-		
ness units		
Acquired assets and liabilities	2 707 022	
Intagible fixed assets	2,707,932	
Tangible fixed assets	14,076	
Inventories	95,546	_
Operating receivables	233,401	_
Liquid funds	122,240	
Total asstes	3,173,195	
Deferred tax liabilities	-737,514	
Operating liabilities	-245,146	_
Total liabilties	-982,660	_
Purchase sum	3,744,627	
Less:	3,744,027	
Issue in kind	-1,656,760	
Discounted value est. future additional	-1,656,760	
Purchase sum paid	1,922,867	
Less:	1,722,007	
Liquid funds in acquired operation	-122,240	
Effect on liquid funds	1,800,627	
2 St. on liquid failus	1,000,027	

SEK thousands	2010	2009
Divestment of subsidiaries and other		
business units		
Divested assets and liabilities:		
Tangible fixed assets	-	1,942
Operating receivables	-	51,854
Liquid funds	_	398
Total assets	_	54,194
Operating liabilities	_	4,127
Total liabilities	_	4,127
Selling price		48,551
Deduction:		10,001
Expenses in connection with divestment	_	-25,439
Selling price received		23,112
Deduction:		
Liquid funds in divested operation	-	-398
Effect on liquid funds	_	22,714
Liquid funds		
Liquid funds include the following:		
Cash and bank balances	38,469	129,594
Short-term investments equivalent to liquid funds	_	128,686
	38,469	258,280

- The above items have been classified as liquid funds on the following basis:

   They are subject to minimal risk for fluctuation in value.

   They can immediately be converted into cash funds.

   They have a maximum maturity of three months from the initial date of validity.

## Parent company income statement

SEK thousands	Note	2010	2009
	1-4		
Total revenues	6-7	1,185,888	1,296,954
Cost of goods and services sold	8	-410,848	-375,740
Gross profit		775,040	921,214
Sales and administration expenses	15	-435,792	-308,985
Research and development expenses		-449,804	-570,689
Restructuring expenses		-81,397	_
Other operating revenues	10	213,702	43,200
Other operating expenses	11	-38,884	-48,338
Operating profit/loss	9, 12, 14, 16, 19, 31	-17,135	36,402
Result from participation in Group companies	13	-6,217	17,625
Financial income	17	-607	28,705
Financial expenses	18	-80,787	-12,303
Financial items – net		-87,611	34,027
Profit/loss before tax		-104,746	70,429
Income tax expense	20	-	-
Profit/loss for the year		-104,746	70,429

# Parent company statement of comprehensive income

SEK thousands	Note	2010	2009
Profit/loss for the year		-104,746	70,429
Other comprehensive income		_	_
Comprehensive income for the year		-104,746	70,429

# Parent company balance sheet

SEK thousands	Note	2010-12-31	2009-12-31
ASSETS	1-4		
Fixed assets			
Intangible fixed assets	21	833,439	959,672
Tangible fixed assets	22	237,103	251,963
Shares in Group companies	23	4,413,948	648,979
Financial fixed assets	24	684	21,359
Total fixed assets		5,485,174	1,881,973
Current assets			
Inventories	26	927,467	578,398
Accounts receivable	27	136,165	105,203
Current receivables	27	36,271	23,194
Receivables from Group companies		22,875	11,519
Prepaid expenses and accrued revenues	28	71,205	256,567
Short-term investments	29	-	48,359
Cash and bank balances	29	9,083	257,977
Total current assets		1,203,066	1,281,217
TOTAL ASSETS		6,688,240	3,163,190
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Restricted equity			
Share capital		117,559	27,936
Statutory reserve		800,257	800,257
Total restricted equity		917,816	828,193
Non-restricted equity			
Share premium reserve		3,530,512	464,750
Own shares		-1,160	-308
Profit/loss carried forward		33,473	-36,957
Net profit/loss for the year		-104,746	70,429
Total unrestricted equity		3,458,079	497,914
Total shareholders' equity		4,375,895	1,326,107
Liabilities			
Long-term liabilities			
Other liabilities	32	1,022,452	290,348
Provisions for other liabilities and charges	33	171,100	365,645
Total long-term liabilities		1,193,552	655,993
Current liabilities			
Liabilities to credit institutions	32	164,286	50,000
Accounts payable		237,086	243,899
Liabilities to Group companies		545,643	428,695
Other liabilities		5,259	137,338
Accrued expenses and prepaid revenues	34	158,212	314,074
Other provisions	33	8,307	7,084
Total current liabilities		1,118,793	1,181,090
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		6,688,240	3,163,190
Pledged assets and contingent liabilities – Parent Company			
Pledged assets	35	-	
Contingent liabilities	35	54,351	78,444

# Parent company change in shareholders' equity

	RESTRICTED E	QUITY	UNRESTRICTED EQUITY		Total share-holders'
SEK thousands	Share capital	Statutory reserve	Share premium reserve	Profit/loss carried forward	equity
Shareholders' equity, Jan 1 2009	27,489	800,257	425,614	-37,112	1,216,248
Issue of shares	447		33,992		34,439
Redemption of shares				-153	-153
Sharebased compensation			5,144		5,144
Comprehensive income for the year				70,429	70,429
Shareholders' equity, Dec 31 2009	27,936	800,257	464,750	33,164	1,326,107
Shareholders' equity, Jan 1 2010	27,936	800,257	464,750	33,164	1,326,107
Issue of shares	89,623		3,057,252		3,146,875
Redemption of shares				-851	-851
Sharebased compensation			8,510		8,510
Comprehensive income for the year				-104,746	-104,746
Shareholders' equity, Dec 31 2009	117,559	800,257	3,530,512	-72,433	4,375,895

Swedish Orphan Biovitrum's share capital at year-end was SEK 117,558,199 shared between 214,249,813 shares with a par value of around SEK 0.55. The issued shares break down as 212,181 279 ordinary shares and 2,068,534 C shares. The ordinary shares carry one vote per share and the C shares carry 1/10 vote per share. All C shares are treasury shares.

## Parent company cash flow statement

SEK thousands	2010	2009
0		
Operations	-104 746	70.420
Loss for the year		70 429
Adjustment for items not affecting cash flow	209 102	-24 631
	104 356	45 798
Tax paid	_	_
Cash flow from operations before	104 356	45 798
change in working capital	104 350	43 / 90
Change in working capital		
Decrease(+) / Increase(-) in inventories	-349 069	9 265
Decrease(+) / Increase(-) in operating receivables	129 967	-144 883
Increase (+) / Decrease (-) in operating liabilities	-101 407	149 996
Cash flow from operations	-216 153	60 176
Investment activities		
Acquisition of subsidiaries1	-1 933 533	-60 809
Divestment of subsidiary	-1 755 555	23 112
Investments in intangible fixed assets	-5 068	-62 666
Investments in tangible fixed assets	-39 428	-96 081
Divestment of tangible assets	_	2 104
Investment in financial fixed assets	1 372	-1 903
Divestment of financial fixed assets	_	35
Divestment of short-term financial assets	48 359	157 474
Cash flow from investment activities	-1 928 298	-38 734
Financing activities		
Loan – Rasing	1 211 023	
Issue of shares	1 415 003	34 437
Redemption of shares	-852	-152
Amortization of loans	-729 617	-50 000
Cash flow from financing activities	1 895 557	-15 715
Net change in liquid funds	-248 894	5 727
Liquid funds at beginning of year	257 977	252 250
Liquid funds at end of year	9 083	257 977

Acquisition of subsidiaries during 2010 is mainly related to the acquisition of Swedish Orphan, during 2009 investment in operation relates to prepaid expenses of acquisition in progress.

# Supplementary disclosures to the Cash Flow Statement – Parent Company

SEK thousands	2010	2009
Interest paid and received		
Interest received	2,067	7,811
Interest paid	36,957	11,457
Adjustments for items not affecting cash flow		
Amortization/depreciation and write down of assets	184,582	107,574
Unrealised exchange rate differences	-932	-6,765
Ravaluation of present value of long-term liabilties	6,371	-12,260
Capital gain/loss from divestment of fixed assets	1,007	-2,063
Capital gain/loss from divestment of financial fixed assets	-	-23,114
Revaluation of financial fixed assets	_	4,663
Allocation of costs for options	8,513	5,144
Appropriation for pensions	2,870	_
Result from limited partnership	-	75
Write-down of shares in subsidiaries	1,119	_
Write-down of financial fixed asset	19,303	-
Restructring costs	-18,760	-97,885
Other items	5,029	-
	209,102	-24,631
Liquid funds		
Liquid funds include the following:		
Cash and bank balances	9,083	129,291
Short-term investments equivalent to liquid funds	-	128,686
	9,083	257,977

The above items have been classified as liquid funds on the following basis:

- They are subject to minimal risk for fluctuation in value.
- They can immediately be converted into cash funds.
- They have a maximum maturity of three months from the initial date of validity.

### Notes

#### Note 1 General information

Swedish Orphan Biovitrum AB (publ), company registration number 556038-9321, the parent company and its subsidiaries, collectively the Group, is a public, listed pharmaceutical company that markets specialist pharmaceuticals in a number of regions.

Revenues, including royalties and contract fees, finance most of the annual research budget.

The parent company is a limited company registered and headquartered in Stockholm, Sweden. The head office address is Tomtebodavägen 23A, Solna. Sweden.

The company has been listed as a mid-cap company on the Stockholm stock exchange (now NASDAQ OMX Stockholm) since September 15, 2006.

#### Note 2 Significant accounting principles and basis for preparation of the parent company's and the consolidated financial statements

#### Summary of significant accounting principles for Groups

The primary accounting principles applied in the preparation of these consolidated financial statements are set out below. These principles have been consistently applied to all the years presented unless otherwise indicated.

The consolidated financial statements have been prepared in accordance with the Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 1.3, supplementary Accounting Rules for Groups, and the International Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the EU. The consolidated financial statements have been prepared according to the historical cost convention except in the case of financial assets and financial assets and liabilities (including derivative instruments) measured at fair value through profit and loss.

### Standards, amendments and interpretations that went into effect in 2010 IFRS 3 (revised) "Business Combinations"

Effective as of July 1, 2009.

The revised standard still requires the acquisition method to be applied for business combinations, but with some significant changes. For example, all payments for the purchase of a business at fair value are recorded on the acquisition date, while subsequent conditional payments are classified as liabilities which are then re-measured in profit or loss. Non-controlling interests (replacing the previous term "minority interest") in the acquired business can either be valued at fair value or at the proportionate portion of the business's net assets held by the party with the non-controlling interest. All acquisition related transaction costs are to be expensed.

The revision applies prospectively for acquisitions after the date it goes into force. The amendment to the standard will not involve any change with respect to previous acquisitions, but will only affect reporting of future acquisitions. The Group is applying the standard from the beginning of the financial year commencing on January 1, 2010, which has had an effect in the group in 2010, amounting to 59 million.

### IAS 27 (amendment) "Consolidated and Separate Financial Statements" The amended standard require the effects of all transaction with owners with

The amended standard require the effects of all transaction with owners with a non-controlling interest (this term has replaced the previous one "minority

interest") to be reported in equity if they do not involve any change in the controlling influence and these transactions no longer give rise to goodwill or gains and losses.

The standard also states that when a parent company loses the controlling influence, any remaining portion should be reassessed at fair value and a gain or loss reported in profit and loss.

Swedish Orphan Biovitrum has applied IAS 27 (amendment) for future transactions with owners with a non-controlling influence as of January 1, 2010. IAS 27 (amendment) is not expected to have any significant effect on the consolidated financial statements.

Other standards that came into effect in 2010 is expected to have no effect on the group.

#### Consolidated accounts

#### General

The consolidated accounts include the parent company and the subsidiaries.

#### Subsidiaries

Subsidiaries are all entities (including special purpose entities) over which Swedish Orphan Biovitrum has the power to govern the financial and operating strategies in a manner generally accompanying a shareholding of more than one half of the voting rights. Subsidiaries are included in the consolidated accounts from the day when decisive influence is transferred to the Group and are excluded when the decisive influence ends.

The acquisition method is used in the preparation of the consolidated accounts. The cost of an acquisition is measured as the fair value of the assets given, equity instruments issued and liabilities incurred or assumed on the transfer date. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured at their fair values at the acquisition date, irrespective of the extent of any minority interest. The excess of the cost of acquisition over the fair value of the Group's share of the acquired assets, and liabilities and contingent liabilities is assumed recorded as goodwill. When an acquisition occur in stages goodwill is to be determined only at the acquisition date rather than at the previous stages. The determination of goodwill when the acquisition occur in stages includes the previously held equity interest to be adjusted to fair value, with any gain or loss recorded in the income statement. For each acquisition, the Group determines whether to measure the non-controlling interest in the acquiree at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets. Goodwill is not amortized according to plan but is instead tested annually for impairment. If the cost of acquisition is less than the fair value of the assets, and liabilities and contingent liabilities assumed of the subsidiary acquired, the difference is recognized directly in the income statement.

Intra-group transactions, balances and unrealized gains on transactions between Group companies are eliminated. Any unrealized losses are considered an impairment indicator of the asset transferred.

The accounting principles of the subsidiaries have been changed where necessary to ensure they are consistent with the principles adopted by the Group.

#### Segment reporting

Operating segments are presented from the management's perspective, which means presented on the same basis that is used for internal report-

ing. The basis for identifying reportable segments is the internal reporting as reported to and followed up by the highest decision-making executive. For Swedish Orphan Biovitrum, this is the Group's CEO.

#### Functional and reporting currency

Items included in the financial reports for each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in Swedish crowns which is the company's functional and reporting currency.

#### Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates that apply on the dates of the transactions. Exchange rate differences resulting from the settlement of such transactions and from the translation at the exchange rate on the balance sheet date of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement.

#### Translation of foreign subsidiaries

The assets and liabilities of foreign subsidiaries are established in the respective functional currency, determined by the primary economic environment in which the company operates. For Swedish Orphan Biovitrum's foreign subsidiaries, all assets, provisions and other liabilities are translated at the exchange rate on the balance sheet date into the Group's reporting currency (SEK) and exchange rate differences arising from this are reported directly against other comprehensive income. All items in the income statement are translated using the average exchange rate for the year.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the entity and translated at the exchange rate on the balance sheet date.

#### Revenues

#### Operating revenues

Revenue from the sale of pharmaceuticals is reported when the goods have been delivered from the company's consignment inventory to the end customer.

Co-promotion revenues from partners are recognized as revenue as the service is performed and the revenue can be measured reliably and it is probable that the economic benefits will accrue to the Group.

Contract manufacturing revenues (ReFacto®) are reported when the goods have been delivered to the customer, i.e. when the responsibility for the risk associated with the goods has been transferred to the customer.

The Group's revenues include revenue from licensing agreements, such as outlicensing revenue, milestone payments and royalties from third parties within the course of normal operations. According to the milestone method, successive milestones are considered as separate from initial licensing fees. The initial licensing fee is distributed over the expected life of the contract because, when it is received, no separate earning period is deemed to have been completed. Subsequent milestone payments on the other hand are considered to belong to a separate completed part of the agreement. This portion of the revenue is recognized as soon as it is received, i.e. when the terms of the agreement have been met.

Revenue from service assignments is recognized when the economic outcome of the completed assignment can be reliably calculated and the economic benefits accrue to the Group.

When the Group has undertaken to carry out research and development assignments and receives payment for services provided by the Group, this is recognized as and when work is carried out. Revenue from research collaboration is recognized in the period in which it is carried out. Milestone payments are recognized when they fall due for payment according to the agreement and the payment is obtained from the counterpart.

#### Government grants

Government grants are recognized when the company fulfills the requirements associated with the grant and when it can be established with certainty that the subsidy will be received. Grants received are recognized in the balance sheet as prepaid income and taken up as income in the period they are earned. Government grants are reported in the income statement as a reduction of the corresponding expense. Swedish Orphan Biovitrum receives government grants mainly in the form of research grants from the EU. A minor part of Swedish Orphan Biovitrum's projects are financed through government grants.

#### Other operating revenues/expenses

Other operating revenues are revenues from activities outside the normal operations. The item includes rental income, divestment of product rights and exchange rate gains on operating receivables and liabilities. Other operating expenses are expenses from activities outside the normal operations. The item includes exchange rate differences on operation receivables and liabilities

#### Non-recurring items

Non-recurring transactions and decisions affecting Swedish Orphan Biovitrums results are reported separately, ("non-recurring items"). This amount includes restructuring costs associated with the acquisition of Swedish Orphan. In addition to EBIT (operating profit), adjusted EBITA is also reported, which reflects the earning capacity of the operational activities of the company. Adjusted EBITA corresponds with operating income before amortization of intangible assets and extraordinary expenses reported in the consolidated statement of comprehensive income. Restructuring costs as described above can arise in association with acquisitions, along with costs for duplicated activities and their discontinuation.

#### Classification etc.

Within the Swedish Orphan Biovitrum Group, assets and liabilities are classified as either current or as long-term receivables and liabilities. Long-term receivables and liabilities consist essentially of the amounts for which payments are due more than one year from the balance sheet date. Current receivables and liabilities fall due within one year of the balance sheet date.

#### Intangible fixed assets

#### Goodwill

Goodwill consists of the amount by which the cost of acquisition exceeds the fair value of the Group's share in the acquired subsidiary/associated company's net identifiable assets at the date of acquisition. Goodwill on acquisition of a subsidiary is included in intangible assets. In connection with the acquisition of associated companies, goodwill is included in the value of the holding in the associated company. Goodwill is tested annually for impairment and carried at cost less accumulated impairment write-downs. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold. If the net fair value of the acquired operation's identifiable assets, liabilities and contingent liabilities exceeds the acquisition cost, the surplus (negative goodwill) is immediately reported in the income statement.

#### Product rights

Products rights in the form of licenses and patents are reported at cost. Licenses and patents have a finite useful life and are carried at cost less accumulated amortization. Amortization is calculated using the straight-line method to allocate the cost of licenses and patents over their estimated useful lives (5 to 12 years).

#### Research and development costs

Expenditure for a development project is recognized as an intangible asset if the company can prove that it is technically possible to complete and profitably commercialize the results and only if the expenditure for the project can be measured in a reliable way. Amortization is calculated using the straight-line method to allocate the cost of development projects over their estimated useful lives, and is implemented once the development project starts to generate revenues. Other development expenditure is recognized as incurred. Swedish Orphan Biovitrum's research expenditures are recognized as expenses for research costs as incurred until a project reaches the stage where it obtains approval from the authorities.

#### Acquired R&D

Expenditures for acquired research and development projects are recognized as intangible assets. When an acquired research project begins to generate revenue, amortization begins and continues over the project's estimated useful life. Research and development projects are tested at least a once a year for impairment.

#### Software and IT projects in progress

Acquired software licenses are capitalized on the basis of the costs incurred when the software in question is acquired and put into operation. These costs are amortized over the estimated useful life of the software.

Costs associated with developing or maintaining software are recognized as an expense as incurred. Costs directly associated with identifiable software products developed specially for Swedish Orphan Biovitrum, which are controlled by the Group and are likely to generate economic benefits exceeding costs beyond one year, are recognized as intangible fixed assets. Direct costs include the software development employee costs and a reasonable portion of relevant overhead.

Expenditure to enhance the performance of software or extend its useful life (development costs) beyond the original plan is capitalized and added to the initial cost of the software.

Amortization according to plan for computer programs that have been recognized as fixed assets is done using the straight-line method over the program's useful life up to a maximum of three years.

#### Tangible fixed assets

Tangible fixed assets are recognized as assets in the balance sheet if it is likely that future economic benefits will accrue to the company and the cost of the asset at acquisition can be calculated in a reliable way.

All tangible assets are stated at cost less depreciation. Cost includes expenditure that can be directly attributed to the acquisition of the asset. Additional expenditure increases the carrying amount of the asset or is reported as a separate asset, depending on which is appropriate, only when it is probable that future economic benefits associated with the asset will accrue to the Group and the initial cost of the asset can be measured in a reliable way. All other forms of repair and maintenance are reported as expenses in the income statement in the period in which they are incurred.

#### Depreciation of tangible fixed assets

Depreciation according to plan of tangible fixed assets is based on the asset's useful life. Depreciation is calculated on a straight-line basis over the asset's estimated useful life. The following depreciation plan applies:

#### Machinery and technical equipment

Laboratory equipment and other investments 3-7 years
Other major investments, for
example redevelopment of property 15 years

#### Equipment, tools, fixtures and fittings

Computers 3 years
Computers servers and other major computer
hardware items 3-5 years
Furniture, fixtures and fittings 5-10 years

The residual value and useful life of the assets are assessed at each closing day and adjusted as needed.

An asset's carrying amount is written down to its recoverable amount if the asset's carrying amount exceeds the estimated recoverable amount.

Gains or losses from the sale or disposal of tangible fixed assets are determined by comparing the difference between the sale price and the carrying amount less direct selling expenses. The profit/loss item is reported as other operating revenues and other operating expenses respectively.

#### Leased assets

Leases are classified in the consolidated accounts either as finance or operating leases. Leased fixed assets where Swedish Orphan Biovitrum is responsible for the same risks and benefits as in the case of direct ownership are classified as finance leases. Accordingly, the asset is reported as a fixed asset in the balance sheet. Corresponding commitments of future lease charges are reported as current or long-term liabilities. The leased assets are depreciated according to plan, while lease payments are reported as interest and repayment of debt. Leased assets where the lessor essentially retains ownership of the assets are classified as operating leases and lease charges are expensed on a straight-line basis over the term of the lease.

#### Write-downs of non-financial assets

Assets with an indeterminable useful life and intangible assets not yet take into operation, are not depreciated but are instead tested annually for impairment. Assets that are subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The write-down is the difference between the carrying amount and the recoverable amount where the recoverable amount is defined as the greater of the asset's net realizable value and its value in use. When testing for impairment, assets are grouped at the lowest levels at which there are separate identifiable cash flows. Since Swedish Orphan Biovitrum has made the assessment that the Group's operations comprise one business segment, the Group as a whole is considered to be the smallest cash-generating unit. A write-down is reversed if there has been a change in the conditions that were the basis for determining the recoverable amount. Reversal amounts do not exceed the carrying amount that would have been recognized, less depreciation, if no write down had been performed. Impairment losses on goodwill are not reversed. Impairment testing of goodwill and capitalized research and development projects are described in Note 21.

An asset is impaired if its carrying amount exceeds its recoverable amount, where the recoverable amount is defined as the higher of the asset's net realizable value and its value in use. When calculating value in use, the future cash flow that the asset is expected to generate is discounted using an interest rate that corresponds to Swedish Orphan Biovitrum's weighted cost of capital.

#### Financial assets

The Group classifies its financial assets in the following categories: loan receivables and accounts receivable, financial assets measured at fair value through profit or loss, held-to-maturity investments and available-for-sale financial assets. Classification depends on the purpose for which the instrument was acquired. Management determines how the instruments will be classified in connection with initial recognition and reviews this decision on each reporting occasion. At present, Swedish Orphan Biovitrum has financial assets measured at fair value through profit or loss and accounts receivable.

Purchases and sales of financial assets are recognized on the trading date, i.e. the date on which the Group commits to purchase or sell the asset. Financial instruments are initially recognized at fair value plus transaction costs for all financial assets not carried at fair value through profit or loss. Financial assets carried at fair value through profit or loss is initially recognized at fair value and transaction costs are expensed in the statement of comprehensive income.

On each reporting occasion, the company evaluates whether there is objective proof of impairment of a financial asset. If there is a need for impairment the value of the asset is impaired and the impairment is recognized in the statement of comprehensive income.

Financial assets reported in the balance sheet include, on the assets side, cash and cash equivalents and accounts receivable. Liabilities and shareholders' equity include accounts payable, issued debt and equity instruments and borrowing. Currency derivatives are stated either as assets or liabilities, depending on the fluctuation in exchange rates.

#### Loans and accounts receivable

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for maturities greater than twelve months after the balance sheet date which are classified as fixed assets. The Group's loans and accounts receivable are classified as accounts and other receivables as well as cash and cash equivalents in the balance sheet.

Loan receivables and accounts receivable are measured at amortized cost less provision for impairment.

#### Financial assets measured at fair value through profit or loss

Financial assets measured at fair value through profit or loss are financial assets held for trading. A financial asset is classified in this category if acquired principally for the purpose of selling in the short term. Assets in this category are classified as current assets.

Gains or losses arising from changes in the fair value of the financial assets measured at fair value through profit or loss are presented in the statement of comprehensive income in the period in which they arise within other losses/gains net or current investments under financial income.

#### Available-for-sale financial assets

Available-for-sale financial assets are non-derivatives that have been identified as available for sale or not classified in any of the other categories. They are included in the fixed assets unless management intends to dispose of the investment within twelve months of the balance sheet date.

A gain or loss on a financial asset in the category of available-for-sale financial assets is reported directly as other comprehensive income. When assets in this category are sold or impaired, the accumulated fair value adjustments of equity are transferred to the consolidated statement of comprehensive income as gains and losses on financial instruments.

#### Derivative instruments

Derivative instruments, in the case of the Group, consist of currency forward contracts used to hedge the risk of exchange rate fluctuation. All derivatives are assigned a market value and the market values are reported in the balance sheet. The accounting method for the profit or loss which occurs in connection with a revaluation depends on if the derivative is identified as a hedge instrument and if so, on the character of the hedged item.

Swedish Orphan Biovitrum's transaction exposure in foreign currencies arises due to the company's exports and imports of goods paid for in foreign currencies. Currency exposure relating to forecast future flows is hedged as necessary primarily through currency forward contracts. The forward contracts are recognized in the balance sheet at fair value. Changes in value are reported directly in the income statement. The hedged flows may be both contracted and forecast transactions. Swedish Orphan Biovitrum has not applied hedge accounting during the year.

#### Borrowina

Borrowing transactions are initially reported at fair value, net after transaction costs. Borrowing is thereafter reported at amortized costs and any difference between the received amount and repaid amount is reported in the income statement distributed over the loan period, applying the effective rate method.

Borrowing is classified as short-term liabilities, unless the Group has an unconditional right to defer the liability no less than 12 months after balance day.

#### **Current assets**

Receivables maturing within one year from the balance sheet date are classified as current assets.

#### Inventories

Inventories are valued at the lower of cost and net realizable value. Cost is calculated using the first in, first out principle (FIFO). The net realizable value is the expected sales price in continuing operations less selling expenses. Obsolescence risk and established obsolescence have been taken into account.

#### Accounts receivable

Accounts receivable are measured at amortized cost and reported at the amounts that are expected to be received after deductions for possible doubtful receivables after individual assessment. The terms for accounts receivable are short and their value is therefore initially recognized at nominal amounts without discounting. Write-downs of accounts receivable are reported as operating expenses.

#### Cash and cash equivalents

The parent company's and the Group's cash and cash equivalents include the balances on the Group's common accounts and other bank accounts, as well as investments with a term of less than three months from the date of acquisition. This means that the Group's cash and cash equivalents are only exposed to minimal risk of value fluctuations.

#### Shareholders' equity

Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new shares or options are reported in equity, net after tax, as a deduction from the proceeds. When a Group company purchases shares in the parent company (treasury share buy-back), the purchase price paid including any costs directly related to the transaction (net after tax) reduces the profit carried forward until the shares are withdrawn or sold. If these shares are subsequently sold, the payment received (net after any direct transaction costs and tax effects) are reported in the profit carried forward.

#### Provisions

Provisions are recognized in the balance sheet when Swedish Orphan Biovitrum has a legal or constructive obligation as a result of an event that has occurred and where it is probable that an outflow of resources will be required to fulfill the obligation. It must also be possible to make a reliable estimate of the amount. Provisions are recognized in the amount corresponding to the best estimate of the payment required to fulfill the obligation. If the outflow of resources is expected to take place at a point far in the future, the expected future cash flow is discounted and the provision is recognized at its present value. The discount rate corresponds with the market rate before tax, and the risks associated with the liability. Provisions are recognized in the balance sheet under other short- and noncurrent liabilities.

Provisions for restructuring, which substantially change the way in which the Swedish Orphan Biovitrum Group works, are recognized when a detailed and formal restructuring plan has been established and publicly announced, at which point clear expectations are created that the plan will be implemented. Provisions for restructuring often include benefits at termination, which can be either voluntary or involuntary. Termination benefits are recognized as described above, except in those cases in which a requirement for service is linked to the benefit, in which case cost is distributed over the period during which the services are carried out. Provisions for restructuring entail estimates of the time and cost of planned, future activities. The most significant estimates relate to the costs required for severance pay or other obligations in connection with termination of employment, as well as costs for termination of agreements and other cost for withdrawing. Such estimates are based on the relevant situation in negotiations with the affected parties and/or their representatives.

#### Liabilities

Financial liabilities are measured at fair value less any transaction costs. After the date of acquisition, loans are measured at amortized cost using the effective interest method. Long-term liabilities have an anticipated life of more than one year while current liabilities mature within one year.

#### Taxes

Taxes recognized in the income statement consist of current tax and deferred tax. Current tax is tax to be paid or received in the current year. Deferred tax is calculated according to the balance sheet method based on temporary differences between the carrying amount and the tax base of assets and liabilities, applying the tax rates and tax rules that have been set or announced as of the balance sheet date. The amounts are calculated based the tax rates and tax rules that have been established or essentially established as of the balance sheet date.

Temporary differences arise when the carrying amount of holdings in subsidiaries differs from the acquisition cost. Deferred tax is not taken into account in the case of goodwill on consolidation, nor in differences attributable to participations in subsidiaries that are not expected to be taxed in the foreseeable future. In the consolidated accounts, however, untaxed reserves are divided between deferred tax liabilities and equity. Deferred tax liabilities are recognized for all taxable differences relating to holdings in subsidiaries, except where the parent company can control the date of the reversal of the temporary differences and it is not likely that such a reversal will take place in the foreseeable future. Deferred tax assets relating to deductible temporary differences and loss carryforwards are reported to the extent it is likely that they will be able to be utilized. The value of deferred tax assets is reduced when it is no longer considered likely that they can be utilized. Tax is reported under the item Income tax in the income statement except for those items that are reported under other comprehensive income.

#### **Employee benefits**

Swedish Orphan Biovitrum offers pension plans to all of its employees and uses both defined contribution and defined benefit plans. The CEO and senior executives are mainly covered by defined contribution plans. For other employees, mainly defined contribution plans are used; defined benefit plans are used to a lesser extent.

Pension costs relating to defined contribution plans are charged to earnings as and when the employees perform their duties. Pension commitments are calculated without discounting, as payments for all such plans fall due within a twelve month period.

In the case of defined contribution plans, the company pays fixed contributions to a separate legal entity and there is no obligation to make additional contributions. The Group's earnings are charged with the costs as and when the benefits are earned.

In the case of defined benefit plans, the amount of the pension is determined as a portion of the pensionable final salary, taking into account the number of years of service and average salary at the time of retirement. The Group bears the risk and is responsible for ensuring that the established benefits are paid out.

Swedish Orphan Biovitrum primarily has defined benefit pension commitments and these commitments are insured through Skandia, Alecta and two pension funds. Pension commitments in Alecta are accounted for as defined benefit pension commitments.

The net amount of the estimated present value of the commitments and fair value of the plan assets is reported in the balance sheet as either a provision or a long-term financial receivable. In cases where it is not possible to fully utilize a surplus in a plan, only the portion of the surplus that can be recovered by the company through reduced future charges or repayments is reported.

Regarding defined benefit plans, pension costs and pension commitments are calculated according to the Projected Unit Credit Method. This method allocates costs for pensions as and when employees perform services for the company that increase the employees' right to receive future remuneration. This calculation is performed annually by independent actuaries. The company's commitments have been valued at the present value of expected future payments by applying a discount rate equivalent to the interest on first-class corporate bonds or government bonds with a duration equivalent to the commitments in question. The most important actuarial assumptions are specified in note 31.

Actuarial gains and losses may arise in connection with the determination of the present value of the commitments and the fair value of the plan asset. Such gains or losses arise either because the actual outcome differs from the previous assumption, or the assumptions have changed. The portion of the accumulated actuarial gains and losses at the end of the previous year that exceeds 10 percent of the greater of the present value of the commitments or the fair value of the plan assets is recognized in the income statement over the employees' average remaining period of service.

Interest expenses, less the anticipated yield on plan assets, are classified as financial expenses. Other expense items in the pension costs are charged to operating profit.

The accounting principle for defined benefit pension plans described above applies only to the consolidated accounts.

Commitments for retirement pensions and family pensions for white-collar employees in Sweden are insured through Alecta. According to statement UFR3 issued by the Swedish Financial Reporting Board, these are defined benefit plans covering multiple employers. For the 2005-2010 financial years, the group did not have access to the information necessary to be able to report this plan as a defined benefit plan. The ITP pension plan insured through Alecta is therefore reported as a defined contribution plan.

A special payroll tax is calculated primarily on the premiums paid to Alecta, Collectum and Skandia. The special payroll tax is not calculated on non-deductible pension expenses and is expensed over the course of the year.

The anticipated outcome of variable salary for the Group is reconciled on a regular basis throughout the year and the reserves are adjusted on a monthly basis. At the end of each reporting period, an assessment is made of the outcome.

In order to attract and keep competent employees, Swedish Orphan Biovitrum has established long-term incentive programs. The value of the options is calculated at the time of allocation. The company reports a payroll cost and social security expenses for the services performed by the employees. A more detailed description of the program can be found in Note 14, Employees, personnel costs and remuneration to the Board and senior executives. The company's incentive plan also includes a long-term share program, the costs of which are recognized over the vesting period. Valuation of the Employee option programs and Share programs are be

based on commonly accepted models. The Black & Scholes model have been used for the valuation of the warrants in the employee option programs and Monte Carlo simulation have been used to calculate the value of the performance shares in the Share programs.

#### Remuneration in connection with terminated employment

A provision is reported in connection with termination only if the company is demonstrably obliged to terminate a position before the normal period of service has ended or when remuneration is offered in order to encourage voluntary resignation, e.g. retirement packages. In cases where the company terminates employment, a detailed plan is drawn up that, as a minimum, contains information on the workplace, positions and approximate number of individuals involved, as well as the remuneration due to each employee category or position and the schedule for the plan's implementation.

#### Contingent liabilities

Contingent liabilities are reported when there is a possible commitment arising from events that have occurred and whose existence is based on the occurrence of one or more uncertain future events, or where there is a commitment which is not reported as a liability or a provision due to the fact that it is unlikely that an outflow of resources will be required.

#### Parent company's accounting principles

The annual report for Swedish Orphan Biovitrum AB (publ), the parent company, has been prepared according to the Swedish Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 2 "Accounting for Legal Entities" and statements from the Financial Reporting Board. The parent company applies the same accounting principles as the Group with the following exceptions:

#### Employee benefits/defined benefit plans

When calculating defined benefit pension plans, the parent company complies with the Swedish law safeguarding pensions and the Swedish Financial Supervisory Authority's instructions, as compliance with these is a prerequisite for exercising the right to tax deductions. The parent company also complies with FAR's recommendation redR4. The most important differences compared with the IAS 19 rules concern how the discount factor is established, that the calculation of the defined-benefit commitment is based on current salary levels without consideration to future increases, and that all actuarial gains and losses are recognised in the income statement as they occur.

#### Leased assets

All of the parent company's leases are reported according to the rule for operating leases.

#### Taxes

For legal entities, untaxed reserves including deferred tax liabilities are reported.

#### Subsidiaries

Holdings in subsidiaries are reported under the cost method of accounting. Testing of the value of subsidiaries occurs when there is an indication of a decline in value. Dividends received from subsidiaries are recognized as revenue. Transaction costs in connection with acquisitions of companies are recognized in the income statement

#### Group contributions

The Parent Company's recognition of Group contributions received and provided is accounted for on the basis of their economic significance. In case a Group contribution is provided or received for tax reasons, the Group contribution including its current tax effect is recognized directly in other

comprehensive income. Group contributions received that are comparable to dividends are recognized as revenue in the income statement.

### Basis for preparation of the parent company's and the consolidated financial statements

The parent company's functional currency is the Swedish krona (SEK) which is also the reporting currency for the parent company and the Group. The financial statements are consequently presented in SEK.

All amounts are reported in thousands of SEK unless otherwise indicated. Assets and liabilities are stated at historical cost, except certain financial assets and liabilities which are stated at fair value.

In order to prepare the financial reports in accordance with generally accepted accounting principles, the Board of Directors and management make estimations and assumptions that affect the company's results and financial position as well as other information submitted. These estimations and assumptions are based on historical experience and are regularly reviewed.

Assessments made by management in conjunction with the implementation of IFRS that have a significant influence on the financial reports and estimations made have not involved any significant adjustments in the financial reports of the subsequent year. The accounting principles stated above are used consistently in the preparation of the financial reports that are published and are based on IFRS/ IAS.

The stated amounts and figures in parenthesis are comparative figures from 2009.

#### Note 3 Financial Risk Management

#### Risk and risk management

Through its operations, the Group is exposed to various kinds of financial risks. The operations are affected by several factors that may impact the company's results and financial position. Swedish Orphan Biovitrum's strategy includes continuously identifying and managing risk to the greatest extent possible. The risks can be divided into operational risks and financial risks. Below is a description of the financial risk factors that are deemed the most significant for Swedish Orphan Biovitrum's development and how the company manages them to minimize the level of risk. Operational risk is also described in a separate section in the Director's Report.

#### Financial risks and policies

Financial risk relates to fluctuations in the company's profits and cash flow as a result of changes in exchange rates, interest rates and credit exposure. Swedish Orphan Biovitrum has a comprehensive finance policy that establishes the division of responsibility regarding financial issues between the Board of Directors, the CEO, the CFO, the central finance department and other Group companies. The Board has appointed an Audit Committee to supervise the structure and content of the finance policy and, if necessary, suggest changes to the Board. The finance policy emphasizes a low level of risk. The aim is to minimize the Group's cost of capital by effectively managing and controlling the Group's financial risks.

#### Market risk

#### Currency risk

#### Transaction exposure

In its operations, the company is also exposed to currency risk. Most of the costs are in Swedish kronor, while a significant portion of the revenues are in other currencies. Consequently, a drop in the US dollar and euro or other foreign currencies in which revenues are generated in relation to the Swedish krona will have a negative impact on Swedish Orphan Biovitrum's earnings and financial position.

To hedge future foreign currency flows, the company has adopted the following finance policy with respect to currency hedging:

- Based on forecasts, natural hedging (offset/netting of incoming and outgoing currency flows) should be applied as far as possible.
- Swedish Orphan Biovitrum will hedge the net exposure of foreign currency as follows:

Currency flow	Expected maturity	Hedge ratio	Minimum amount
Known/Secure	-	80-100%	SEK 1 million
Unknown/Not secure	<1 år	<50%	SEK 1 million

#### Translation exposure

The Group's results are affected by exchange rate fluctuation when the foreign subsidiaries' results are translated into SEK. Hedging of this exposure is evaluated on a case by case basis.

#### Interest risk

Swedish Orphan Biovitrum's financial management policy is to limit the short-term effects on the Group's results and cash flow due to changes and movement on the financial markets. Interest risk consists partly of changes in fair value (price risk) and partly of changes in cash flow (cash-flow risk). Fixing interest rates mainly affects cash flow risk. The duration of fixed interest rates for the Group's assets and liabilities is usually short. The Board may decide to extend the duration of fixed interest rates in order to limit the impact of increased interest rates.

#### Credit risk

Swedish Orphan Biovitrum's financial transactions give rise to credit risk relating to financial counterparties. The risk of a counterparty not fulfilling its obligations is limited partly by the Group choosing counterparties with a good credit rating and partly by limiting the size of the counterparty's obligations.

#### Liquidity risk

Liquidity risk relates to the risk that the Group will not secure sufficient financing or that the cost of financing will increase significantly. Investments of any surplus liquidity should only be made in instruments with low credit risk and a high level of liquidity. Investments should only be made in the Swedish Government and in banks, financial institutes and enterprises assigned a credit rating of at least A- by independent evaluators. A high level of liquidity means that the investments can be converted into liquid funds at any given time.

The table below shows when the loans mature:

#### Loan maturity

	Less than 1 year	1-2 year	2-5 year	More than 5 year
As per december 31, 2010				
Other liabilities – long term	214,945	207,789	477,580	119,243
Accounts payable	289,367	-	-	-
Other liabilities	303,485	-	-	_
As per december 31, 2009				
Other liabilities – long term	56,058	55,168	163,725	91,956
Accounts payable	243,899	_	-	_
Other liabilities	454,643	_	_	_

#### Capital risk

The Group's goal regarding capital structure is to secure the Group's ability to continue its business, so that it can continue to generate earnings to its shareholders and benefits to other stakeholders, and retain an optimal capital structure in order to keep costs of capital down.

The Group's capital is based on the Group's equity ratio. It is the Group's goal to have an equity ratio of at least 40 percent. The equity ratio has increased compared with previous years. The increase is mainly attributable to the acquisition of Swedish Orphan and the rights issue in connection with the acquisition.

The equity ratio as of December 31, 2009-1010 was as follows:

	2010	2009
Shareholders equity	4,342,371	1,352,795
Total assets	7,069,550	2,805,530
Equity ratio	61,4%	48,2%

### Note 4 Important estimations and assumptions for accounting purpose

The Group makes estimations and assumptions about the future. The resulting estimations for accounting purposes, by definition, seldom correspond fully to actual results. The estimations and assumptions that involve a high risk of significant adjustments in the reported amounts of assets and liabilities for the coming financial year are discussed below.

#### Intangible assets

Intangible assets at Swedish Orphan Biovitrum are essentially attributable to acquired product rights, acquired R&D and "acquisition goodwill". The goodwill stems from the acquisitions of Arexis and Swedish Orphan.

All goodwill items and other intangible assets when indicated are subject to annual impairment testing. Impairment testing of acquired product rights and acquisition goodwill is based on recoverable amounts including important assumptions about sales trends and margins. When discounting to present value, Swedish Orphan Biovitrum uses its average cost of equity (currently 12 percent before taxes). To the extent the above parameters change negatively, an impairment loss may arise. On December 31, 2010, Swedish Orphan Biovitrum's goodwill amounted to SEK 1,601.0 million (25.3). The impairment tests carried out did not show any impairment loss.

The key parameters for impairment testing of acquired R&D are future cash flow, the probability of realizing a positive outcome in clinical studies and the assumption of best commercial outcome. Future cash flow is estimated in terms of the project's progress in the short and long term and adjusted for the probability that the combined costs and earnings are realized. The earlier the phase of development of a project, the higher the risk. The possibility of reaching the market improves at the rate the project completes the pre-defined phases of development. An assessment of the probability that a project will successfully complete a certain phase of development is made based on the scientific potential that the project can reach a positive outcome in the individual phase of the development process. A best case assumption is made using parameters that affect the project's development into a pharmaceutical with the highest possible commercial potential based on what is reasonable to assume of the project's scientific profile given the information available today. The forecast period is based on the product's estimated useful life on the market.

#### Assumptions for the calculation of pension benefits

The actuarial calculations of pension commitments and pension costs are based on actuarial assumptions as specified in Note 2 and Note 31.

#### Inventory

#### Indirect production costs

Costs for production consist of direct production costs such as raw materials, consumables, media and manpower, as well as indirect costs such as personnel costs, depreciation, maintenance, etc.

Indirect cost calculations are based on a method for calculating standard costs. This method is revised on a regular basis to ensure a reasonable calculation of the degree of usage, lead times and other relevant factors. Changes in the method of calculating the indirect production costs, including the degree of usage, lead times, etc. may have an impact on gross margins and the overall valuation of inventories.

#### Obsolescence

Inventory consists of drug substance and drug product for Kepivance®, Stemgen®, Orfadin® and Kineret® as well as finished stock for other products. For this inventory no provision for obsolescence is made. Stock levels for Kineret®, Kepivance® and Stemgen® is estimated to last for several years. The stocked product durability can vary over time. This can lead to an increased risk of obsolescence when a significant change in the demand for a product or change in sustainability could lead to an impairment. Products not approved at quality inspection will be directly expensed.

Other stock mainly consists of ReFacto®, consisting of biological crops with potentially defective components and Multiferon®. Production of ReFacto® cultivation and purification. If a certain portion of the stock is not approved by the quality department of Swedish Orphan Biovitrum and/ or Pfizer, Swedish Orphan Biovitrum will do an obsolescence assessment of the batch that was not approved, based on historical obsolescence. Swedish Orphan Biovitrum is part of the pharmacological industry, which is regulated and controlled by several authorities in and outside Sweden. Also, the company collaborates with external partners, both Swedish and foreign, who control and evaluate the business. Externally acquired finished stock is continually evaluated.

#### Revenues

The Group assesses the likelihood of future economic benefits accruing to the Group on the basis of a number of factors, including a customer's payment history and credit rating. On certain occasions, the Group requests payment in advance in the form of a signing fee from customers. If a receivable is deemed doubtful by the Group, a provision is made for the receivable until it is possible to determine whether the Group will receive payment or not. According to the Group's routine for advances, advanced payments are recognized as other current liabilities until they are earned.

The Group also recognizes deferred revenue from licensing agreements. According to the milestone method, successive milestones are considered as separate from the initial licensing fee. The initial licensing fee is distributed over the expected life of the contract because, when it is received, no separate earning period is deemed to have been completed. However, subsequent milestones are considered to belong to a particular completed portion of the contract. This portion should therefore be able to be recognized as revenue as soon as it is received, i.e. when the terms of the underlying agreement have been met.

#### Taxes and legal disputes

The Group's deferred tax receivables have been recognized based on the assumption that it will be possible to utilize them to reduce future tax payments. Deferred tax is calculated according to the balance sheet method based on temporary differences between reported amounts and the written down value of assets and liabilities. The amounts are calculated using the tax rates and tax regulations that apply or have been announced as of the balance sheet date. The parent company and one Swedish subsidiary report tax loss carry-forwards. In accordance with current tax regulations, these never mature. Deferred tax assets are only reported for these tax loss

carry-forwards when it is deemed probable that the Group will utilize them against future taxable profits.

#### Research and development costs

The company conducts research and development in internal projects as well as with external partners. In those cases where the company runs projects with an external partner and both parties share certain costs, an assessment is made of costs in connection with the start of the project. This cost is then used as a basis for deductions reconciled with the external partner. The calculation is assessed and updated regularly.

In certain partnership agreements, the company agrees to pay a milestone payment. This payment is carried forward as research and development and amortization only starts when the project has reached the commercialization phase. Evaluation of the project's progress and impairment testing are carried out regularly, at least once a year.

Expenses for internal R&D projects are expensed at the time they occur if they do not fulfill the requirements of IAS 38 Intangible Assets. Standards and uncertainty usually mean that the criteria are not fulfilled. In cases where all the criteria are fulfilled, however, the intangible assets are capitalized and amortized on a straight-line basis from the time the company can prove that it is technically possible to fulfill and profitably commercialize the results.

Payments concerning the projects and substances in agreements with third parties, which are generally defined as prepaid payment and conditional payments, are capitalized and amortized on a straight-line basis from the time the product can be commercialized.

#### Note 5 Acquired operations

On January 14, 2010 Biovitrum acquired Swedish Orphan, creating a new specialty pharmaceutical company, focused on rare diseases. The transaction is built on strong industrial logic and profitable future growth of the business.

During the year restructuring costs of SEK 71.9 M were reported.

Below is a purchase price allocation for the acquisition of Swedish Orphan.

Amounts in SEK million	Fair value
Purchase price allocation	
Purchase price	
- cash payment	1,922.9
- discounted value est. future additional purchase price	165.0
- fair value of shares issued	1,656.8
Total purchase price	3,744.7
Assets and liabilities in acquired operation	
Other intangible assets	2,707.9
Tangible assets	14.1
Financial fixed assets	2.3
Other current assets	448.9
Total assets in acquired operation	3,173.2
Long-term borrowings	30.8
Retirement benefit obligations	2.9
Deferred income tax liabilities	737.5
Current liabilities	211.5
Total liabilities in acquired operation	982.7
Acquired net assets	2,190.5
Goodwill	1,554.2
Total purchase sum	3,744.7

Goodwill pertains to the established sales structure and market presence in most countries and the synergy effects that are expected to arise by coordinating the operations of Biovitrum and Swedish Orphan.

Fair value of shares issued was based on the quoted share price on January 14, SEK 28.40. The revenue from Swedish Orphan included in the consolidated statement of comprehensive income since January 1, 2010, amounts to SEK 725 M. It is not possible to calculate the costs attributable to Swedish Orphan in the consolidated income statement due to restructuring of the operations to achieve synergies. expenses related to the acquisition occurred in 2009 and amounted to SEK 59 M.

The future conditional purchase sum is based on expected future sales volume of Multiferon®. The future conditional purchase sum is calculated on a yearly basis and amounts to the net volume which exceeds a "High Watermark amount" multiplied by three. The initial high watermark amount is SEK 200 M and the maximum conditional purchase sum is SEK 425 M. The duration of the future conditional purchase sum is 60 months after certain approvals and commercial launches in a number of EU countries, though no later than December 31, 2017.

Amounts in SEK million	
Liquid funds	
- cash payment	-1,922.9
Liquid funds in acquired operation	122.2
Effect on liquid funds	-1,800.7

The acquisition agreement includes e.g. an undertaking by former CEO of Swedish Orphan, Bo Jesper Hansen, not to compete with Swedish Orphan Biovitrum or its subsidiaries during a period of three years from completion of the transaction. For this undertaking, during the relevant three-year period Bo Jesper Hansen is entitled to monthly compensation of about DKK 565,000, though reduced by any compensation payable to Bo Jesper Hansen during the same period by Swedish Orphan Biovitrum or any group company under any employment or consultancy arrangement.

#### Note 6 Distribution of revenues

Group	2010	2009
Total revenues by major type of income		
Product sales	1,262,480	564,780
Co-promotion revenues	122,984	127,308
Manufacturing and contract Development	388,025	376,517
Royalty revenues	109,652	165,650
Licensing and Milestone Revenues	23,600	62,616
Other	-	102
	1,906,741	1,296,973

Parent Company	2010	2009
Total revenues by major type of income		
Product sales	541,627	564,780
Co-promotion revenues	122,984	127,308
Manufacturing and contract Development	388,025	376,517
Royalty revenues	109,652	165,650
Licensing and Milestone Revenues	23,600	62,616
Other	-	83
	1,185,888	1,296,954

#### Note 7 Segment reporting

The Group reports one operating segment, Product sales. The basis for identifying reportable segments is the internal reporting as reported to and followed up by the highest executive decision-maker. The Group has identified the highest executive decision-maker as the CEO. Swedish Orphan Biovitrum reports revenue distributed by geographical segments.

Swedish Orphan Biovitrum single largest customer is Pfizer, with net sales of SEK 388 M (362), corresponding to 20% (28%) of the company's total revenues. Swedish Orphan Biovitrum has not had any other customer for which revenue exceeds 10% of the company's total revenues in 2009 and 2010. The majority of fixed assets are in Sweden; no fixed assets amounting to any material value are abroad.

#### Revenues by regions

Total revenues	1,906,741	1,296,973
Other	46,590	54,115
North America	476,857	259,981
Europe	939,564	701,977
Nordic 1)	443,730	280,900
Group	2010	2009

Parent Company	2010	2009
Nordic <sup>2)</sup>	162,967	280,900
Europe	606,451	701,958
North America	406,803	259,981
Other	9,667	54,115
Total revenues	1,185,888	1,296,954

<sup>1)</sup> Net sales in Sweden totaled SEK 196 M (105)

#### Note 8 Cost for goods and services sold

Group	2010	2009
Cost of goods sold	-685,720	-375,740
	-685,720	-375,740
Parent Company	2010	2009
Cost of goods sold	-410,848	-375,740
	-410.848	-375.740

<sup>2)</sup> Net sales in Sweden totaled SEK 75 M (105)

Note 9 Depreciation/amortization and write-down of intangible and

Group	2010	2009
Depreciation according to plan by type of asset		
Capitalized software expenses	-3,358	-2,527
Patents and licenses	-216,909	-49,297
Land and buildings	-336	-
Plant and machinery	-19,663	-29,339
Equipment, tools, fixtures and fittings	-27,832	-28,501
Cars	-677	_
	-268,775	-109,664
Depreciation according to plan by function		
Cost of goods and services sold	-24,954	-30,242
Sales and administration expenses	-230,142	-52,271
Research and development expenses	-13,679	-27,151
	-268,775	-109,664
Write-downs by type of asset		
Patents and licenses	-78 829	_
Plant and machinery	-959	_
Equipment, tools, fixtures and fittings	-6,615	_
	-86,403	_
Write-downs by function <sup>1</sup>		
Sales and administration expenses	-86,403	_
Research and development expenses	-	_
	-86,403	_

Parent Company	2010	2009
Depreciation according to plan by type of asset		
Capitalized software expenses	-2,437	-2,527
Patents and licenses	-50,036	-49,297
Plant and machinery	-19,663	-29,339
Equipment, tools, fixtures and fittings	-26,043	-26,411
	-98,179	-107,574
Depreciation according to plan by function		
Cost of goods and services sold	-23,974	-30,242
Sales and administration expenses	-61,470	-52,271
Research and development expenses	-12,735	-25,061
	-98,179	-107,574
Write-downs by type of asset		
Sales and marketing expenses	-78,829	-
Research and development expenses	-959	-
Equipment, tools, fixtures and fittings	-6,615	-
	-86,403	-
Write-downs by function <sup>2</sup>		
Sales and administration expenses	-86,403	_
Research and development expenses	-	_
	-86,403	_

<sup>1)</sup> SEK 8 249 thousands is included in "Restructuring expenses" in income statement for 2010.

#### Note 10 Other operating revenues

Group	2010	2009
Divestment real estate property	6,202	_
Rental income	483	2,445
Exchange rate gains on operating receivables/ liabilities	90,411	38,311
Result from cash flow hedging	_	266
Gain on sale of fixed assets	-	2,095
Contribution received	-340	128
Disposal of intangible assets	134,110	-
Other	3,242	17
	234,108	43,262
Parent Company	2010	2009
Rental income	433	2,445
Exchange rate gains on operating receivables/liabilities	79,312	38,259
Result from cash flow hedging	-	266
Gain on sale of fixed assets	-	2,095
Disposal of intangible assets	134,110	_
Contribution received	-340	128
Other	187	7
	213,702	43,200

#### Note 11 Other operating expenses

Group	2010	2009
Exchange rate losses on operating receivables/liabilities	-66,089	-49,199
Capital loss divestment of operation	-	-26,956
Scrapping costs	249	-
Cost related to divestment of business	-6,217	-
Reimbursed foreign VAT	824	822
Other	-890	-665
	-72,123	-75,998
	-72,123	-75,998
Parent Company	-72,123 2010	-75,998 2009
Parent Company Exchange rate losses on operating receivables/liabilities		
Exchange rate losses on operating receiva-	2010	2009
Exchange rate losses on operating receivables/liabilities	2010	2009

<sup>2)</sup> SEK 7 574 thousands is included in "Restructuring expenses" in income statement for 2010.

#### Note 12 Expenses for operational leasing

Contractual future leasing costs with non-cancellable contracts, due for payment as follows:

Group		Parent company	
2010	2009	2010	2009
6,863	4,710	3,396	4,710
5,839	3,713	1,359	3,713
12,702	8,423	4,755	8,423
11,707	6,539	5,435	6,534
	5,839 12,702	2010 2009 6,863 4,710 5,839 3,713 12,702 8,423	2010         2009         2010           6,863         4,710         3,396           5,839         3,713         1,359           12,702         8,423         4,755

Contractual future rental costs for premises with non-cancellable contracts, due for payment as follows:

	Group		Parent company	
	2010	2009	2010	2009
Within 1 year	83,517	85,747	76,794	85,747
Between 1 and 5 years	331,787	320,998	326,316	320,998
Later than 5 years	732,347	899,599	732,347	899,599
	1,147,651	1,306,344	1,135,457	1,306,344
Leasing costs for the year:	91,854	69,595	84,066	64,176

In 2010 Swedish Orphan Biovitrum entered into leasing agreements for equipment through Swedbank Finans. The total contract cost for these agreements is SEK 18 (2,123) thousands.

The decisive factor in the classification of leases is to what extent the economic risks and benefits associated with ownership of the leased object are retained by the lessor or transferred to the lessee. As regards properties, assessments of the lease agreement must be made both for the building and the land. As regards properties, assessments of the lease agreement must be made both for the building and the land.

Swedish Orphan Biovitrum bases its position mainly on the fact that the present value of minimum lease charges does not constitute a significant portion of the fair value of the property and that there are otherwise no significant indications that a finance lease exists.

Swedish Orphan Biovitrum subleased parts of its premises in Gothenburg in January and February. This agreement is considered an operating lease and rental income is recognized over the term of the lease.

Note 13 Result from participation in Group companies

Parent company	2010	2009
Result from limited partnership	_	-75
Capital gain from divestment of subsidiaries	-6,217	23,112
Write-down of shares in subsidiaries	-	-5,412
	-6,217	17,625

### Note 14 Personnel, personnel costs and remuneration to Board members

#### Average number of employees

Group and Parent Company	2010	of which men	2009	of which men
Sweden	415	40%	403	41%
Denmark	12	17%	1	_
Finland	10	60%	2	100%
Norway	11	48%	2	100%
United Kingdom	8	73%	25	57%
France	9	33%	_	-
Germany	13	57%	_	-
Italy	8	43%	_	-
Spain	6	17%	_	-
Russia/Balticum	5	21%	_	-
Central Eastern Europe	11	38%	_	-
Total	508	40%	433	42%

#### Salaries, other remunerations and social security expenses

	, i					
		2010		2009		
Group and Parent Company	Salaries and remunerations	Social security costs	Salaries and remunerations	Social security costs		
Parent Company	266,702	162,258	237,013	135,765		
(of which pension cost <sup>1</sup> )		(55,372)		(54,024)		
Subsidiary	110,244	40,230	13,325	2,302		
(of which pension cost <sup>1</sup> )		(14,593)		(782)		
Group total	376,946	202,488	250,338	138,067		
(of which pension cost <sup>1</sup> )		(69,965)		(54,806)		

<sup>1</sup> Of the Group's and Parent Company's pensions costs, SEK 1,662 thousand (1,478) pertain to the Board and CEO. The Group's outstanding pension commitments for the Board and CEO amount to SEK 0 thousand (0).

continued on next page>

Salaries and other remuneration distributed by country and among board members, etc., and other employees

	Board and CEO	Other employees	Board and CEO	Other employees
Parent Company				
Sweden	35 177	231 525	14,059	216,609
(of which bonuses, etc.)	(122)	(9 127)	(2,382)	(14,035)
Denmark	-	_	_	1,356
Finland	-	_	_	2,652
Norway	-	-	_	2,337
Parent company total	35 177	231 525	14,059	222,954
(of which bonuses, etc.)	(122)	(9 127)	(2,382)	(14,035)
Subsidiaries in Sweden	1,521	34,274	-	_
(of which bonuses, etc.)	(266)	(3,620)	()	()
Subsidiaries outside Sweden				
Denmark	1,525	9,721	_	_
(of which bonuses, etc.)	(109)	(1,102)	()	()
Finland	1,899	8,292	_	_
(of which bonuses, etc.)	(143)	(697)	()	()
Norway	1,140	12,354	_	_
(of which bonuses, etc.)	(98)	(777)	()	(-)
United Kingdom	1,324	4,940	1,895	11,429
(of which bonuses, etc.)	(111)	(423)	(-)	(70)
France	1,746	6,288	-	_
(of which bonuses, etc.)	(248)	(945)	()	()
Germany	1,679	8,835	_	_
(varav tantiem o.d.)	(48)	(476)	(-)	(-)
Spain	840	2,891	-	_
(of which bonuses, etc.)	(153)	(467)	()	(-)
Italy	1,164	3,463	_	_
(of which bonuses, etc.)	(114)	(344)	()	(-)
ChezhRepublic	1,085	5,048	-	_
(of which bonuses, etc.)	(122)	(499)	()	()
Russia	-	215	_	_
(of which bonuses, etc.)	(-)	(-)	(-)	(-)
Subsidiary total	13,923	96,321	1,895	11,429
(varav tantiem o.d.)	(1,412)	(9,350)	(-)	(70)
Group total	49 100	327 846	15,954	234,383
(of which bonuses, etc.)	(1 534)	(18 477)	(2,382)	(14,105)

#### Remuneration policy 2010

The remuneration policy decided by the 2010 Annual General Meeting states that Swedish Orphan Biovitrum will provide market conditions to enable the company to recruit and retain skilled personnel. Remuneration of directors can be composed of a fixed salary, variable salary, pension and other customary benefits. Long-term incentive could be offered as a supplement to the above and will then be submitted for approval of Annual General Meeting. The compensation is based primarily on the level of the position, performance and the company's and the person's achievement of predetermined targets.

The full guidelines are described in the Directors' Report on page 35.

#### Remuneration to the CEO

Martin Nicklasson took up the position as Chief Executive Officer on May 14, 2007.

In 2010 Martin Nicklasson received SEK 4,860 thousand (4,765) in fixed salary. The CEO's salary is reviewed annually on January 1 by the Board and the company's Compensation & Benefits Committee. Besides fixed salary, a variable salary of no more than 50 percent of the fixed annual cash salary (basic salary) is paid. The variable salary adheres to a system approved by the Board and is based on comprehensive company objectives. The 2010 variable salary amounted to SEK 122 thousands (2,382).

Swedish Orphan Biovitrum pays a contribution of 30 percent of pensionable salary for Martin Nicklasson's future pension benefits. Pensionable salary in 2010 was SEK 4,860 thousand annually and the retirement age is 65. Martin Nicklasson resigned as CEO December 31, 2010. Martin Nicklasson receives a severance pay of a total of 24 months.

Martin Nicklasson participates in three of Swedish Orphan Biovitrum's long-term incentive programs. He holds 300,000 employee options in option program 2007/2012 and is entitled to hold no more than 94,589 shares in Share Program 2008.

#### Fixed and variable salaries

The CEO, executive management, managers, and a number of key employees receive a variable salary in addition to their fixed salary. The variable portion is in line with a system approved by the Board and is based on company objectives and individual goals.

Variable salaries for the CEO and executive management are based 100 percent on company objectives. The maximum individual levels are between 30 and 50 percent of basic salary.

For other executives and key employees, the variable salary is based 30 percent on company objectives and 70 percent on individual goals. Variable salary levels for these individuals are between 5 and 30 percent of fixed pay and this is paid annually in cash for the previous year. The variable salary is pensionable income and calculation is based on Alecta's calculation and on a three-year average.

The expected outcome is reconciled regularly throughout the year and reserves are adjusted monthly. On each reporting occasion, an assessment is made of the variable salaries.

#### Pensions for executive management

Swedish Orphan Biovitrum's pension plan for executive management is principally a defined contribution plan. This means that Swedish Orphan Biovitrum makes contributions equal to 27 percent of the employee's pensionable salary into a pension plan set up for the employee. The employee is covered by the ITP plan and the Manager Plan constitutes the alternate ITP. The contribution paid to Alecta is included in the contracted contribution. The pensionable salary is maximized at 50 income base amounts.

In conjunction with the transition from defined benefit to defined contribution plans, individual agreements were reached with percentages exceeding 27 percent. This applies to three individuals who have contributions of 30-35 percent, and in these cases, the contributions paid to Alecta for the ITP plan's basic benefits were excluded and paid in addition to the agreed contribution level.

In addition, one person has a defined benefit or ITP and one person is still covered by the defined benefit Manager Plan. This plan entitles retirement at age 60 with a benefit level as per the ITP plan as well as 32.5 percent in pension on salary portions between 30 and 50 income base amounts. The plan also includes a guarantee of 50 percent in pension if the employee resigns his post after having completed a full period of service by retirement age.

#### > Continued Note 14

#### Remuneration and other benefits for the Board, CEO and other senior executives

	Basic pay/ fees	Variable remuneration	Pension cost	Other benefits	Financial instrument	Other remuneration	Total
2010				·		· ·	
Chairman of the Board <sup>1</sup>	_	-	-	-	-	8,687	8,687
Other board members <sup>2</sup>							
Håkan Åström³	325	_	_	_	_	-	325
Mats-OloF Ljungkvist <sup>3</sup>	100	_	_	-	_	-	100
Adine Grate Axén	193	_	_	_	_	_	193
Lennart Johansson	217	_	_	-	_	-	217
Wenche Rolfsen	275	_	_	_	_	-	275
Michael Steinmetz	300	_	_	_	_	_	300
Hans Wigzell	275	_	_	_	_	_	275
Hans Glemstedt	277	_	_	-	_	-	277
Peter Sellei³	100	-	-	-	-	-	100
Chief Executive Officer							
Martin Nicklasson <sup>4</sup>	4,860	122	1,662	244	907	16,633	24 428
Other senior management <sup>5</sup>	13,783	1 397	5,096	344	4,018	_	24 638
	20,705	1 519	6,758	588	4,925	25,320	59 815

<sup>1)</sup> The purchase agreement relating to Swedish Orphan includes a commitment by Bo Jesper Hansen not to compete with Swedish Orphan Biovitrum and its subsidiaries for a period of three years from completion of the acquisition, see Note 5. Bo Jesper Hansen is employed as Executive Chairman and receives a monthly compensation amounting to about 565,000 DKK, which is entirely deducted from the compensation in the same amount that Bo Jesper Hansen is entitled to in accordance with the acquisition agreement.

<sup>5)</sup> Other senior management refers to Swedish Orphan Biovitrum's management group in which 8 (7) individuals, excluding the Managing director, are included.

	Basic pay/ fees	Variable remuneration	Pension cost	Other benefits	Financial instrument	Other remuneration	Total
2009							
Chairman of the Board	983	_	-	_	=	_	983
Other board members							
Mats-Olof Ljungkvist	292	-	-	-	-	_	292
Anders Hultin <sup>1</sup>	92	-	_	-	-	-	92
Wenche Rolfsen	275	-	_	-	-	-	275
Michael Steinmetz	300	-	-	-	-	_	300
Toni Weitzberg <sup>1</sup>	83	-	-	-	-	_	83
Hans Wigzell	275	_	-	_	_	_	275
Hans Glemstedt	167	_	-	_	_	-	167
Peter Sellei	200	_	_	_	_	_	200
Chief Executive Officer							
Martin Nicklasson	4,765	2,382	1,478	233	2,534	_	11,392
Other senior management <sup>2</sup>	11,939	4,000	5,977	177	2,928	381	25,402
	19,371	6,382	7,455	410	5,462	381	39,461

<sup>1)</sup> Anders Hultin and Toni Weitzberg were members of the board of directors during 2008. The remuneration refers to work carried out during this period.

<sup>2)</sup> Information regarding the directors fees can be found in the Corporate Governance Report on page 45.

<sup>3)</sup> Håkan Åström, Mats-olof Ljungkvist and Peter Sellei were members of the board of directors during 2009. The remuneration refers to work carried out during this period.

<sup>4)</sup> Other compensation for the CEO include a severance pay totaling 24 months.

<sup>2)</sup> Other senior management refers to Swedish Orphan Biovitrum's management group in which 7 (7) individuals, excluding the Managing director, are included.

# Remuneration and other benefits for the Board, CEO and other senior executives – Parent Company and subsidiaries

	2010	2009
Parent Company		
Salaries and remunerations		
(of which bonuses etc)	49,997	32,006
Pension cost	(854)	(6,382)
Number of persons (excl. union representatives)	5,563	7,455
Antalet personer (exkl. arbetstagarrepresentanter)	16	17
Subsidiaries		
Salaries and remunerations	16,983	1,809
(of which bonuses etc)	(2,077)	-
Pension cost	2 587	87
Number of persons	12	1
Group		
Salaries and remunerations	66,980	33,815
(of which bonuses etc)	(2,931)	(6,382)
Pension cost	8,150	7,542
Number of persons (excl. union representatives)	28	18

#### Long-term incentive programs

In order to attract and keep competent employees, Swedish Orphan Biovitrum has established long-term incentive programs. Below is a description of the share-related programs that are currently in existence.

# Employee option program 2006/2011

In May 2006 Swedish Orphan Biovitrum issued 150,000 warrants, each carrying the right to subscribe for two shares, intended for an employee option program for certain key individuals. After the issue in 2009 each warrant carries the right to subscribe for 3.78 shares. The exercise price for these warrants is SEK 58.21 per share with an exercise period ending on May 31, 2011.

The allocation was carried out following a decision by Swedish Orphan Biovitrum's Compensation & Benefits Committee. The options were allocated and give the employees the right to earn an equal amount of warrants, with allocation of one third of the total allocated amount per year during the first three years. Options and their subsequent warrants are allocated free of charge (without payment). If employment is terminated within this three-year period, the employee forfeits his/her allocated options and the right to the warrants.

In 2010 no new allocations were made within the employee option program 2006/2011.

# Warrants

2010	2009
35 000	40 000
_	_
-	_
-20 000	-5 000
15 000	35 000
15 000	35 000
	35 000 - - -20 000 15 000

The cost of the employee option program 2006/2011 is expected to be earned on a straight-line basis, which means that the total amount of allocated options will be expensed at one third per year.

The following valuation parameters were used on the issue date:

	Date of i	issue
Valuation parameters	May 2006	September 2006
Share price (SEK)	70.65	83.74
Exercise price, SEK	58.21	58.21
Volatility (percent)	30	30
Dividend (SEK)	No expected dividends	No expected dividends
Risk free interest rate (%)	3.55	3.51
Fair value per warrant (SEK)	29.40	39.70

### Employee option program 2007/2012

The 2007 Annual General Meeting resolved to initiate an employee stock option program for 2007/2012. As part of the plan, employee options may be issued with the right to acquire up to 567,000 shares in the company. Each employee option may be exercised through April 1, 2012, to acquire 1.89 shares in Swedish Orphan Biovitrum at an exercise price of SEK 58.21.

The right to acquire new shares under the employee stock option program will be exercisable with one-third of the total amount of employee warrants allocated from the date falling one year from the allocation date (the "anniversary date") and an additional one-third from each of the two subsequent anniversary dates, provided that the holder as of these dates is still employed by the company and has not been given notice of termination of employment.

To guarantee that the company can fulfill its obligation to employee option holders when they exercise their options, the Annual General Meeting also decided that 300,000 warrants for the subscription of new shares will be issued to the wholly-owned subsidiary Swedish Orphan Biovitrum Treasury AB. The company will use the warrants to cover its obligations to the employee option holders when exercising their options.

#### Warrants

	2010	2009
Outstanding January 1	300 000	300 000
Allocated during the period	_	_
Exercised during the period	_	_
Repurchased during the period	_	-
Outstanding as per December 31	300 000	300 000
Redeemable as per December 31	300 000	200 000

When expensing the employee option program 2007/2012, 100,000 of the allocated warrants are estimated to have an earning rate of one year, a further 100,000 warrants have an earning rate of two years, and the last 100,000 warrants have an earning rate of three years. This means that a proportionally larger share of the costs is reported in the first year of the program.

The following data was used to calculate the cost of the 2007/2012 program at the time of issue  $\frac{1}{2}$ 

- Share price SEK 73.06.
- Exercise price SEK 58.21.
- Volatility 30 percent.
- No expected dividends.
- Risk free interest rate of 3.95 percent

The fair value per option amounts to SEK 30.97.

Swedish Orphan Biovitrum has selected the Black & Scholes model for valuation of the warrants. When selecting a model, the company has taken into account the same considerations as knowledgeable and interested parties independent of each other would have done. Important factors in the underlying model are the following:

- exercise price
- the life of the option
- current price of the underlying shares
- the shares' expected volatility
- expected dividends, and
- the risk-free interest rate during the life of the option

The expected volatility is a measure of the share price fluctuations over a period of time. Swedish Orphan Biovitrum has taken the following into account in estimating the expected volatility:

- Implicit volatility for other company instruments that are traded and have the characteristics of warrants.
- Historical volatility of the share price and, since the company was only recently listed, the historical share price development of similar companies. The historical period is the same as the warrants' exercise period.
- The long-term average level of volatility.

#### Financial instruments pertaining to employees

	2010	2009
Alloted	335,000	1,503,068
Sold	-20,000	-586,534
Used	=	-581,534
	315,000	335,000

# Share Program 2008 and 2009

At the 2008 Annual General Meeting a decision was made to introduce a performance-based, long-term share program and at the 2009 AGM a decision was made regarding an additional performance-based, long-term share program. The terms and the conditions of the two programs are the same. The programs cover managers and key employees who have the opportunity to be allotted common shares in Swedish Orphan Biovitrum free of charge. The outcome of Share Program 2008 and 2009 is dependent on the fulfillment of set value creation targets determined by the Board of Directors and linked to the total shareholder return of the Swedish Orphan Biovitrum common share (the share price development adjusted with respect to dividends), for a three year period from the date of the offer to participate in the program (the "Performance Period"). These targets are designated Performance Condition 1 and Performance Condition 2.

**Performance Condition 1:** For any allotment of common shares to be possible under Share Program 2008 and Share Program 2009, the total share-holder return for the Swedish Orphan Biovitrum common share must amount to at least 15% during the Performance Period.

Performance Condition 2: Upon fulfillment of Performance Condition 1, an evaluation is carried out of the total shareholder return for the Swedish Orphan Biovitrum common share in relation to a group of comparable companies, as established by the Board of Directors. As a condition for the allotment of common shares, it has been established that a minimum level for the total shareholder return of the Swedish Orphan Biovitrum common share must correspond to the median performance for the comparable group. It has been established that full allotment will be carried out if the total shareholder return for the Swedish Orphan Biovitrum common share corresponds to the upper quartile for the comparable group (the maximum level) or exceeds this level. If the minimum level is reached, an allotment of 35% of the maximum number of common shares, in accordance with what has been

described previously, will be carried out. If the total shareholder return for the Swedish Orphan Biovitrum common share exceeds the minimum level but falls below the maximum level, a pro rata allotment will be carried out. The allotment of common shares requires that the individuals participating in the program are employed in the Swedish Orphan Biovitrum Group for the entire Performance Period and have not, at the time of allotment of the gratuitous common shares, terminated their employment. If all conditions in the Share Program 2008 and 2009 are met, allotment of common shares will take place free of charge after the end of the Performance Period.

Share Program 2008 was implemented at the end of 2008 and the Performance Period will run from November 26, 2008 until November 25, 2011. The program may involve a total maximum allotment of 422,280 shares in Swedish Orphan Biovitrum AB (publ).

The value of the performance shares, using Monte Carlo simulation, has been calculated on the allotment date, taking market conditions into account but without regard to expected dividends. Important input data in the model were volume-weighted average share price of SEK 48.70 on the allotment date, volatility of 27.1 percent and a risk free interest rate of 2.40 percent. Volatility is measured as the standard deviation for expected return on the share price based on a statistical analysis of daily share prices for the Sobi common share over the last three years. The valuation model also reflected corresponding historical volatility for the share prices of comparable companies during the same period.

When the share program is carried as an expense 2008, the shares are calculated according to the following parameters:

- Number of shares 422,280
- Vesting period 36 months
- Fair value per performance share SEK 18.63
- Anticipated turnover of 10% among the relevant employees

# Share program 2008

	Number of performance shares	Value	Purchase price	Benefit
CEO (until 31/12/2010),				
Martin Nicklasson	94,589	1,762,193	-	1,762,193
Other senior managment, 8	156,211	2,910,211	-	2,910,211
Sum	250,800	4,672,404	_	4,672,404

Share Program 2009 was implemented in June 2009 and the performance period runs from June 10, 2009 until June 9, 2012. The program may involve a total maximum allotment of 322,148 shares in Swedish Orphan Biovitrum AB (publ).

The value of the performance shares, using Monte Carlo simulation, has been calculated on the allotment date, taking market conditions into account but without regard to expected dividends. Important input data in the model were volume-weighted average share price of SEK 66.05 on the allotment date, volatility of 29.0 percent and a risk free interest rate of 1.74 percent. Volatility is measured as the standard deviation for expected return on the share price based on a statistical analysis of daily share prices for the Sobi common share over the last three years. The valuation model also reflected corresponding historical volatility for the share prices of comparable companies during the same period.

When the share program is carried as an expense 2009, the shares are calculated according to the following parameters:

- Number of shares 322,148
- Vesting period 36 months
- Fair value per performance share SEK 30.12
- Anticipated turnover of 10% among the relevant employees

#### Share program 2009

	Number of performance shares	Value	Purchase price	Benefit
CEO (until 31/12/2010), Martin Nicklasson	_	_	_	_
Other senior managment, 8	112,394	3,385,307	_	3,385,307
Sum	112,394	3,385,307	_	3,385,307

#### Share Program 2010

The 2010 Annual General Meeting resolved to approve a performance-based, long-term share program. Share Program 2010 is essentially the same as the share programs from earlier years, except that in Share Program 2010 participants are required to invest in Sobi shares and hold these shares throughout the three-year vesting period. The program covers management and key individuals, who receive the opportunity for allocation of common shares in Sobi on condition that involved employees invest in Sobi shares and on condition that involved employees remain employed throughout the vesting period. Provided that the abovementioned requirements are met, involved employees may receive Sobi shares free of charge equivalent to the number of shares the employee invested in under the Share Program 2010 ("Matching shares") as well as additional Sobi shares depending on whether targets set by the board of directors for value creation are met ("Performance shares").

The targets for value creation, determined by the board of directors, are connected to the total shareholder return of the Sobi common share (the share price development adjusted with respect to dividends), during a three year period as from the date of the offer to participate in the program (the "Performance Period"). These targets comprise market conditions as stated in IFRS 2 Employee benefits, and are called Performance condition 1 and Performance condition 2 in this program.

Performance Condition 1: For any allotment of common shares to be possible under Share Program 2010, the total shareholder return for the Sobi common share must amount to at least 15 percent during the Performance Period.

Performance Condition 2: Upon fulfillment of Performance Condition 1, an evaluation is carried out of the total shareholder return for the Sobi common share in relation to a group of comparable companies, established by the board of directors. As a condition for allotment of common shares, it has been established that a minimum level for the total shareholder return of the Sobi common share shall correspond to the median performance for the comparable group. It has been established that full allotment will be carried out if the total shareholder return for the Sobi common share corresponds to the upper quartile for the comparable group (the maximum level) or exceeds this level. If the minimum level is reached, an allotment of 35 percent of the maximum number of common shares, in accordance with what has been described previously, will be carried out. If the total shareholder return for the Sobi common share exceeds the minimum level but falls below the maximum level, a pro rata allotment will be carried out.

The value of the matching shares has been calculated on the allotment date based on the volume weighted price of the Swedish Orphan Biovitrum common share on that date under the assumption that no dividends are expected to occur during the measurement period.

The value of the performance shares, using Monte Carlo simulation, has been calculated on the allotment date, taking market conditions into account but without regard to expected dividends. Important input data in the model were volume-weighted average share price of SEK 39.71 on the allotment date, volatility of 32.8 percent and a risk free interest rate of 2.06 percent. Volatility is measured as the standard deviation for expected return on the share price based on a statistical analysis of daily share prices for the Sobi common share over the last three years. The valuation model

also reflected corresponding historical volatility for the share prices of comparable companies during the same period.

Share Program 2010 was implemented at the end of 2010 and the performance period will run from December 13, 2010 until December 12, 2013. The program may involve a total maximum allotment of 510,547 shares in Swedish Orphan Biovitrum AB (publ).

Expensing of Share Program 2010 is calculated with the following parameters:

- Number of matching shares 88,851
- Number of performance shares 421,696
- Vesting period 36 months
- Fair value of matching share SEK 39.71
- Fair value per performance share SEK 20.05
- Anticipated turnover of 10 percent among the relevant employees.

#### Share program 2010

	Number of performance shares	Number of matching shares	Value	Purchase price	Benefit
CEO (until 31/12/2010), Martin Nicklasson	_	_	_	_	_
Other senior management, 8	126,127	22,123	3,432,576	_	3,432,576
Sum	126,127	22,123	3,432,576	_	3,432,576

Specification of men and women in the Board and executive management. The data in the table does not include employee representatives and refers to the status as of the balance sheet date.

Group	2010	2009
Board		
Men	5	8
Women	2	1
	7	9
CEO and executive management		
Men	7	6
Women	2	2
	9	8

#### Absence due to illness - Parent company

Leave of absence due to illness in relation to ordinary working hours specified according to age and sex:

ned according to age and sex.		
Parent Company	2010	2009
29 years and younger	1.00%	1.30%
30-49 years	1.70%	1.40%
50 years and older	2.30%	1.90%
Total leave of absence due to illness in relation to ordinary working hours of which:	1.90%	1.60%
men	29.60%	26.16%
women	70.40%	73.84%
Portion of leave of absence due to illness for leave of absence of 60 consecutive days or more	29.19%	24.80%

# Note 15 Remuneration and reimbursement

Group	2010	2009
PwC		
Auditing assignments <sup>1</sup>	2,778	3,454
of which auditing in addition to audit assignment	983	1,323
Tax assignements	1,459	458
Other assignments	1,761	4,931
	5,998	8,843
Other auditor		
Auditing assignments	-	175
Parent Company	2010	2009
PwC		
Revisionsuppdrag <sup>1</sup>	1,766	3,454
varav revisionsverksamhet utöver revisionsuppdraget	916	1,323
Skatterådgivning	1,345	458
Övriga tjänster	1,761	4,931
	4,872	8,843

Auditing assignments" refer to the statutory audit to be able to provide the audit report and counseling related to the audit. The category "Other auditing services" refers to services such as reviewing interim reports.

# Note 16 Costs according to type of cost

Group	2010	2009
Raw materials and consumables	-467,603	-134,387
Other external costs	-681,595	-601,987
Personnel costs	-574,273	-402,025
Depreciation and write-downs	-355,524	-109,664
Other operating expenses	-72,123	-75,998
	-2,151,118	-1,324,061

Personnel costs -	-431,786 -184,582 -38,884	-391,782
Personnel costs -	-431,786	-391,782
Other external costs	,	/
Other external costs	-565,337	-621,672
Raw materials and consumables	-196,136	-134,387
Parent Company	2010	2009

# Note 17 Financial income

Group	2010	2009
Interest income, miscellaneous	-1,206	1,342
Result from short-term investments	1,623	8,148
Exchange rate gains/losses on short term receivables	-7,981	77
Exchange rate difference long-term liability	2,712	12,269
Exchange rate difference loan in USD	_	6,764
Other	121	3
	-4,731	28,603
Parent Company	2010	2009
Interest income, miscellaneous	-1,353	1,438
Result from short-term investments	1,623	8,148
Exchange rate gains/losses on short term receivables	-3,691	86
Exchange rate difference long-term liability	2,712	12,269
Exchange rate difference loan in USD	-	6,764
Other	101	_
	-607	28,705

# Note 18 Financial expenses

Group	2010	2009
Interest expenses, bank loan	-49,722	-11,523
Interest expenses, miscellaneous	-5,263	-761
Exchange rate difference liabilities	3,273	_
Financing expenses	-151	-221
Re-evaluation of short-term investments	-6,100	_
Write-down of financial fixed asset	-19,303	_
Other	-173	165
	-77,439	-12,340

2010	2009
-49,722	-11,523
-3,411	-723
-2,100	-
-151	-221
-6,100	_
-19,303	-
-	164
-80,787	-12,303
	-49,722 -3,411 -2,100 -151 -6,100 -19,303

# Note 19 Exchange rate differences affecting operating profit/loss

Group	2010	2009
Exchange rate differences affecting operating		
profit/loss	24,322	-10,503
	24,322	-10,503
Parent Company	2010	2009
Exchange rate differences affecting operating		
profit/loss	39,281	-10,517
	39,281	-10,517

# Note 20 Income tax expense

# Current tax expense (-)/ tax income (+)

Group	2010	2009
Tax expense / income for the year	-38,137	_
Adjustment of taxes related to previous years	-375	_
Total tax reported for the Group	-38,512	_
Deferred tax relating to:		
Pensions	-1,886	-
Change in tax allocation reserve and excess depreciation	-14,319	_
Internal profit in inventories	986	_
Depreciation of immaterial assets	40,807	_
Other	912	_
Total deferred tax reported for the Group	26,500	_
Total tax reported for the Group	-12,012	_

Parent Company	2010	2009
Tax income for the year	-	-
Adjustment of taxes related to previous years	-	-
Total tax reported for the Parent Company	-	_

# Reconciliation of actual tax

Pre-tax profit	-92,439	00.407
		32,437
Tax on the basis of prevailing tax rate for Parent Company	24,311	-8,531
Effect of foreign taxrates	-676	
Other non-deductible expenses	-6,284	-9,205
Non-taxable income	1,337	1,476
Interest on tax allocation reserve	-922	-
Adjustment of tax previous years	-5,725	-
Decrease (+) / Increase (-) in loss carry-forward without corresponding capitalization of deferred tax	-24,053	16,261
Reported actual tax	-12,012	-

Parent Company	2010	2009
Pre-tax profit	-104,746	70,429
Tax on the basis of prevailing tax rate for Parent Company	27,548	-18,523
Other non-deductible expenses	-1,925	-2,116
Non-deductible loss on sale of shares in		
limited partnerships	-1,635	-1,423
Non-taxable income	-	6,082
Decrease (+) / Increase (-) in loss carry-forward without corresponding capitalization of deferred tax	-23,988	15,980
Reported actual tax	-	_

Prevailing tax rate for the Parent Company is 26.3 % (26.3%).

Note 21 Intangible fixed assets and impairment testing

Group	Goodwill	Research & Development	Trademarks & licences	Product rights	Software and other	IT-software in progress	Total
1 January – 31 December 2009						p. 25. 222	
Net book value – Opening balance	25,342	172,239	133,217	690,981	4,229	_	1,026,008
Additions		126,957	14,657	43,740	4,269	_	189,623
Disposals	_	-	-28,317	-4,663	-	_	-32,980
Depreciation			-1,367	-47,930	-2,527		-51,824
Reclassification			28,317	-		_	28,317
Net book value – Closing balance	25,342	299,196	146,507	682,128	5,971	_	1,159,144
A. D							
At December 31, 2009	50.440	100.010	454.044	700.050	00.404		4 004 005
Acquisition value	59,660	408,342	151,344	730,058	32,431	_	1,381,835
Accumulated depreciation and amortization	-34,318	-109,146	-4,837	-47,930	-26,460		-222,691
Net book value	25,342	299,196	146,507	682,128	5,971	-	1,159,144
1 January – 31 December 2010							
Net book value – Opening balance	25,342	299,196	146,507	682,128	5,971	-	1,159,144
Additions	1,575,617	10	496 007	2,284,700	4,615	3,297	4,365,348
Reclassification of acquisition value	_	_	_	_	-684	684	_
Disposals	_	_	-78,829	_	_	_	-78,829
Depreciation	_	_	-54 004	-162 905	-3,358	_	-221,369
Reclassification of acc depreciations	_	_	_	_	-	_	_
Net book value – Closing balance	1,600,959	299,206	666,431	2,647,173	6,544	3,981	5,224,294
At December 31, 2010							
Acquisition value	1,635,277	408,352	813,453	2,849,758	36,362	3,981	5,747,183
Accumulated depreciation and amortization	-34,318	-109,146	-147,022	-202,585	-29,818		-522,889
Net book value	1,600,959	299,206	666,431	2,647,173	6,544	3,981	5,224,294
		Possarch &	Tradomarke &	Product	Software	IT coftware in	
Parent Company	Goodwill	Research & Development	Trademarks & licences	Product rights	Software and other	IT-software in progress	Total
Parent Company 1 January – 31 December 2009	Goodwill						Total
	Goodwill						Total 826,536
1 January – 31 December 2009			licences	rights	and other	progress	
1 January – 31 December 2009 Net book value – Opening balance	_	Development	131,326	rights 690,981	4,229	progress —	826,536
1 January – 31 December 2009 Net book value – Opening balance Additions	_ 	Development	131,326 14,657	690,981 43,740	4,229 4,269	progress —	826,536 189,623
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value	- - -	Development – 126,957 –	131,326 14,657 -28,317	690,981 43,740 -4,663	4,229 4,269	progress — — —	826,536 189,623 -32,980
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation	- - - -	Development – 126,957 –	131,326 14,657 -28,317 -1,367	690,981 43,740 -4,663	4,229 4,269	progress	826,536 189,623 -32,980 -51,824
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations	- - - -	126,957 — — — — — — — — — — — — — — — — — — —	131,326 14,657 -28,317 -1,367 28,317	690,981 43,740 -4,663 -47,930	4,229 4,269 - -2,527	progress	826,536 189,623 -32,980 -51,824 28,317
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance	- - - -	126,957 — — — — — — — — — — — — — — — — — — —	131,326 14,657 -28,317 -1,367 28,317	690,981 43,740 -4,663 -47,930	4,229 4,269 - -2,527	progress	826,536 189,623 -32,980 -51,824 28,317
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009	- - - - -	Development  - 126,957  126,957	131,326 14,657 -28,317 -1,367 28,317 144,616	690,981 43,740 -4,663 -47,930 - 682,128	4,229 4,269 - -2,527 - 5,971	progress — — — — — — — —	826,536 189,623 -32,980 -51,824 28,317 959,672
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009  Acquisition value	- - - - - -	Development  - 126,957  126,957	131,326 14,657 -28,317 -1,367 28,317 144,616	rights 690,981 43,740 -4,663 -47,930 - 682,128	4,229 4,269  -2,527  5,971	progress	826,536 189,623 -32,980 -51,824 28,317 959,672
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009  Acquisition value  Accumulated depreciation and amortization  Net book value	- - - - - - -	Development  - 126,957 126,957  126,957	131,326 14,657 -28,317 -1,367 28,317 144,616	rights 690,981 43,740 -4,663 -47,930 - 682,128 730,058 -47,930	4,229 4,269  -2,527  5,971 32,431 -26,460	progress	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009  Acquisition value  Accumulated depreciation and amortization  Net book value  1 January – 31 December 2010	- - - - - - - -	Development  - 126,957 126,957  126,957 126,957	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616	rights 690,981 43,740 -4,663 -47,930 - 682,128 730,058 -47,930 682,128	4,229 4,269 	progress	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b>
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009  Acquisition value  Accumulated depreciation and amortization  Net book value  1 January – 31 December 2010  Net book value – Opening balance	- - - - - - -	Development  - 126,957 126,957  126,957 - 126,957	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616	rights 690,981 43,740 -4,663 -47,930 - 682,128 730,058 -47,930	4,229 4,269 	progress	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b>
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009  Acquisition value  Accumulated depreciation and amortization  Net book value  1 January – 31 December 2010  Net book value – Opening balance  Additions	- - - - - - - - -	Development  - 126,957 126,957 - 126,957 - 126,957 - 126,957 - 23	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616	rights  690,981  43,740  -4,663  -47,930  -  682,128  730,058  -47,930  682,128	4,229 4,269 	progress	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b>
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009  Acquisition value  Accumulated depreciation and amortization  Net book value  1 January – 31 December 2010  Net book value – Opening balance  Additions  Reclassification of acquisition value	- - - - - - - - - -	Development  - 126,957 126,957  126,957 - 126,957 - 126,957 - 23 -	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616 1,549	rights 690,981 43,740 -4,663 -47,930 - 682,128 730,058 -47,930 682,128	4,229 4,269 	progress	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b> 959,672
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009  Acquisition value  Accumulated depreciation and amortization  Net book value  1 January – 31 December 2010  Net book value – Opening balance  Additions  Reclassification of acquisition value  Disposals	- - - - - - - - - - -	Development  - 126,957 126,957  126,957 - 126,957 - 126,957 - 23	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616 1,549 - -78,829	730,058 -47,930 -730,058 -47,930 -730,058 -47,930 682,128	4,229 4,269 2,527  5,971 32,431 -26,460 5,971 245 -684	progress	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b> 959,672 5,068 -
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009  Acquisition value  Accumulated depreciation and amortization  Net book value  1 January – 31 December 2010  Net book value – Opening balance  Additions  Reclassification of acquisition value  Disposals  Depreciation	- - - - - - - - - - -	Development  - 126,957 126,957  126,957 - 126,957 - 126,957 - 23 -	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616 1,549 - - -78,829 -1,366	rights  690,981  43,740  -4,663  -47,930  -  682,128  730,058  -47,930  682,128	4,229 4,269 	progress  3,297 684	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b> 959,672
1 January – 31 December 2009  Net book value – Opening balance  Additions  Reclassification of acquisition value  Depreciation  Reclassification of acc depreciations  Net book value – Closing balance  At December 31, 2009  Acquisition value  Accumulated depreciation and amortization  Net book value  1 January – 31 December 2010  Net book value – Opening balance  Additions  Reclassification of acquisition value  Disposals	- - - - - - - - - - -	Development  - 126,957 126,957  126,957 - 126,957 - 126,957 - 23	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616 1,549 - -78,829	730,058 -47,930 -730,058 -47,930 -730,058 -47,930 682,128	4,229 4,269 2,527  5,971 32,431 -26,460 5,971 245 -684	progress	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b> 959,672 5,068 -
1 January – 31 December 2009 Net book value – Opening balance Additions Reclassification of acquisition value Depreciation Reclassification of acc depreciations Net book value – Closing balance  At December 31, 2009 Acquisition value Accumulated depreciation and amortization Net book value  1 January – 31 December 2010 Net book value – Opening balance Additions Reclassification of acquisition value Disposals Depreciation Reclassification of acc depreciations Net book value – Closing balance	- - - - - - - - - - - -	Development  - 126,957 126,957  126,957 - 126,957 - 23	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616 1,549 - - -78,829 -1,366	rights 690,981 43,740 -4,663 -47,930 - 682,128  730,058 -47,930 682,128  682,128 48,670 -	32,431 -26,460 5,971  5,971  245 -6842,437	progress	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b> 959,672 5,068 - - -78,829 -52,473
1 January – 31 December 2009 Net book value – Opening balance Additions Reclassification of acquisition value Depreciation Reclassification of acc depreciations Net book value – Closing balance  At December 31, 2009 Acquisition value Accumulated depreciation and amortization Net book value  1 January – 31 December 2010 Net book value – Opening balance Additions Reclassification of acquisition value Disposals Depreciation Reclassification of acc depreciations Net book value – Closing balance  At December 31, 2010	- - - - - - - - - - - - - - - -	Development  - 126,957 126,957  126,957 - 126,957 - 126,957 - 126,957 - 126,957 - 126,957 - 126,957	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616 1,549 - - -78,829 -1,366 - - 65,970	rights  690,981  43,740  -4,663  -47,930  -  682,128  730,058  -47,930  682,128  682,128  -  -  -  -48,670  -  633,458	32,431 -26,460 5,971  5,971  245 -684 -2,437 -3,095	progress  3,297 684 3,981	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b> 959,672 5,068 - -78,829 -52,473 - 833,438
1 January – 31 December 2009 Net book value – Opening balance Additions Reclassification of acquisition value Depreciation Reclassification of acc depreciations Net book value – Closing balance  At December 31, 2009 Acquisition value Accumulated depreciation and amortization Net book value  1 January – 31 December 2010 Net book value – Opening balance Additions Reclassification of acquisition value Disposals Depreciation Reclassification of acc depreciations Net book value – Closing balance  At December 31, 2010 Acquisition value	- - - - - - - - - - - - - -	Development  - 126,957 126,957  126,957 - 126,957 - 23	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616 1,549 - - -78,829 -1,366 - - 65,970	730,058 682,128 682,128 682,128 682,128 683,128 683,128 683,128	32,431 -26,460 5,971  5,971  245 -684 -2,437 -3,095	progress	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b> 959,672 5,068 - - -78,829 -52,473 - 833,438
1 January – 31 December 2009 Net book value – Opening balance Additions Reclassification of acquisition value Depreciation Reclassification of acc depreciations Net book value – Closing balance  At December 31, 2009 Acquisition value Accumulated depreciation and amortization Net book value  1 January – 31 December 2010 Net book value – Opening balance Additions Reclassification of acquisition value Disposals Depreciation Reclassification of acc depreciations Net book value – Closing balance  At December 31, 2010	- - - - - - - - - - - - - - - -	Development  - 126,957 126,957  126,957 - 126,957 - 126,957 - 126,957 - 126,957 - 126,957 - 126,957	131,326 14,657 -28,317 -1,367 28,317 144,616 147,297 -2,681 144,616 1,549 - - -78,829 -1,366 - - 65,970	rights  690,981  43,740  -4,663  -47,930  -  682,128  730,058  -47,930  682,128  682,128  -  -  -  -48,670  -  633,458	32,431 -26,460 5,971  5,971  245 -684 -2,437 -3,095	progress  3,297 684 3,981	826,536 189,623 -32,980 -51,824 28,317 <b>959,672</b> 1,008,427 -48,755 <b>959,672</b> 959,672 5,068 - - -78,829 -52,473 - 833,438

#### > Continued from Note 21

Intangible assets consist primarily of product rights, goodwill, licenses, patents and research projects. In some cases agreements on royalties or profit sharing can be linked to the product rights. These can vary in size and are often dependent on how the revenue develops.

# Testing for impairment of intangible fixed assets

Assessment of the value of the Group's goodwill items are based on the groups, defined as the only cash-generating unit, value in use. Value in use is based on the cash flows generated during the unit's expected remaining lifetime.

#### Product rights/Research projects

Testing for impairment of product rights and research is carried out as needed and done at least once a year. Impairment tests have been carried out for each product or project separately. Impairment tests are based on a calculation of future value in use. The value in use is based on cash flows that are expected to be generated over the remaining life of the unit. In cases where the contract or patent rights to the product exceeds five years, the contract- or the patent term is used as the remaining lifetime.

The future cash flows used in calculating the various units' value in use are based on a detailed review of the units. The forecast future cash flows for all units have been calculated at present value with a 9 percent discount rate after tax. The discount rate is based on a market assessment of the average cost of capital taking into account the evaluated risk level in the units' cash flow.

### Other assumptions regarding the rate of return:

**Risk free interest rate:** 10-year government bond or comparable investment with the lowest possible risk.

Market risk premium: 4 percent

**Beta:** Swedish Orphan Biovitrum's development largely follows the general trend on the market and is therefore calculated as 1.

Interest expense: according to Swedish Orphan Biovitrum's borrowing costs Tax rate: According to Swedish tax rates

#### Important variables

Swedish Orphan Biovitrum is dependent on the success of its research and development projects. Swedish Orphan Biovitrum has conducted a review of the forecast future cash flows for each of the projects. The cash flow was then adjusted for the probability of the project being commercialized. This rate fluctuates depending on the phase of development of the projects.

#### Sensitivity analysis

Other impairment tests have been performed using such a margin that the management considers it reasonable to possible changes in individual variables would not cause utility value to be below book value. Management is therefore of the opinion that even if there is a certain variation in the most important variables, there will be no write-down requirement.

Note 22 Tangible fixed assets

Group	Land and buildings	Plant and machinery	Equipment, tools, fixtures and fittings	Cars	Plant in progress	Total
1 January – 31 December 2009	3.		3.		1 3	
Net book value – Opening balance		73,295	123,432	_	18,790	215,517
Exchange differences		1,247	365	_	-1,612	
Additions		2,357	4,930	_	88,794	96,081
Disposals		-3,885			-	-3,885
Depreciation		-29,339	-26,411		_	-55,750
Net book value – Closing balance	_	43,675	102,316	_	105,972	251,963
At December 31, 2009		.0,0,0	.02,0.0		.00,772	201,700
Acquisition value		613,086	246,895	_	105,972	965,953
Accumulated depreciation and amortization		-569,411	-144,579			-713,990
Net book value	-	43,675	102,316	_	105,972	251,963
1 January – 31 December 2010						
Net book value – Opening balance		43,675	102,316	_	105,972	251,963
Exchange differences		16,659	81,693	_	-98,352	
Acquistion of subsidiary	6,399	-	5,210	2,269	, 0,002	13,878
Additions	84	17,926	16,434	1,311	7,665	43,420
Disposals		-934	-410	-389	- 7,000	-1,733
Depreciation	-336	-19,663	-27,832	-677	_	-48,508
Write-downs	_	-959	-6,615		_	-7,574
Net book value – Closing balance	6,147	56,704	170,796	2,514	15,285	251,446
At December 31, 2010	0,147	30,704	170,770	2,514	13,203	231,440
Acquisition value	6,483	624,367	293,237	2,848	15,285	942,220
Accumulated depreciation and amortization	-336	-567,663	-122,441	-334		-690,774
Net book value	6,147	56,704	170,796	2,514	15,285	251,446
Parent Company	Land and buildings	Plant and machinery	Equipment, tools, fixtures and fittings	Cars	Plant in progress	Total
1 January – 31 December 2009						
Net book value – Opening balance	=	68,973	123,910	-	18,790	211,673
Exchange differences	=	1,247	365	-	-1,612	-
Additions	-	2,357	4,930	-	88,794	96,081
Disposals	_	-41	_	_	_	-41
Depreciation	_	-29,339	-26,411	-	_	-55,750
Net book value – Closing balance	_	43,197	102,794	_	105,972	251,963
At December 31, 2009						
Acquisition value	-	608,055	242,819	-	105,972	956,846
Accumulated depreciation and amortization	-	-564,858	-140,025	-	_	-704,883
Net book value	_	43,197	102,794	_	105,972	251,963
1 January – 31 December 2010						
Net book value – Opening balance	_	43,197	102,794	_	105,972	251,963
Exchange differences	_	16,659	81,693	-	-98,352	_
Additions	-	17,926	13,837	-	7,665	39,428
Disposals	_	-933	-74	_	_	-1,007
Depreciation	-	-19,663	-26,043	-	_	-45,706
Write-downs	_	-959	-6,615		_	-7,574
Net book value – Closing balance						007.400
The Book Faller Globing Balance	_	56,226	165,592	-	15,285	237,103
At December 31, 2010	_	56,226	165,592	_	15,285	237,103
	-	<b>56,226</b> 619,336	<b>165,592</b> 283,103		15,285 15,285	
At December 31, 2010						917,724
At December 31, 2010 Acquisition value	_	619,336	283,103	-		237,103 917,724 -680,621 237,103

# Note 23 Participation in Group companies

Parent Company	2010	2009
Accumulated acquisition values		
Accumulated acquisition values, opening		
balance	974,866	914,133
Prepaid expenses acquisition in progress	-	60,808
Acquisitions	3,767,027	_
Participation in limited partnerships	-	-75
	4,741,893	974,866
Accumulated write-down		
Opening balance	-325,887	-325,887
This years write-down	-2,058	_
	-327,945	-325,887
Net book value end of period	4,413,948	648,979

# Specification of Parent Company and Group's holdings in Group companies

Subsidiary/ Corp. identity No/ Domicile	No of shares	Share in%1	Book value
Swedish Orphan Biovitrum International Holding AB, 556613-7674	947,128	100,0	3,804,318
Swedish Orphan Biovitrum International AB, 556329-5624	100	100,0	_
Biovitrum Treasury AB, 556616-7317, Stockholm, Sweden	1,000	100,0	100
Paradiset B.V., 34209249, Amsterdam, Netherlands	180	100,0	164
Fastighetsaktiebolaget Paradiset, 556149-2611, Stockholm, Sweden	900	90,0	90
Hornet Fastighetsbolag KB, 916613-5534, Stockholm, Sweden	1	1,0	_
Fastighetsbolaget Paradiset KB, 916400-9350, Stockholm, Sweden	1	1,0	_
Hornet Fastighetsbolag KB, 916613- 5534, Stockholm, Sweden	1	99,0	381,372
Fastighetsbolaget Paradiset KB, 916400-9350, Stockholm, Sweden	1	99,0	36,140
Nya Paradiset 19 AB, 556603-1943, Stockholm, Sweden	1,000	100,0	100
Fastighetsaktiebolaget Paradiset, 556149-2611, Stockholm, Sweden	100	10,0	_
Arexis AB, 556573-5130, Gothen- burg, Sweden	1,000	100,0	191,664
Arexis Inflam AB, 556584-4676, Gothenburg, Sweden	1,000	100,0	_
- · ·		· .	4,413,948

<sup>1)</sup> Refers to the percentage of capital holding, which is equal to the percentage of voting rights.

# Note 24 Financial Fixed Assets

Group	2010	2009
Accumulated acquisition values		
Opening balance	102,707	34,426
Acquisition <sup>1</sup>	-60,812	60,830
Acquistion of subsidiary	2,306	-
Write-down of loan and shares	-19,303	-
Loan	_	1,342
Received payments of loan	-1,372	-
Deposit	_	541
Reclaimed deposition	-	-34
Change in pension committment	-13,373	5,598
Other	-120	4
Accumulated acquisition values	10,033	102,707
Book value at end of period	10,033	102,707

Accumulated acquisition values	684	21,359
Return of deposit		-34
Deposit	_	541
Write-down of loan and shares	-19,303	_
Recived payments of loan	-1,372	_
Loan	_	1,342
Acquisition	_	21
Opening balance	21,359	19,489
Accumulated acquisition values		
Parent Company	2010	2009

<sup>1)</sup> Prepaid expenses acquisition in progress

# Note 25 Deferred tax receivables and liabilities

# Accounted deferred tax receivables and liabilities

	Deferred tax	Deferred tax	
Group 2010	receivable	liability	Net
Inventory	6,326	_	6,326
Acquired R&D	-	-49,171	-49,171
Acquired product rights	_	-654,627	
Deferred pension expense	-	-1,083	-1,083
Tax allocation reserve	-	-57,714	-57,714
Other	-	-13	-13
Loss carry-forward	8,873	_	8,873
	15,199	-762,608	-747,409
Offsetting	-3,399	3,399	_
Net deferred tax			
receivable/liability	11,800	-759,209	-747,409

		- 1 L	
Group 2009	Deferred tax receivable	Deferred tax liability	Net
Acquired R&D	_	-45,273	45,273
Deferred pension expense	-	-5,598	5,598
Loss carry-forward	14,471	-	14,471
	14,471	-50,871	-36,400
Offsetting	-5,598	5,598	_
Net deferred tax			
receivable/liability	8,873	-45,273	-36,400

For the Parent Company there is no deferred tax receivable or tax liability.

#### Non accounted deferred tax receivables

Group	2010-12-31	2009-12-31
Deductable temporary differences	_	-
Deficit for tax purpose	264,417	240,408
	264,417	240,408
Parent Company	2010-12-31	2009-12-31
Deductable temporary differences	-	-
Deficit for tax purpose	219,993	196,004
	219,993	196,004

The loss carry-forwards for tax purposes pertain to the parent company and the Swedish subsidiaries included in the Group prior to the acquisition of Swedish Orphan. According to tax legislation, this deficit can be carried forward indefinitely. Deferred tax receivables will be reported for the above items when it is deemed likely that the Group will be able to utilize the amounts to offset future taxable profits. The tax rate used is 26.3 percent as per 2010 (26.3).

Following a tax audit, the amounts from last year have been changed. Swedish Orphan Biovitrum AB may be charged an additional amount of 232.2 million as revenue, in connection with the sale of the property Paradiset 14, as a result of a decision announced by the administrative court on March 3, 2011. This would result in reduced deferred tax deficit in both Parent Company and Group. See page 32 for more information.

# Change in deferred tax in temporary differences and loss carry-forward

9	'	,		,
Group 2010	Amount January, 1	Reported in income statement	Acquired operations	Amount December, 31
Inventory	_	986	5,340	6,326
Acquired R&D	-45,273	364	-4,262	-49,171
Acquired product rights	_	40,443	-695,070	-654,627
Deferred pension expense	-5,598	3,712	803	-1,083
Tax allocation reserves/exess depreciation	_	-14,312	-43,402	-57,714
Other	_	905	-918	-13
Utilization of loss carry-forward	14,471	-5,598	_	8,873
	-36,400	26,500	-737,509	-747,409

Group 2009	Amount Janu- ary, 1	Reported in income statement	Acquired operations	Amount December, 31
Acquired R&D	-45,273	-	-	-45,273
Deferred pension expense	-3,928	-1,670	_	-5,598
Utilization of loss carry-forward	12,801	1,670	_	14,471
	-36,400	_	_	-36,400

# Note 26 Inventories

Group	2010	2009
Raw materials and consumables	17,025	9,149
Work-in-progress	685,785	396,957
Finished products and goods for resale	367,624	172,292
	1,070,434	578,398

The expenditure for the inventories that was carried as an expense is included in cost of goods sold amounts to SEK 387,509 thousand (134,387). Provision for obsolescence amounts to SEK 13,121 thousand (6,922).

Parent Company	2010	2009
Raw materials and consumables	10,383	9,149
Work-in-progress	665,764	396,957
Finished products and goods for resale	251,320	172,292
	927,467	578,398

The expenditure for the inventories that was carried as an expense is included in cost of goods sold amounts to SEK 179,720 thousand (134,387). Provision for obsolescence amounts to SEK 11,359 thousand (6,922).

Note 27 Accounts receivable and Other receivables

Group	2010	2009
Accounts receivable	327,433	106,539
Deduction: Provision for decrease in receivable	-4,815	-1,336
Accounts receivable – net	322,618	105,203
Tax receivables	278	26,572
Other receivables	63,286	6,537
Total other receivables	63,564	33,109
Total accounts receivable and		
other receivables	386,182	138,312

Total accounts receivable and other receivables	172,436	128,397
Total other receivables	36,271	23,194
Other receivables	19,431	6,336
Tax receivables	16,840	16,858
Accounts receivable – net	130,103	103,203
Accounts receivable – net	136,165	105,203
Deduction: Provision for decrease in receivable	-1,629	-1,336
Accounts receivable	137,794	106,539
Parent Company	2010	2009

No established credit losses are charged against profit for the year.

As of December 31, 2010, accounts receivable amounting to SEK 149,004 thousand (25,639) were past due and no write-down was deemed necessary. Of the past due accounts receivable per December 31, 2010, SEK 32,477 thousand were settled in January 2011. Provisions for doubtful receivables amounted to SEK 4,815 thousand (1,336) as of December 31, 2010.

# Accounts receivable past due

Group	2010	2009
Past due 1-30 days	81,753	10,974
Past due 31-90 days	16,332	6,631
Past due 91-180 days	5,261	5,472
Past due > 181 days	45,658	2,562
	149,004	25,639
Parent Company	2010	2009
Past due 1-30 days	46,906	10,974

		· · · · · · · · · · · · · · · · · · ·
	64,354	25,639
Past due > 181 days	7,733	2,562
Past due 91-180 days	1,678	5,472
Past due 31-90 days	8,037	6,631
Past due 1-30 days	46,906	10,974

# Amounts, per currency, for accounts receivables and other receivables

Group	2010	2009
SEK	144,004	43,738
NOK	10,219	1,936
DKK	7,443	1,129
USD	46,654	32,595
EUR	156,496	52,951
GBP	14,121	2,927
CHF	149	199
AUD	2,538	1,128
Other currencies	4,558	1,709
	386,182	138,312

Parent Company	2010	2009
SEK	96,211	33,823
NOK	2,016	1,936
DKK	1,468	1,129
USD	34,381	32,595
EUR	32,135	52,951
GBP	534	2,927
CHF	109	199
AUD	2,538	1,128
Other currencies	3,044	1,709
	172,436	128,397

# Note 28 Prepaid expenses and accrued revenues

Group	2010	2009
Accrued royalty revenues	3,456	36,784
Accrued co-promotion revenues	20,537	33,769
Accrued revenues product sales	_	1,136
Prepaid leasing fees	1,343	1,651
Prepaid rents	3,675	14,113
Prepaid insurance expenses	11,966	11,714
Prepaid service and maintainance expenses	402	733
Prepaid IT Software & Licenses	1,546	3,247
Prepaid issuing costs	_	84,400
Advance, raw material production of Kineret	23,203	31,999
Receivable on BiogenIdec, expenses during		
2009 related to project FIX and FVIII	_	26,084
Other items	10,764	10,937
	76,892	256,567
Parent Company		
rarent Company	2010	2009
Accrued royalty revenues	2010 3,456	2009 36,784
, ,		
Accrued royalty revenues	3,456	36,784
Accrued royalty revenues Accrued co-promotion revenues	3,456	36,784 33,769
Accrued royalty revenues Accrued co-promotion revenues Accrued revenues product sales	3,456 20,537 –	36,784 33,769 1,136
Accrued royalty revenues Accrued co-promotion revenues Accrued revenues product sales Prepaid leasing fees	3,456 20,537 – 1,059	36,784 33,769 1,136 1,651
Accrued royalty revenues Accrued co-promotion revenues Accrued revenues product sales Prepaid leasing fees Prepaid rents	3,456 20,537 – 1,059 2,195	36,784 33,769 1,136 1,651 14,113
Accrued royalty revenues Accrued co-promotion revenues Accrued revenues product sales Prepaid leasing fees Prepaid rents Prepaid insurance expenses	3,456 20,537 - 1,059 2,195 10,514	36,784 33,769 1,136 1,651 14,113 11,714
Accrued royalty revenues Accrued co-promotion revenues Accrued revenues product sales Prepaid leasing fees Prepaid rents Prepaid insurance expenses Prepaid service and maintainance expenses	3,456 20,537 - 1,059 2,195 10,514 342	36,784 33,769 1,136 1,651 14,113 11,714 733
Accrued royalty revenues Accrued co-promotion revenues Accrued revenues product sales Prepaid leasing fees Prepaid rents Prepaid insurance expenses Prepaid service and maintainance expenses Prepaid IT Software & Licenses	3,456 20,537 - 1,059 2,195 10,514 342	36,784 33,769 1,136 1,651 14,113 11,714 733 3,247
Accrued royalty revenues Accrued co-promotion revenues Accrued revenues product sales Prepaid leasing fees Prepaid rents Prepaid insurance expenses Prepaid service and maintainance expenses Prepaid IT Software & Licenses Prepaid issuing costs	3,456 20,537 - 1,059 2,195 10,514 342 1,457	36,784 33,769 1,136 1,651 14,113 11,714 733 3,247 84,400
Accrued royalty revenues Accrued co-promotion revenues Accrued revenues product sales Prepaid leasing fees Prepaid insurance expenses Prepaid service and maintainance expenses Prepaid IT Software & Licenses Prepaid issuing costs Advance, raw material production of Kineret Receivable on Biogenldec, expenses during	3,456 20,537 - 1,059 2,195 10,514 342 1,457	36,784 33,769 1,136 1,651 14,113 11,714 733 3,247 84,400 31,999

# Note 29 Short-term investments and Liquid funds

#### Specification of security

2010		200	9
Fair value	Book value	Fair value	Book value
-	-	48,359	48,359
-	-	48,359	48,359
_	-	123,687	123,687
_	_	5,000	5,000
38,469	38,469	129,593	129,593
38,469	38,469	258,280	258,280
	Fair value	Fair value Book value	Fair value Book value Fair value  - 48,359 - 48,359  - 123,687  - 5,000 38,469 38,469 129,593

	201	0	200	9
Parent Company	Fair value	Book value	Fair value	Book value
Short-term investments				
Coupon securities	_	-	48,359	48,359
	_	_	48,359	48,359
Liquid funds				
Interest rate funds	-	-	123,687	123,687
Short term investments equivalent to liquid funds	_	_	5,000	5,000
Cash and Bank	9,083	9,083	129,290	129,290
	9,083	9,083	257,977	257,977

# Note 30 Financial assets per category (Group)

	Loans and receivables		Total
December 31, 2010			
Assets as per balance sheet			
Accounts receivable	322,618	_	322,618
Short-term investments	_	_	_
Liquid funds	38,469	-	38,469
Total	361,087	_	361,087
December 31, 2009			
Assets as per balance sheet			
Accounts receivable	105,203	-	105,203
Short-term investments	_	48,359	48,359
Liquid funds	258,280	_	258,280
Total	363,483	48,359	411,842

# Note 31 Employee benefits (pension commitments)

The pension commitments are calculated annually on the closing day, based on actuarial calculations.

The figures below do not include a special payroll tax of 24.26 percent of reported assets in accordance with URA 43 (Swedish Financial Accounting Standards Council's Emerging Issues Task Force statement No. 43).

Pension costs are reported under the items: selling expenses, administration expenses and research and development expenses.

#### Pension benefits

Commitments for retirement pensions and family pensions for white-collar employees in Swedish Orphan Biovitrum AB Sweden are insured through Alecta. According to statement URA 42 issued by the Swedish Financial Accounting Standards Council's Emerging Issues Task Force, these are defined benefit plans covering multiple employers.

For the 2009 financial year, the group did not have access to the information necessary to be able to report this plan as a defined benefit plan. The ITP pension plan insured through Alecta is therefore reported as a defined contribution plan.

The cost for the year of pension insurance through Alecta amounted to SEK 13,298 thousands (20,459). Alecta's surplus is distributable among the policy holders and/or the insured parties. At the end of 2008 Alecta's surplus in the form of the collective consolidation level amounted to SEK 143.0 percent (141.0). The collective consolidation level consists of the market value of Alecta's assets as a percentage of insurance commitments calculated according to Alecta's actuarial calculation assumptions, which do not correspond to IAS 19.

# Change in benefit obligation during the year:

	2010	2009
Benefit obligation at start of year	107,725	106,541
Acquired operations	7,663	_
Service cost	14,818	15,112
Interest cost	4,758	3,446
Actuarial gains (-) /losses (+)	14,639	8,857
Benefits paid	-861	-120
Collective agreement pension	_	12,100
Remunerations	_	-38,211
Settlement	-12,611	_
This year's translation difference	-573	
Benefit obligation at end of year	135,558	107,725

# Change in fair value of plan assets during the year:

g pg y			
	2010	2009	
Fair value of plan assets at start of year	94,781	97,432	
Acquired operations	3,433	_	
Return on assets	3,594	4,189	
Actuarial gain (+) /loss (-)	668	-2,173	
Contributions	14,638	35,434	
Remunerations	_	-38,211	
Settlement	-10,830	_	
Remunerations one-time items	-1,687	-1,890	
This year's translation difference	-257	_	
Fair value of plan assets at end of year	104,340	94,781	

# The amounts recognized in the income statement are as follows:

	2010	2009
Service cost	14,818	15,112
Interest cost	4,758	3,446
Expected return on plan assets	-3,594	-4,189
Amortization on actuarial gains/losses	1,438	2,691
Administration cost	78	_
Collective agreement pension	7,335	12 100
Total, included in employee benefits	24,834	29,160

# Actuarial assumptions on the balance sheet date

Swedish plan:	2010	2009
Discount rate (government borrowing rate)	3,40%	3,90%
Future salary increases	3,00%	3,00%
Future pension increases	2,00%	2,00%
Expected increase of basic amount	3,00%	3,00%
Expected return on plan assets	3,30%	3,30%

Norweigan plan:	2010	
Discount rate	3,20%	
Future salary increases	4,00%	
Future pension increases	3,75%	
Expected increase of basic amount	3,75%	
Expected return on plan assets	4,60%	

# The amounts recognized in the balance sheet are as follows:

	2010	2009
Fair value of plan assets	104,340	94,781
Fair value pension commitment	-135,558	-107,725
Net asset value	-31,218	-12,944
Unrecognized actuarial gains (-) / losses (+)	34,475	29,470
Net asset value	3,257	16,526

# The amounts are recognized in the balance sheet as follows:

	3.257	16.526
Provisions	-2,508	_
Financial fixed assets	5,765	16,526
	2010	2009

# Specification of changes in net assets reported in the balance sheet:

	2010	2009
Net asset/liability at beginning of year according adopted balance sheet	16,526	12,022
Acquired operations	-2,513	
Net pension expense	-24,834	-29,160
Benefits paid	14,716	35,434
Withdrawal from plan assets (-)	-1,687	-1,890
Remunerations	861	_
Benefits paid	188	120
Net asset value	3,257	16,526

The actual return on plan assets was SEK 4,263 thousands (2,016)

#### Allocation of asset type

	2010	%	2009	%
Shares	44,578	43	41,704	44
Bonds	47,144	45	42,651	45
Other	12,618	12	10,426	11
Insurance company provision	-	0	-	0
Total	104,340	100	94,781	100

# Other information

The anticipated return on plan assets is established by taking into account the anticipated return on the assets that are covered by the investment policy in question. The anticipated return on investments with fixed interest is based on the return received if these securities are held to maturity. The anticipated return on equities and properties is based on the long-term return in the respective market.

Contributions, made to plans for remuneration after terminated employment, are expected to amount to SEK 16,611thousands for the financial year 2011.

As per December 31	2010	2009	2008	2007	2006
Present value of defined benefit obligation	-135,558	-107,725	-106 541	-86 154	-87 154
Fair value of plan assets	104,340	94,781	97 432	86 199	69 534
Surplus/(Deficit)	-31,218	-12,944	-9 109	45	-17 620
Experience adjustments on plan liabilities, gain (-) / loss (+)	1,704	11,170	1 030	-808	12 283
Change in assumptions of plan liabilities, gain (-) / loss (+)	12,935	-2,312	10 080	-8 118	_
Experience adjustments on plan assets, gain (+) / loss (-)	668	-2,173	-2 116	2 697	3 139

Note 32 Other liabilities, long-term

Group	2010	2009
Liabilities to credit institutions (in USD)	1,022,452	200,000
Liabilities to credit institutions (in SEK)	-	90,348
	1,022,452	290,348
Parent company	2010	2009
Liabilities to credit institutions (in USD)	1,022,452	200,000
Liabilities to credit institutions (in SEK)	_	90,348
	1,022,452	290,348

The company has a loan facility amounting to a total of SEK 1,350 M. The facility includes a 7-year loan of SEK 1,100 M with straight-line amortization and a variable credit for SEK 250 M with the same maturity. In 2010 a total of SEK 164 M was amortized and at the year-end the loan balance was SEK 1,186 M, of which SEK 164 M is reported under current liabilities.

In connection with the company's acquisition of the drugs Kepivance® and Stemgen® and the exclusive licensing agreement for Kineret®, at the end of 2008 the company took two long-term loans for a total of SEK 400 M to finance the transactions. One loan of SEK 300 M is denominated in Swedish kronor and one loan equivalent to SEK 100 M is denominated in USD. In 2010 the loan denominated in USD was refinanced into a loan denominated in SEK. The loan was divided into a seven-year loan for SEK 350 M with straight-line amortization and maturity on October 1, 2015, and a variable line of credit for SEK 50 M. In 2010 SEK 50 M was amortized on the part of the loan taken in connection with the product acquisition.

In connection with the acquisition of Swedish Orphan in early 2010 the Company took out an additional loan denominated in SEK for a total of SEK 950 M, including a seven-year loan of SEK 800 M with straight-line amortization and maturity on October 1, 2016 and a variable line of credit for SEK 150 M. In 2010 SEK 164 M was amortized on the part of the loan taken in connection with the corporate acquisition.

Security for the bank loan consists of future royalty revenues from ReFacto<sup>®</sup>. Interest on the loan is charged at STIBOR or equivalent reference interest rate plus a margin.

When these loans were taken, the company made a commitment to the bank regarding earnings and debt benchmarks and from 2011 onwards, cash flows.

**Note 33 Provisions** 

	Group		Parent Company	
	2010	2009	2010	2009
Opening balance	372,729	477,231	372,729	477,231
Provision through aquired business	30,800	-	-	_
Costs incurred	-449,754	-92,242	-430,019	-92,242
Currency exchange difference	_	-12,260	_	-12,260
Provision this year	243,042	_	236,697	_
Closing balance	196,817	372,729	179,407	372,729

Of this year's provisions in the Group, SEK 71,942 thousand relate to integration costs within the restructuring program and SEK 171,100 thousand relate to the discounted additional consideration for Multiferon®, for more information please see note 5 and note 35.

	Group		Parent Company	
	2010	2009	2010	2009
Long-term	188,380	365,645	171,100	365,645
Short-term	8,437	7,084	8,307	7,084
Total provisions	196,817	372,729	179,407	372,729

In 2010 a restructuring program was carried out in connection with the acquisition of Swedish Orphan that was completed on January 14. The organization was subjected to a thorough review during the year and a number of overlapping positions were identified and staff have either been redeployed or made redundant. In 2010 the restructuring expenses were SEK 71.9 M, including SEK 27.2 M for personnel costs, SEK 8.2 M for amortization of tangible and intangible assets, SEK 16.2 M for premises and the remaining SEK 20.3 M mainly relates to IT-related costs.

Note 34 Accrued expenses and deferred revenues

Group	2010	2009
Provision for vacation pay and bonus incl social security contributions	75,422	60,735
Accrued social security contributions	23,868	26,520
Accrued expenses	96,229	93,192
Prepaid revenues	_	423
Accrued expenses acquisition in progress	_	45,000
Accrued expenses new share issue	_	79,357
Accrued expenses sale of subsidiary	_	4,994
Other items	1,113	_
	196,632	310,221

Parent Company	2010	2009
Provision for vacation pay and bonus incl social security contributions	59,532	60,735
Accrued social security contributions	21,424	26,520
Accrued expenses	76,156	97,045
Prepaid revenues	_	423
Accrued expenses acquisition in progress	_	45,000
Accrued expenses new share issue	_	79,357
Accrued expenses sale of subsidiary	-	4,994
Other items	1,100	-
	158,212	314,074

Note 35 Pledged assets and contingent liabilities

Parent Company	2010	2009
Contingent liabilities	-	-
Bank guarantee	54,351	78,444

In connection with certain acquisition and in-licensing agreements, Sobi has undertaken to make additional milestone payments when certain targets are achieved. The most important agreements are presented below.

The acquisition of Arexis may lead to payments in respect of the development of Kiobrina, amounting to a total of about SEK 70 M be paid as various defined steps in development are achieved. For more information please see below about requirements from the sellers off Arexis.

The acquisitions of the products Kineret®, Kepivance® and Stemgen® included several commitments for future payments. The remaining commitment concerns a sales milestone, which is expected to be achieved in 2012, and amounting to a maximum of USD 55 M.

Biogen Idec. In 2010 Sobi entered into a supplementary agreement for Biogen Idec to take over responsibility, including risks and financing, for development of the Factor IX:Fc and Factor VIII:Fc products. Sobi has the option to buy into the project again for a price of USD 10 M for each product. Royalties and payments have been adjusted in this agreement for a six-year period after the time that Swedish Orphan Biovitrum begins commercial sale of the products to reimburse Biogen Idec for its development costs. If Biogen Idec does not receive full reimbursement for its share of the development costs during this period Sobi will pay the difference to Biogen Idec at the end of the six-year period.

A few small milestone payments are also linked to distribution agreements.

As a result of the acquisition of Swedish Orphan International Holding, which was implemented on January 14, 2010, Sobi may have to pay an additional purchase consideration of a maximum of SEK 425 M at a defined sales target linked to Multiferon®. A provision was made for the discounted value of the additional consideration when the acquisition analysis was prepared.

In Swedish Orphan Biovitrum's loan agreement with Handelsbanken assets are pledged as security for loans. The group has pledged the shares in all the subsidiaries, after the acquisition of Swedish Orphan International Holding AB in January 2010, defined as material subsidiaries, as collateral. The group has also provided all future royalty income related to the product ReFacto as collateral for loans. A floating charge amounting to 100 million has also been pledged as collateral for loans.

# Not 36 Tax and legal disputes

Swedish Orphan Biovitrum has an ongoing dispute with the Tax Agency regarding the sale of the property Paradise 14, the company and external lawyers' assessment is that the company has not acted in violation of applicable laws. On March 3, 2011, The administrative court announced that they uphold the Tax Agency's request, explaining that Swedish Orphan Biovitrum AB under the tax law will be charged an amount of 232.2 million as revenue in the 2005 tax year. The company intends to appeal.

The sellers of the pharmaceutical company Arexis, which was acquired in August 2005, have made a claim against Swedish Orphan Biovitrum of about SEK 325 million, alleging that Swedish Orphan Biovitrum has not performed its obligations under the share purchase agreement entered into at the time of the acquisition. Swedish Orphan Biovitrum have contested all claims presented by the sellers. The sellers have recently requested arbitration regarding parts of the above mentioned claim as well as, regarding the other parts, an expert determination provided for in the agreement.

# Not 37 Transactions with related parties

#### Loans to related parties

	2010	2009
Loan to executive management in Parent Company:		
At beginning of the year:	153	153
Loan paid during the year	-	_
	153	153

The following terms and conditions apply to the loans issued to senior executives:

- The loans are interest free. A benefit is assigned to the borrower annually corresponding to the borrowed amount multiplied by the government loan interest plus one percentage point per year, which is in line with the rules in the Income Tax Act for valuation of loans in Swedish currency with an interest rate that is fixed in relation to the market interest rate or interest free loans. The benefit is measured on the date the loan is taken and updated annually.
- The borrowers agree to repay the entire borrowed amount to the lender, or for endorsement, the first of the following occasions:
- the day the borrower resigns his/her position within the Swedish Orphan Biovitrum Group
- May 31, 2011, when the warrants expire
- the day the borrower receives the issued shares as a result of the borrower converting all warrants into shares

#### Othe

A company related to the chairman of the Board, Orfacare, provides consultation as regards making available, marketing and distribution of drugs for the Swedish Orphan Biovitrum group in e.g. Switzerland and Austria. Consulting expenses were SEK 3.1 M in 2010. During 2011, Swedish Orphan Biovitrum entered into an agreement with Investor AB, to obtain consulting services to a limited extent. These services will not be executed by Investor's representatives on the board.

### Not 38 Significant events after balance sheet date

- On January 11, 2011, Sobi and BL&H Co., Ltd. signed a distribution agreement for the products Orfadin and Kepivance in South Korea, yet another step in the geographic expansion of Sobi's products. Under the agreement BL&H will be responsible for registration and distribution of the products in South Korea. Since the South Korean Food and Drug Administration registration process is adapted to products already approved by the FDA or EMA, registration is expected approximately one year from application. Sales on a named patient basis may be initiated already during 2011.
- On January 27, 2011, Sobi announced that a distribution agreement with Fresenius Biotech had been signed to distribute Removab® in Sweden, Denmark, Norway, Finland, Iceland, Poland, Czech Republic, Slovak Republic, Slovenia, Romania, Bulgaria, Hungary, Estonia, Latvia and Lithuania over seven years. Removab® was granted marketing authorization by the European Commission in April 2009 for the treatment of malignant ascites associated with cancer and has been launched in Germany, Austria and France so far. Removab® is an innovative product that holds great value to patients with high medical needs. Moreover, Removab® is a perfect fit with our cancer product portfolio such as Yondelis® which is distributed in similar territories.
- On February 22, 2011, Sobi announced changes to its management team and a strengthening of its Business Development function. The changes illustrates Sobi's commitment to a growth strategy built both on products coming from its own late stage pipeline as well as aggressively pursuing partnerships with other pharmaceutical and biotech companies, in-licensing activities and acquisitions. In addition, the broadening of the Executive Management Team is a reflexion of Sobi's international focus. Many of the team members have vast international experience.
- On March 3, 2011, the administrative court announced that they uphold
  the Tax Agency's request, explaining that Swedish Orphan Biovitrum AB
  under the tax law will be charged an amount of 232.2 million as revenue
  in the 2005 tax year. The Company intends to appeal.

The Board of Directors and the CEO of Swedish Orphan Biovitrum certify that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and provide a fair and true description of the Group's financial position and results.

The financial statements of the Parent Company have been prepared in accordance with generally accepted accounting principles in Sweden and give a true and fair view of the Parent Company's financial position and results of operations.

The Board of Directors and the CEO of Swedish Orphan Biovitrum provide their assurance that the directors report provides a fair and true overview of the Parent Company's and the Group's operations, financial position and results, and describes material risks and uncertainties faced by the parent Company and the companies in the Group.

The income statements and balance sheets will be submitted to the AGM on April 28, 2011, for approval.

# Stockholm, March 28, 2011

Bo Jesper Hansen Chairman	Hans Glemstedt	Adine Grate Axén
Michael Steinmetz	Wenche Rolfsen	Lennart Johansson
Hans Wigzell	Catarina Larsson Employee representative	Bo-Gunnar Rosenbrand Employee representative
	Kennet Rooth CEO	

Our audit report was submitted on March 28, 2011

 ${\bf Pricewater house Coopers\ AB}$ 

Mikael Winkvist Authorized Public Accountant

# Audit report

To the annual meeting of the shareholders of Swedish Orphan Biovitrum AB (publ) Corporate identity number 556038-9321

We have audited the annual accounts, the consolidated accounts, the accounting records and the administration of the board of directors and the managing director of Swedish Orphan Biovitrum AB (publ) for the year 2010. The annual accounts and the consolidated accounts of the company are included in the printed version of this document on pages 22-86. The board of directors and the managing director are responsible for these accounts and the administration of the company as well as for the application of the Annual Accounts Act when preparing the annual accounts and the application of international financial reporting standards IFRSs as adopted by the EU and the Annual Accounts Act when preparing the consolidated accounts. Our responsibility is to express an opinion on the annual accounts, the consolidated accounts and the administration based on our audit.

We conducted our audit in accordance with generally accepted auditing standards in Sweden. Those standards require that we plan and perform the audit to obtain reasonable assurance that the annual accounts and the consolidated accounts are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the accounts. An audit also includes assessing the accounting principles used and their application by the board of directors and the managing director and significant estimates made by the board of directors and the managing director when preparing the annual accounts and consolidated accounts as well as evaluating the overall presentation of information in the

annual accounts and the consolidated accounts. As a basis for our opinion concerning discharge from liability, we examined significant decisions, actions taken and circumstances of the company in order to be able to determine the liability, if any, to the company of any board member or the managing director. We also examined whether any board member or the managing director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association. We believe that our audit provides a reasonable basis for our opinion set out below.

The annual accounts have been prepared in accordance with the Annual Accounts Act and give a true and fair view of the company's financial position and results of operations in accordance with generally accepted accounting principles in Sweden. The consolidated accounts have been prepared in accordance with international financial reporting standards IFRSs as adopted by the EU and the Annual Accounts Act and give a true and fair view of the group's financial position and results of operations. A corporate governance statement has been prepared. The statutory administration report and the corporate governance statement are consistent with the other parts of the annual accounts and the consolidated accounts.

We recommend to the annual meeting of shareholders that the income statement of the parent company, the statement of comprehensive income of the group and balance sheet of the parent company and the group be adopted, that the profit of the parent company be dealt with in accordance with the proposal in the statutory administration report and that the members of the board of directors and the managing director be discharged from liability for the financial year.

Stockholm in March 28, 2011

PricewaterhouseCoopers AB

Mikael Winkvist Authorized Public Accountant

# **Board of Directors**



# Bo Jesper Hansen

Chairman

Born 1958. MD with a Ph.D. from Copenhagen University. Board member as of January 2010. Chairman of Sobi's Compensation & Benefit Committee. Board member of Gambro AB, MipSalus, TopoTarget A/S and Zymenex A/S. Has previously held various executive positions in Swedish Orphan International AB since 1993, CEO 1998-2010. Founder of Scandinavian Medical Research, through which he worked as medical advisor for Synthelabo, Yamanouchi and Pfizer.

Shares: 7,115,077 Warrants: 0



# Adine Grate Axén

Born 1961. MBA from Stockholm School of Economics. Harvard AMP. Board member since 2010. Member of Sobi's Financial & Audit Committee. Chairman of the Listing Committee of Nasdaq OMX Stockholm. Board member of EDB Business Partners (member and chairman of the Audit committee) and Swedavia, advisor and working board member of 3 Scandinavia. Member of the Commission for the sale of shares in companies with state ownership until this was closed in 2010. 1994 – 2007 various senior management positions within Investor AB and member of the management group 1999 – 2007.

Shares: 0 Warrants: 0



# Hans Glemstedt

Born 1962. M.Sc. Business Administration and Economics. Board member since 2009. Member of Sobi's Financial & Audit Committee as well as the Compensation & Benefits Committee. Member of Investor AB's investment organization since 2006. Board member of Aleris AB. Previously Senior Consultant at McKinsey during 9 years. More than 10 years of private equity and venture capital investment experience.

Shares: 6,000 Warrants: 0



### Lennart Johansson

Born 1955. MBA from Stockholm School of Economics. Board member since 2010. Chairman of Sobi's Financial & Audit Committee. Member of the management team and head of the Operating Investment group at Investor AB. Board member in Mölnlycke AB and Gambro AB. Previously CEO in b-business partners och Emerging Technologies AB.

Shares: 10,000 Warrants: 0



# Wenche Rolfsen

Born 1952. Pharm. Dr. Professor Pharmaceutical Faculty, Uppsala University. Board member since 2004. member of Sobi's Scientific Committee. Board member of Aprea (Chairman), Denator (Chairman), Artimplant, Moberg Derma, Industrifonden, Aker Biomarine AS, Norway and Axis Shield, United Kingdom. Has previously held various senior management positions at former PharmaciaUpjohn, has been CEO at Quintiles AB and Vice President Quintiles Europe, Explorative Clinical Research.

Shares: 33,400 Warrants: 0



# Michael Steinmetz

Born 1947. Ph.D. Board member since 2001. Chairman of Sobi's Scientific Committee and member of the Compensation & Benefits Committee. Managing Director Clarus Ventures LLC. Board member of Allozyne (Chairman), Heptares, MacroGenics, Oxford Immunotec, TaiGen, Tetra-Logic and Virdante. Previously GeneralPartner MPM Capitals Funds Bio Ventures I, II and III.

Shares: 0 Warrants: 0



# Hans Wigzell

Born 1938. Med Dr. h.c. , Ph. D. Professor Immunology. Board member since 2004. Member of Sobi's Scientific Committee Member of the Royal Swedish Academy of Sciences and the Royal Swedish Academy of Engineering Sciences. Board Member of the Karolinska Development AB (Chairman), RaySearch AB, Rhenman and Partner Asset Management (Chairman), Intercell AG, HuMabs AG and AVI Biopharma. President of Karolinska Institutet 1995-2003.

Shares: 180,000 Warrants: 0



# Catarina Larsson

Union Representative

Born 1952. Laboratory engineer. Board member since 2001. Representative of Federation of Salaried Employees in Industry and Services.

Shares: 600 Warrants: 0



# Bo Gunnar Rosenbrand

Union Representative

Born 1963. Laboratory engineer. Deputy board member 2001 – 2005. Board member since 2006. Representative of Federation of Salaried Employees in Industry and Services.

Shares: 1,050 Warrants: 0

# Senior Management



# Kennet Rooth<sup>1)</sup>

CEO (pro .term.)

Born 1955. Chemistry and Biology at Stockholm University and General Management at INSEAD-CEDEP. Kennet joined Swedish Orphan International in 2005 as Country Manager for Sweden. In 2006 he became Director International Marketing & Sales with responsibility for the international expansion and the establishment of subsidiaries in several European countries. From 1989 to 2005 Kennet was working at Bristol-Myers Squibb, where he held various positions both in Sweden and internationally, such as Executive Director, Country Manager, Business Unit Manager and Product Manager. Kennet began his career in 1985 as a Product Specialist at Ciba-Geigy.



# Göran Arvidson

Vice President and Head of Mergers and Acquisitions

Born 1960. B.Sc. in Economics and Business Administration. Göran Arvidson joined Procordia in 1988 as Group Controller and has been actively involved in all major transactions within Procordia/Pharmacia, the acquisition of Pharmacia in 1989, Carlo Erba in 1993, the merger of Pharmacia and Upjohn in 1995, and the acquisition of Monsanto in 1999. Göran has held various controller positions within Procordia and Pharmacia.



# Fredrik Berg

Vice President, General Counsel and Head of Legal & Intellectual Property, Risk- Safety and Environment Management

Born 1955. Master of Law. After having started his legal career at the law firm Tisell & Co., Fredrik Berg joined KabiVitrum in 1988. He has since held various positions as company lawyer and head of legal services at Procordia, Kabi Pharmacia and Pharmacia & Upjohn. In 1996, he joined the law firm Lindahl, but was recruited back to Pharmacia & Upjohn in 1997. Prior to joining Biovitrum, Fredrik was Head of Legal/Intellectual Property at Pharmacia AB and General Counsel for Pharmacia Europe, Middle East, and Africa.



#### Maria Berggren

Vice President and Head of Human Resources Born 1961. Behavioural science. Maria joined Biovitrum from Capgemini Sverige AB, where she was employed as People Relationship Manager for Technology Services. As a member of the management team, Maria was responsible for human-resources issues for the organization's 850 employees. Maria began her career in 1986 at Ericsson, where she held various senior humanresources positions over a period of ten years, including at Ericsson Data AB, Ericsson Business Networks AB and the Enterprise Networks division. Before being employed by Capgemini Sverige AB in 2001, Maria had her own business and worked as a consultant in human resources and management development.



#### Peter Edman

Vice President, Chief Scientific Officer and Head of Research & Development

Born 1954. Ph.D. and Associate Professor in biochemistry from University of Uppsala. Peter Edman joins Biovitrum as Chief Scientific Officer from his current position as Vice President and Global Project Director, Global Development, at AstraZeneca. Peter Edman has previously held a number of senior research leadership positions within Pharmacia, Astra and AstraZeneca. He has also held a position as Director and Associate Professor at the Swedish Medical Product Agency. In addition, Peter has been Professor in Pharmaceutical Formulation and Adjunct Professor in Drug Delivery at the Faculty of Pharmacy, University of Uppsala.



#### Anders Edvell

Vice President and Head of Marketing & Sales Born 1969. MD and PhD in medicine and holds an MBA degree from the Stockholm School of Economics. Anders has held several positions in the pharmaceutical industry, nationally as well as internationally. He joined Swedish Orphan International in August 2006 as Country Manager for Sweden and has, since March 2010, acted as Northern European Regional Director at Sobi. Furthermore, he has also from time to time been significantly involved the business development of Swedish Orphan International.

<sup>1)</sup> On 25 November, 2010 it was announced that the than CEO Martin Nicklasson would leave the company on the 31st of December, 2010. He was replaced by Kennet Rooth as temporary CEO until the recruiting process for a new CEO is completed.



# Sylvain Forget

Regional Director Western Europe

Frenchman born 1966, PhD in Pharmacy, holds an MBA degree from ESC of Tours (France) and a Medical Marketing Strategy degree from SIMI (Copenhagen). Sylvain joined Swedish Orphan International during 2006 as Country Manager for France with the responsibility to establish the affiliate based in Paris, and has since March 2010 acted as Western Europe Regional Director. Sylvain began his career at Glaxo in France in 1990 and has since, held various managerial positions both in France and internationally. Before joining SOBI, Sylvain has been working in several corporations including the two Scandinavian companies Lundbeck and Novo Nordisk. Sylvain is operating from our office in Paris.



#### Stefan Fraenkel

Vice President, Head of Business Development Born 1972. Ph.D. in international economics & management, MBA from Copenhagen Business School and BSc in Engineering from Chalmers University of Technology. Stefan has a history in management consulting and has been in several international managerial positions within Wyeth Pharmaceuticals. Stefan joined Sobi in 2009 coming from Wyeth's headquarter in the United States.



# Lena Nyström

Vice President and Head of Operations
Born in 1956. Master of Science in Chemical
Engineering from KTH (Royal Institute of Technology) in Stockholm. Lena Nyström joined Kabi
Vitrum in 1984 in the Process Development
organization. From 1995 onwards, Lena has held
several management positions within the Process

Development and Manufacturing units.



# Lars Sandström

CFO

Born 1972. M.Sc. in Finance. Lars joined Swedish Orphan Biovitrum in 2010 as head of Finance. In 2011 he became Chief Financial Officer. From 1998 to 2010 Lars was working at Scania, where he held various leading positions both in Sweden and internationally in the area of Finance.



# Åsa Stenqvist

Vice President and Head of IR and Communication, (pro .term.)

Born 1947, B.A. in Business Administration and Economics from University of Stockholm. Åsa was appointed as Director of Communications (pro .term.) at Sobi as from March 2011. Previously, Åsa held the position as Communications Director and was a member of Group Management at the Husqvarna AB Group between 2006 to March 2010. Before 2006 Åsa hold various leading positions within AB Electrolux since 1982 including Head of Investor Relations within Group Staff Mergers & Acquisitions between 1988-1993, Head of Investor Relations and financial information from 1993 to 1999 and Head of Investor Relations and Financial information within Group Staff Communications and Branding from 1999 to 2005.



# Annual General Meeting 2011

The Annual General Meeting of Swedish Orphan Biovitrum AB (publ) will be held on Thursday, April 28, 2011, at 4:00 p.m. in Wallenbergsalen at the Royal Swedish Academy of Engineering Sciences (IVA), Grev Turegatan 16, Stockholm.

Shareholders who wish to attend the Meeting must be recorded in the share register maintained by Euroclear Sweden AB (the Swedish Central Securities Depository) on Wednesday 20 April 2011, and must notify the company of their intention to participate in the Meeting not later than Wednesday 20 April 2011 in the following ways:

- by web site: www.sobi.com
- by phone no: +46 8 697 34 27
- by mail to Swedish Orphan Biovitrum AB (publ), "Annual General Meeting", SE-112 76 Stockholm, Sweden

The notification shall set forth the:

- name
- personal/corporate identity
- address and telephone number (daytime)
- the number of shares held
- when applicable, information about representatives and assistants.

#### Nominee shares

Shareholders, whose shares have been registered in the name of a nominee through the trust department of a bank or similar institution, must temporarily re-register their shares in their own names in the shareholders' register maintained by Euroclear Sweden AB to be entitled to participate in the Meeting. Shareholders must inform their nominee of such re-registration well before Wednesday 20 April 2011, when such re-registration must have been executed.

# Proxy, etc

Shareholders represented by proxy shall issue a written and dated power of attorney for the proxy. If the power of attorney is issued on behalf of a legal entity, a certified copy of a registration certificate for the legal entity shall be appended. The power of attorney is valid for one year from the issue thereof or such longer period of time stated in the power of attorney, however not more than five years. A registration certificate shall evidence the circumstances prevailing at the day of the Meeting and should not be older than one year at the time of the Meeting.

The power of attorney in original and, when applicable, the registration certificate, should be submitted to the company by mail at the address indicated above well before the Meeting. A proxy form is held available at the company's web site, www.sobi.com, and will also be sent to shareholders who so request and who inform the company of their postal address.

### Financial calendar

20 April Interim Report January 1 – March 31, 2011

28 April Annual General Meeting, 2011
19 July Interim Report April 1 – June 30, 2011
20 October Interim Report July 1 – September 30, 2011

Additional financial information is available at our web site. The annual report can be downloaded in pdf format from www.sobi.com, as can previous annual reports, interim reports and press releases.

# Contact details

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Telephone: 08-697 20 00 Fax: 08-697 23 30 Web site: www.sobi.com

# Disclaimer

In order to utilize the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, Swedish Orphan Biovitrum is providing the following cautionary statement. This presentation contains forward-looking statements with respect to the financial condition, results of operations and businesses of Swedish Orphan Biovitrum. By their nature, forward-looking statements and forecasts involve risk and uncertainty because they

relate to events and depend on circumstances that will occur in the future. There are a number of factors that could cause actual results and developments to differ materially from that expressed or implied by these forward-looking statements. These factors include, among other things, the loss or expiration of patents, marketing exclusivity or trade mark's; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the

impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any failure by third parties to supply materials or services; the risk of delay to new product launches; the difficulties of obtaining and maintaining governmental approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect: and the risk of environmental liabilities.





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