



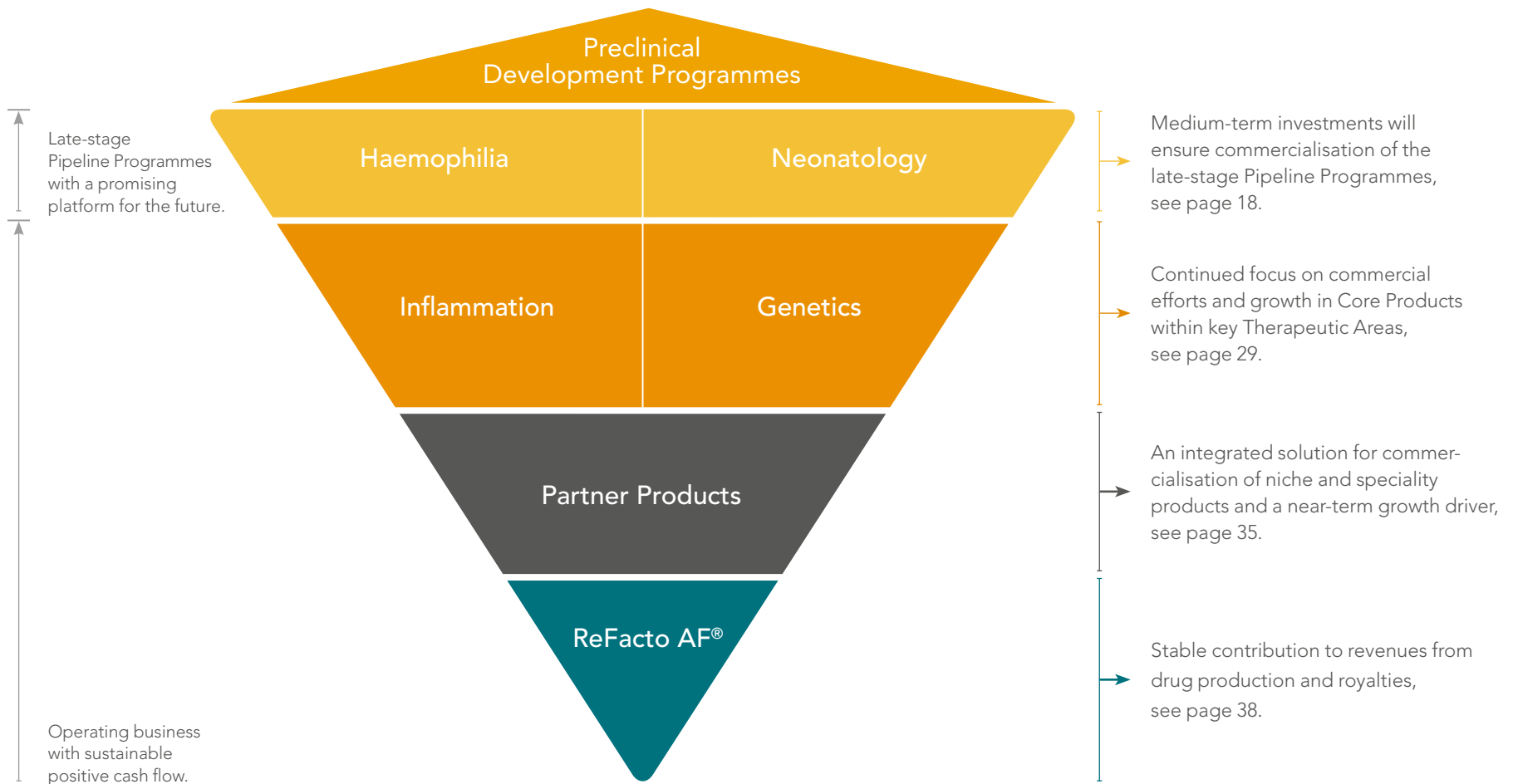
ANNUAL REPORT • 2012

*Building value for patients,
partners and shareholders*

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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 trademarks; 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.

A sustainable business with a promising future



Sobi's key Therapeutic Areas are Inflammation and Genetics with a growing focus on Haemophilia and Neonatology.

Sobi in brief

Sobi is an international speciality healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies that improve the lives of patients.

Our key Therapeutic Areas are Inflammation and Genetic diseases, with a growing focus on Haemophilia and Neonatology.

We deliver products to specialist physicians and their patients through our integrated and focused team approach to sales and marketing, medical affairs and patient access.

We leverage our world-class capabilities in protein biochemistry and biologics manufacturing to develop next-generation biological products.

Total revenues

2012

2011

1,923 SEK M **1,911** SEK M

Gross margin

2012

2011

54% **51%**

EBITA before non-recurring items

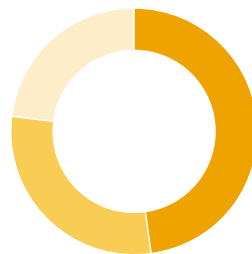
2012

2011

404 SEK M **127** SEK M

Revenues by business line

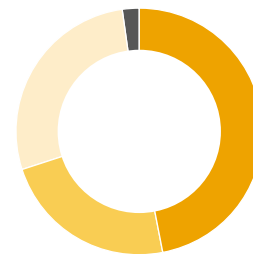
2012



■ Core Products, 48% ■ Partner Products, 23%
■ ReFacto Manufacturing, 29%

Product revenues by region

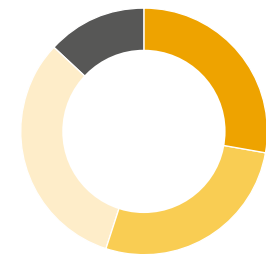
2012




■ Europe excl. Nordic countries, 47% ■ North America, 28%
■ Nordic countries, 23% ■ RoW, 2%

Employees by function

2012



■ R&D, 28% ■ Market & Sales, 32%
■ Manufacturing, 27% ■ Admin & Other, 13%



*Sobi is an international
speciality healthcare company
dedicated to rare diseases.
Our mission is to develop and deliver
innovative therapies that improve
the lives of patients.*



“Creating value for patients and our stakeholders is central to everything we do at Sobi”

Our mission at Sobi is to develop and deliver innovative therapies that improve the lives of patients with rare diseases and, in doing so, to create value for our partners, society and shareholders.

During the year, we achieved strong sales growth in Inflammation and Genetics, our key Therapeutic Areas, while revitalising our Partner Products portfolio, growing the ReFacto® business and reducing our cost base. At the same time, we have significantly advanced our three biological programmes in phase III development, which represent an exciting platform for building our future.

Patient and Customer Centric commercialisation

At Sobi we believe that an integrated approach to delivering therapies is essential to ensuring that patients will benefit in practice from the innovative medicines we develop. The patient journey, from diagnosis and treatment, to on-going disease management and long-term outcomes is at the centre of how we prioritise our capabilities and investments. Our objective is to identify where we can add value for patients and their physicians, by reducing the time to diagnosis, improving diagnostic accuracy, developing and delivering monitoring tools, understanding the barriers to consistent health outcomes, and working with physicians and other health-care providers to provide sustainable solutions for patients in the real world. By creating and maintaining dialogue with this community, and also with governments and payers, we seek to ensure that our treatments are delivered in a sustainable way. At Sobi we refer to this as a Patient and Customer Centric approach to commercialisation.

Our business focus

Our key Therapeutic Areas are Inflammation and Genetic diseases, with a growing focus on Haemophilia and Neonatology. Kineret®, a biological inhibitor of Interleukin-1 (IL-1) for Rheumatoid Arthritis (RA) and for Neonatal-Onset Multisystem Inflammatory Disorder (NOMID) is the focus in Inflammation. Orfadin®, Ammonaps® and Ammonul® are the focus in Genetic diseases.

Our Development Programmes include two long-lasting recombinant coagulation factors for the treatment of haemophilia A and B which are being developed in partnership with Biogen Idec, and Kiobrina®, an oral enzyme replacement therapy for preterm infants, which we hope will form the basis of our emerging neonatology Therapeutic Area.

These activities are supported by a diversified and growing base business. Our Partner Products portfolio is composed of products which we commercialise on behalf of speciality and rare disease partner companies. We represent our partners in European markets with the same care, clinical acumen and dedication to patient service as we do for our proprietary products. Finally, we are the long-standing manufacturer of ReFacto AF, a recombinant factor VIII, sold by Pfizer for the treatment of haemophilia A.

2012 – a pivotal year

On an operational level, 2012 was a year of strategic reorientation towards our key Therapeutic Areas, with a focus on improving our gross margin and near-term net cash flow. Total revenues 2012 increased to SEK 1,923.2 M (1,910.8). 2011 included revenues from co-promotion for ReFacto AF/ BeneFIX® and discontinued products of SEK 150 M. Adjusted for currency effects and discontinued products, revenues increased by 8%. The gross margin increased to 54% in 2012 from 51%, and operating expenses decreased by 5% to SEK 941.2 M from SEK 994.6 M. Cash flow for the full year from operations, before changes in working capital amounted to SEK 367.7 M, up from SEK 118.3 M.

Financial stability

In June 2012 we strengthened our balance sheet with the issuance of a 5-year SEK 600 M senior bond. The bond replaced Sobi's existing term facility and has improved the company's financial flexibility, as well as extending the maturity profile of Sobi's debt. Net debt as of 31 December 2012 amounted to SEK 143 M compared with SEK 481 M at year-end 2011. Cash and cash equivalents and short-term investments for the year amounted to SEK 457.0 M, compared with SEK 219.0 M at year-end 2011.

Late-stage Development Programmes

2012 was an important and exciting year in the evolution of our late-stage development pipeline. In the second half of the year together with our partner Biogen Idec, we announced positive results from two separate phase III clinical studies which evaluated two new long-lasting recombinant coagulation factors in people with haemophilia A and haemophilia B, rare inherited disorders that impair blood coagulation. There is a significant demand amongst patients and healthcare professionals for long-lasting agents for the treatment of haemophilia A and haemophilia B. The findings from these studies may represent a major step forward for the haemophilia community and a significant commercial opportunity for the company.

We are also developing recombinant human bile salt stimulating stable lipase (BSSL) to improve growth in preterm infants. BSSL is essential for normal growth in the neonatal period, and is an enzyme naturally secreted in breast milk. Many babies who are born prematurely lack access to this enzyme. Kiobrina – an investigational orally delivered, enzyme replacement therapy may become an important therapy for premature infants, if they are not fed with fresh breast milk, by increasing growth and thereby reducing short- and long-term health complications caused by prematurity. Kiobrina will possibly reduce length of stay in the Neonatal Intensive Care Unit (NICU) in the first instance and, for the longer term, reduce complication rates for these babies and their families.

Beyond our clinical trials on BSSL in premature neonates, we will also explore the impact of Kiobrina on long-term outcomes for premature infants in their early childhood development through an extension study.

Early stage research

During the year we made significant steps towards increasing our support for the paediatric inflammation field, one of our key Therapeutic Areas. Kineret is a recombinant protein currently approved for the treatment of RA.

The filing of Kineret for Cryopyrin-Associated Periodic Syndromes (CAPS) and NOMID in the EU and the US, respectively, both of which occurred in 2012, are important milestones and reflect Sobi's mission to provide a treatment to benefit patients affected by Interleukin-1 (IL-1) -related conditions. In December the US Food and Drug Administration (FDA) approved Kineret for the treatment of children and adults with NOMID. Kineret is the first and only FDA-approved therapy for NOMID, the most severe form of CAPS. This is the first approval allowing the use of Kineret in children. Kineret was approved in the US for NOMID under an Orphan Drug designation.

As well as working towards evolving Kineret's position in IL-1 driven diseases, we also deepened our development work in Inflammation by entering into research collaboration with Affibody AB for the discovery and development of novel treatments for inflammatory diseases where IL-1 is implicated.

A commitment to paediatric indications

A key theme across our development initiatives, both in our late-stage pipeline and our efforts to expand the labels of existing products, is our steadfast commitment to making novel biological products available to children with debilitating, often life-threatening conditions. This evolving focus on paediatric indications, underlined by our existing key Therapeutic Areas of Inflammation and Genetics, and by our Development Programmes in Haemophilia and

Neonatology, is a component of our vision for the future of Sobi. We are passionate about the health and potential of children and we are dedicated to developing and delivering products that will help restore vitality and hope to young lives.

Foundations of future success

As anticipated at the outset of the year, 2012 was a crucial period in our development. We have focused on building a sustainable operating platform via the growth in key Therapeutic Areas, via a new set of partnerships in our Partner Product portfolio, and by improving key operating metrics such as our gross margin and cash flow from operations. The positive read-out from the haemophilia A and haemophilia B studies, combined with our on-going work with Kiobrina and the positive developments to potentially apply Kineret to specific paediatric inflammatory syndromes, provide significant momentum for building on this platform in the future.

Our company is a community of committed people who apply their significant expertise and energy to make a difference for patients every day. During 2012 we have strengthened the senior leadership team of our community with the appointments of Alan Raffensperger as Chief Operating Officer, Birgitte Volck as Chief Medical Officer and Wills Hughes-Wilson as Chief Patient Access Officer. The appointment and integration of these three functions in the leadership of the company will be a crucial element in our ability to secure delivery of our treatments to patients in healthcare context of the future.

Thank you for your support and interest in our work.



Geoffrey McDonough
President and CEO

Highlights 2012

- ReFacto AF supply agreement extended through 2020.
- Sale of co-promotion rights to Pfizer for ReFacto AF and BeneFIX for SEK 307.5 M.
- Sobi and Biogen Idec released positive top-line data from two phase III trials for long acting recombinant factor VIII Fc (rFVIII Fc) and recombinant factor IX Fc (rFIX Fc). Results signal a potential paradigm shift for patients and families in the haemophilia community.
- Sobi and Biogen Idec initiated global paediatric clinical trials for recombinant factor VIII Fc and recombinant factor IX Fc.
- In June 2012 the transfer of production of Kineret from Amgen in the US to a contract manufacturer in Europe was approved by the European Medicines Agency (EMA) and the FDA, as well as the Therapeutic Goods Administration (TGA).
- Kineret Paediatric Investigation Plan (PIP) for CAPS and Systemic Juvenile Idiopathic Arthritis (SJIA) accepted by EMA.
- Submitted a Biologics License Application (BLA) for Kineret to the FDA in NOMID and a market authorisation application to the EMA for CAPS.
- Kineret becomes the first and only FDA-approved treatment for NOMID, the most severe form of CAPS. The FDA approval of Kineret for NOMID results from a long-term collaboration with an investigator at the National Institutes of Health (NIH) and patient societies, and is an important milestone in the company's effort to bring therapeutic options to patients with rare inflammatory diseases.
- Successful transfer and validation of the Kiobrina drug substance process to contract manufacturer.
- Enrollment in Europe continued for phase III registrational study for Kiobrina, with last patient enrolled expected in the first half of 2013.
- Sobi became an active member of an innovative and unique multi-stakeholder consortium which was awarded the highest evaluation possible from the European Commission through the FP7 programme for the development of Orfadin for alkaptonuria.
- A research and licence agreement with Affibody AB was established to deepen our work in the IL-1 field with five protein targets under investigation.
- Geographical expansion into new territories, with the establishment of a full affiliate structure in the United States and creation of Sobi Middle East, which represents a strong platform for our future in the region.

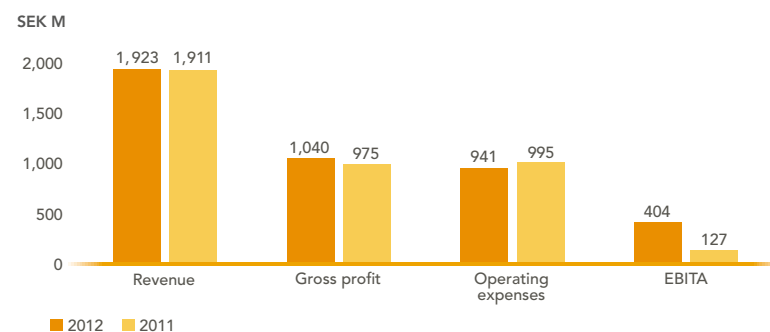
Key figures 2012

- Total revenues increased to SEK 1,923.2 M (1,910.8). 2011 included revenues from co-promotion for ReFacto AF/BeneFIX and discontinued products of SEK 150 M.
- Gross margin¹ increased to 54% (51).
- Operating expenses decreased by 5% to SEK 941.2 M (994.6).
- The flexibility of the financial position improved through the issue of a 5-year SEK 600 M senior bond in June 2012.
- During the fourth quarter 2012, Sobi reached the sales volumes for Kineret that triggered a contractual milestone payment of USD 55 M due to Amgen. This was paid in the first quarter 2013.

SEK M	2012	2011
Total revenues	1,923.2	1,910.8
Gross profit	1,040.4	974.6
Gross margin ¹	54%	51%
Operating profit before amortisations (EBITA) ²	404.1	127.3
Operating profit (EBIT) ²	-54.6	-318.6
Profit/loss for the year	-100.9	17.9
Earnings per share, SEK	-0.38	0.07
Cash flow from operations	405.5	102.9
Equity per share, SEK	18.2	18.7
Equity assets ratio	76.6%	74.1%

¹ Adjusted for balance sheet write-downs.

² Before non-recurring items.



Building value

At Sobi, the creation of value for our external stakeholders is central to how we think about what we do and how we do it. We believe that our integrated approach to developing and delivering therapies to patients with high unmet needs enables us to create value for our key external stakeholders, patients, partners and shareholders.

Building value for patients

The Sobi approach ensures that the patient journey – from identification and diagnosis through to optimising current care and developing better products – is approached as a holistic and integrated process. We believe that by optimising the way in which we develop and deliver innovative therapies to patients with high unmet needs, we can deliver enhanced value, not only to those patients we serve, but to the partners we collaborate with and the shareholders who support our work.

Underpinning everything we do at Sobi is a commitment to improving the lives of patients living with rare diseases. These diseases are often life-threatening or cause chronic disability and, therefore, have a severe impact on the patients and their families, friends and society as a whole.

A Patient and Customer Centric approach

The unique characteristics of the rare disease space makes collaboration between patients, industry, payers and regulators vital to ensuring that essential therapies are made available to small patient populations with very high unmet medical needs. Because rare diseases affect a small number of patients and because these diseases are often life-threatening, prompt action is required in identifying, diagnosing and treating patients. However, Sobi's involvement in the patient journey extends beyond treatment; we remain actively committed to supporting

improved patient care, in close collaboration with physicians and Centres of Excellence, by facilitating the continuous monitoring of patient outcomes and ensuring optimal disease management.

Stakeholder engagement is vital to ensuring patients have access to our innovative therapies and that their treatment is optimised. Relationships with governmental and regulatory authorities as well as key stakeholders, such as specialist physicians and patient organisations, are at the heart of Sobi's Patient and Customer Centric approach to commercialisation.

At Sobi, we work closely with Centres of Excellence, key opinion leaders and professional societies on local, regional and global levels to ensure that the process of developing and delivering novel treatments to patients is conducted in a sustainable manner for all partners in the healthcare systems. Through collaboration, within the healthcare compliance framework, with doctors, patients and patient organisations, we are able to gain a greater insight into how we can best serve the small patient communities we are committed to helping.

Furthermore, through our engagement with patient groups, Sobi has initiated a substantial investment in education and information materials, for medical staff, patients and relatives. Sobi supports numerous patient organisations and we maintain an active dialogue with them to share knowledge and increase our understanding of their needs.



Sobi is passionate about the health and potential of children and we are dedicated to developing and delivering products that will help restore vitality and hope to young lives.

Dr Ranganath

Director of the Alkaptonuria (AKU) Society of the United Kingdom



“ Sobi supported the launch of the AKU Society back in 2003 with a grant to set up the website, which enabled us to better support patients. Sobi is also a key member of the EU-funded consortium, ‘DevelopAKUre’. They are supporting us with high quality clinical trials and are always willing and open to advising us and to receiving our guidance; it is a two-way dialogue. Sobi is engaged far beyond their commercial interests; they demonstrate goodwill, altruism and have been invaluable in their support and guidance.”

Building value for partners

Sobi has a long history of creating value in collaboration with partners in all phases of the product life cycle, from early research and development through to commercialisation. Our Partner Products portfolio offers an integrated solution to small and mid-sized pharmaceutical and biotech companies for commercialisation of products for rare and niche indications throughout Europe, Middle East and Russia.

Our value proposition as a partner is driven by our unique distribution capabilities and our unsurpassed knowledge of the markets in which we operate. Our long heritage in the commercialisation of orphan medicinal products and the treatment of rare diseases means that we have the expertise to deliver life-saving treatments to the patients who need them in the markets we cover.

We do this through the integrated efforts of our marketing and sales force, medical affairs and access infrastructure who work from named-patient access through registration and value assessment, and on to formal reimbursement and full commercialisation.

As a small company, we understand the beauty of truly effective products for small populations and we seek partnerships where establishing a highly clinically focussed approach to supporting these products is required and appreciated.



Adrian Haigh

Senior Vice President of
Commercial Operations, Gentium

“ I have been very pleased with the working relationship between Gentium and Sobi. Sobi possess all the qualities I look for in a distribution partner – a patient-focused approach, an integrated commercialisation infrastructure, local knowledge and a deep heritage and strong commitment to making medicines available to rare disease patients.

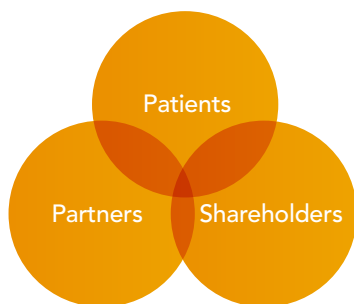
Sobi are responsible for managing named-patient requests and achieving pricing and reimbursement approvals for Defibrotide in their territories. Time and time again they have demonstrated their expertise in dealing with life-saving orphan drugs that are not yet approved, but are accessible on a named-patient basis, which is the situation we are currently in. They have a dedicated product manager who is our initial point of contact but I have very good relationships with Sobi senior management. There is a great communication and contact. Our strategy is to always be open and transparent with our partners and Sobi share that value, it is like having an extension of our business that is better operating in their territories than we could ever afford to be.”

Building value for shareholders

Our responsibility to create long-term value for our shareholders informs the way we think about our future and how we will achieve our goals.

Throughout 2012 we have focused on growth in our key Therapeutic Areas of Inflammation and Genetics, as well as in our Partner Products and ReFacto AF manufacturing businesses. We have significantly improved gross margin as part of achieving positive net cash flow and profitability in our operations over the near-term. We have also taken steps towards streamlining our product portfolio and we have reduced our overall cost base by 5%.

Our efforts to enhance our operational performance are driven by the need to secure a sustainable base of operations, which will allow us to earn our way into our future when we begin to commercialise our pipeline.



At Sobi, we believe that our integrated approach to developing and delivering therapies to patients with high unmet needs enables us to create value for our key external stakeholders.

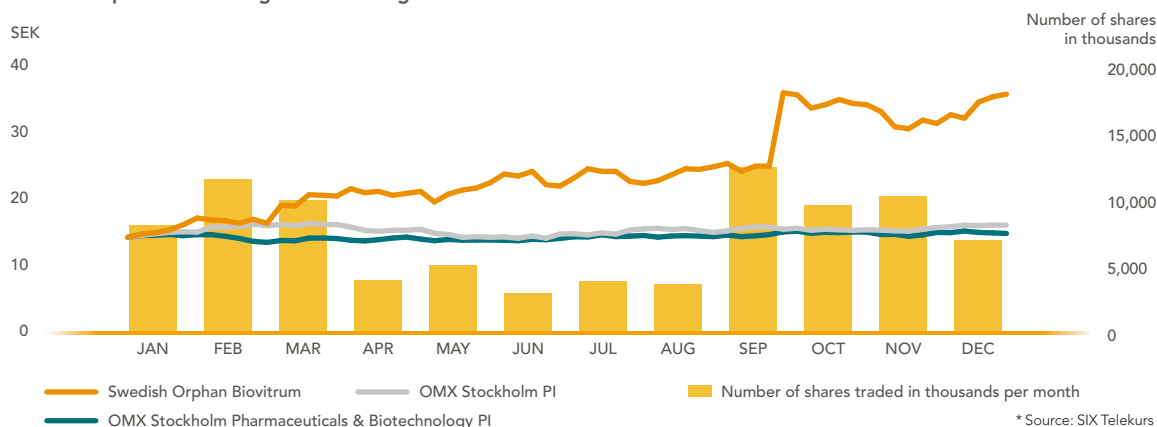
While we believe that we have grown a strong and sustainable operating business, we remain convinced that, by effectively commercialising our late-stage biologics pipeline, we will unlock further long-term, sustainable value for our shareholders. During 2012 we saw accelerated pipeline development of our two programmes in Haemophilia, and we have begun market development planning. Over the medium-term, we will seek to make targeted investments aimed at ensuring that we are optimally positioned to successfully commercialise our late-stage pipeline and unlock its value for patients and, therefore, for our shareholders.

Over the long-term, we will focus on creating value through organic growth and acquisitions in key Therapeutic Areas. We recognise that the value of our pipeline will not be realised overnight and nor can our vision for

the business be actualised in the short-term. Rather, by setting and executing on clearly defined and realistic near-term goals, we will evolve towards our vision of the future: Sobi as an international speciality healthcare company dedicated to rare diseases.

Finally, we are acutely aware of our responsibility to communicate with our shareholders in a timely, clear and transparent manner, and to provide a realistic and compelling vision of our future to all stakeholders. This is a commitment we take very seriously and is underpinned by our Core Values, a commitment to be Collaborative, Accountable, Respectful and Engaged (CARE).

Sobi share price and trading volume during 2012*



Sustainability & values

Sobi's mission is to develop and deliver innovative therapies that improve the lives of patients. Rare diseases are chronic, debilitating and often life-threatening; and have a severe impact on patients and their families. Providing treatment options for patients with rare diseases very often results in improved quality of life and enhanced independence: factors that are important, not only to the individual patient and their families, but to society at large.

In our overarching ambition to provide valuable medicines and improve lives, Sobi strives to always ensure the highest levels of patient and product safety, research ethics, environmental protection and working conditions. We believe that, in order to ensure our long-term sustainability and to effectively serve the patients who depend on us, we must always act in an open and responsible way in relation to our stakeholders.

At Sobi, we believe that an integrated and holistic approach to developing and delivering innovative therapies to patients is essential to ensuring that they benefit from the medicines we develop. We recognise that, in order to optimally serve the patients who rely on our products, we must create and maintain an on-going dialogue with all stakeholders at all stages of the patients' journey in the healthcare system. Through these discussions with patients, employees, decision-makers, government bodies, healthcare system developers and managers, industry organisations and other stakeholders, Sobi continues to develop an understanding of how we can best meet the needs of all our stakeholders.

Dialogue with patients, families and carers

Learning that a child has a serious or even potentially fatal rare disease is a life-changing moment for both the child and the child's family. The diagnosis must be followed up with the greatest of care. Treatment and related supportive healthcare is often complicated. Due to the rarity of these diseases, knowledge about the condition in question, even amongst healthcare professionals, may be limited. Patients and relatives often have a great desire for knowledge. Sobi prioritises investment in education and information materials for medical staff, patients and relatives. Sobi supports numerous patients' organisations and maintains an active dialogue with them to understand their needs and to build mutual understanding of the nature of specific rare diseases and

their treatment. A complete list of patient organisations supported by Sobi is available on www.sobi.com.

Workplace and employees

Sobi's business model combines advanced research with commercial activity. Sobi is a knowledge-intensive company with high expectations of the individual employees. This is essential for creating a shared culture of innovation and high performance; and this is central to our ability to create value for our stakeholders. Our objective is to attract, retain and nurture the best talent in our field and to create an environment where our people can thrive and feel engaged in their contribution to Sobi's mission of improving the lives of patients.

Competence development, shared values, innovation & engagement

At Sobi, we aim to create a culture of individual responsibility and accountability. In order to help each person understand how their individual efforts contribute to our mission, Sobi has a strong internal culture of shared goal-setting and transparent communication.

Continuous development for each employee at Sobi is a vital element of ensuring that we can develop our portfolio, strengthen production processes and successfully launch and sell products in the market. The company has a well-defined Performance Management Process to ensure that managers and employees jointly set personal objectives, based on the corporate objectives, on an annual basis. These are formally followed up on at defined points during the year.

The objectives are set and evaluated on what individual employees achieve, but also how they achieve it. The Sobi "CARE" values – Collaborative, Accountable, Respectful and Engaged – measure both elements, and form the foundation for the annual evaluation of employee performance.

Attracting, retaining and nurturing a world-class workforce

Good terms of employment are required in order to recruit and retain qualified employees of the highest standard. Sobi strives to offer competitive salaries and benefits packages, determined on an individual basis and reflecting the local labour market. Sobi aims to offer a working environment that promotes health and wellness, which comprises various elements aimed at fostering this. We strive to offer a healthy work-life balance within the framework of the company's operations.

Diversity and equal opportunity

In 2012, 40% of the total employees were men and 60% were women. In the Executive Leadership Team and the Board of Directors the corresponding figure was 50/50% and 71/29%¹, respectively. All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

Employee turnover

The employee turnover within the Sweden-based headquarters operations (385 people) was 6.5% during 2012.

Respect for labour market regulations

Sobi complies with and respects labour market regulations. The company works constructively with trades unions and employee-employer organisations and makes it a priority to continue to foster an ongoing and collaborative understanding.

¹ This figure does not include employee representatives.

Maria Berggren

Sobi, Vice President,
Human Resources



“ At Sobi we firmly believe that each one of us has to take responsibility for our own development and lead through example. We recognise that, in order for our company to develop and for us to reach our collective goals as an organisation, we continuously have to develop as individuals. We view all of our people as leaders in the organisation, regardless of their title. Our collective desire to develop and to drive our business forward through strong leadership at every level of the organisation is inspired by our mission to help people with rare diseases. That is the beating heart of this company: the desire to make a difference in the lives of people with rare diseases. This is what motivates everything we do.”





Bruce Faulkner-Dunkley

Sobi, Managing Director
for UK Ireland and BeNeLux

“ Our mantra of People with Passion and Pride in their Performance is, without doubt, ingrained throughout Sobi. We are not confined by titles; and that is very empowering and enhances the entrepreneurial spirit. Senior management speak to people – and they listen and act on what they hear. There is a strong sense that people have a voice here and that they are heard. Ultimately, I firmly believe we at Sobi have some of the best people in the world, working in the development and delivery of innovative therapies to patients with real unmet needs. At Sobi we all feel the same – we’re here because what we do makes a difference.”

Ongoing medical education

Knowledge about rare diseases is often scarce, inadequate and geographically diverse, even after treatments become available. Knowledge about the condition in question, the natural history and other aspects is increasing on an on-going basis. Sobi is committed to facilitating enhanced knowledge-sharing amongst healthcare providers. To this end Sobi has produced, in collaboration with medical expert groups, several extensive training programmes for healthcare providers who treat rare disease patients. Several of these training programmes are now certified by public health services.

Working with industry colleagues

In order to stay up-to-date with the changing external environment; and to contribute to evolving the robust systems that govern pharmaceuticals and healthcare systems, Sobi is a member of several representative industry bodies, both at national and international levels. It is also important for our business model to be part of creating and sustaining a public environment that favours research, development and investment in the knowledge-based economy and the scientific sector. Sobi is also a member of a number of industry groups committed to building understanding and fostering a collaborative external environment. A list of organisations that Sobi is a member of is available on www.sobi.com.

Product liability and research ethics

Patient safety

Sobi's products are subject to strict, well-established and harmonised standards by existing national and regional regulatory frameworks before they are granted a marketing authorisation. For products on the market, as well as molecules in all stages of development, Sobi continually

monitors, analyses and balances the risks and benefits for patients. Protecting patient safety is our most important obligation and, in our clinical programmes, we always adhere to the Helsinki declaration for human rights. Employees are tasked with ensuring compliance with both internal and external rules with respect to any clinical trials that Sobi sponsors.

In Sweden, Sobi is part of the Pharmaceutical Insurance scheme, a funded system for those in Sweden suffering from any adverse effects that may have arisen from pharmaceutical treatment or participation in clinical trials.

Clinical trials

All Sobi-sponsored clinical trials are conducted and reported in accordance with applicable laws and global standards of good practice. All Sobi-sponsored clinical trials undergo an internal Sobi approval process, as well as regulatory authority and independent ethics committee review and approval, prior to trial initiation.

Sobi strives to maintain the highest ethical, technical and scientific standards in all clinical research conducted. The company ensures that the clinical investigators and sites participating in Sobi-sponsored trials are qualified by training and experience; and that they have adequate resources to conduct the trial.

The majority of our clinical trials are operationally executed by Contract Research Organisations and the Sobi outsourcing process is regulated in internal Standard Operating Procedures (SOPs). The ultimate responsibility for the strategy, quality and integrity, including the implementation and maintenance of quality control systems; and the reporting of a trial always remains with Sobi as the sponsor.

Sobi publishes information about all company sponsored clinical trials on www.clinicaltrials.gov.



Our Core Values – Collaborative, Accountable, Respectful and Engaged – are an essential part of our culture and guide us in our day-to-day interactions with all stakeholders, including our colleagues.

Handling of adverse event reports

Sobi has marketing authorisation for a number of drugs in different markets. This brings an obligation to collect, process and report adverse events and other safety information to regulatory authorities in accordance with international laws and regulations.

Sobi maintains an efficient system and network for the collection, analysis and communication of adverse effects and other safety information associated with the products we market and develop. Sobi's Drug Safety Unit is tasked with capturing, analysing and communicating signals to secure the benefit of our products and the well-being and safety of patients on an ongoing basis. All employees are responsible for reporting any suspected adverse effects of Sobi's products that come to their attention, a process that is governed by internal SOPs, which all Sobi employees are required to review and commit to on a regular basis. Sobi regularly updates these SOPs to reflect changes in legislation and best practice.

Animal experiments

Safety legislation at national and international level requires pharmaceuticals to be tested on laboratory animals at certain stages in their development. An important part of Sobi's commitment to safety and compliance with the law therefore requires us to conduct safety testing on laboratory animals. Sobi adhere to legislation for animal protection, and is striving to reduce the number of tests conducted on animals. We therefore follow the "three Rs" – Replace, Reduce and Refine – in animal research to ensure that, wherever possible, we can reduce the number of animals to a minimum. This means, in practice, that animal research programmes are designed to ensure that the most appropriate laboratory model is being used, in order to reduce the number of animals needed to obtain the necessary information.

Drug development can also use a large number of methods that are not based on laboratory animals – e.g. *in vitro* tests. Sobi's aspiration is to continue to develop *in vitro* methods, amongst others, to replace or reduce the number of laboratory animals needed to demonstrate the safety data required by governments.

Safe production of pharmaceutical proteins

Sobi complies with Good Manufacturing Practice (GMP) requirements. Sobi manufactures the active ingredient for ReFacto AF in its Stockholm facility and Multiferon® in its facility in Umeå, Sweden. Other production is outsourced to external manufacturers. External manufacturing is covered by specific agreements to ensure supply and quality. The European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) regulatory authorities, as well as authorities from other countries, regularly inspect the production facilities of both internal and external manufacturers and suppliers.

Safe purchasing procedures

Raw materials, other material, equipment and other services for manufacturing are purchased according to Sobi's SOPs. The SOPs require that all procurement and purchasing takes place professionally and competitively, in accordance with Sobi's rules and GMP requirements. Our Environmental Health and Safety (EHS) policy requires that suppliers conduct their activities in such a way that employee health and the environment are protected and that energy and natural resources are saved.

Environmental protection

Environmental management

Managing our environmental impact is a core commitment. Proactive environmental management is part of creating a sustainable business. Sobi works according to an environmental management system based on the

international standard ISO 14001, but is not certified. The responsibility for EHS management is delegated to the line managers and coordinated by the environmental coordinator.

Sobi strives to fully comply with all environment-related laws and regulations. The 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, including conditions for waste-water management. The company has a licence to work with radioactive substances from the Swedish Radiation Safety Authority, but no such work was performed during 2012. Sobi also has an import licence from the Swedish Board of Agriculture for animal by-products and a licence to handle flammable goods. Sobi takes producer's responsibilities for packaging by being associated with recycling systems, such as the REPA register in Sweden.

In order to protect people and the environment, as well as Sobi's business interests, a variety of Environmental Health & Safety issues are considered while developing and continuing supplier relationships. Sobi has issued a standard Contract Manufacturer Environment, Health and Safety Due Diligence Questionnaire to assist in the evaluation of EHS management systems of current and candidate contract manufacturers.

Environmental training

Environmental awareness among all personnel is crucial for successful environmental management. As of 31 December 2012, 76% of all employees in Sweden had completed a general environmental training programme covering sustainable development, recycling and the greenhouse effect, amongst others. The company offers continuing education and relevant environmental training is included in the annual action plans.

Work environment

Sobi complies with occupational health and safety related laws and regulations and the formal responsibility is delegated to line managers. All operations are required to perform annual safety inspections, surveys and risk assessments for fire safety, security, ergonomics and electrical safety.

For Manufacturing and Research & Development, there are additional requirements for annual safety inspections concerning chemicals and Genetically Modified Microorganisms (GMMs). In 2012 Sobi did not handle any chemicals that require permission from the Swedish Work Environment Authority and there was no work performed with radioactive substances. The company reports to the Swedish Work Environment Authority regarding its use of biological agents and the contained use of GMMs. The GMM systems are all established models in the biopharmaceutical industry.

There were no workplace accidents to report to the Swedish Work Environment Authority in 2012.

Pharmaceuticals in the environment

The environmental hazard of a specific drug refers to its inherent properties, including toxicity, ability to break down in nature and potential to be stored in the fat of animals, amongst others. Pharmaceutical substances are classified with respect to their decomposition, based on standardised laboratory tests. EU guidelines on environment risk assessment of drug substances have established that certain drugs are not expected to have any environmental impact – including products composed of carbohydrates, amino acids, peptides and proteins, amongst others. The majority of Sobi's products are biopharmaceutical products composed of amino acids, proteins and peptides, therefore, their environmental impact is considered insignificant.



Stephen James

Sobi, Vice President, Head of
Drug Design and Development

“ At Sobi, we have a clear understanding of what it means to be a leader. I think we understand the importance of collaboration. And we also understand that success can only come through strong partnerships. This collaborative approach is at the heart of our approach towards leadership and people. We recognise that we must create an environment in which people feel empowered to contribute to the advancement of the business. This collegiality is very important at Sobi and, in my view, is what makes it such a challenging and fun environment to work in. The whole team works well together and there is a clarity of purpose right throughout the organisation.

When I look at our later-stage pipeline, I can see how close we are to making a difference to patients who are still in need of new or better treatments; and that is genuinely exciting. I believe that everyone at Sobi recognises that they are part of something potentially very special.”

Energy and resource consumption

Sobi continually works to improve the energy efficiency at our sites and we regularly review the operating costs in buildings in which we operate. A programme to review and reduce the water consumption in the Stockholm production facility was initiated in 2011 and resulted in a decrease of 35% to 105,809 m³ in 2012, compared with 162,956 m³ in 2011. The total consumption of electricity, district heating and cooling in 2012 for the two Stockholm and the Umeå facilities was 17,845 MWh, see table below. We intensified the efforts to reduce the energy and resource consumption in the production facility in Stockholm by starting an energy-efficiency project in late 2012. Knowledge and experience from the project will be used in other buildings where Sobi operates.

The active management of waste is another key aspect of our commitment to reducing our impact on the environment. The total amount of waste decreased in 2012 compared with 2011; see the diagram below. Air emissions in the Sweden-based companies primarily come from travel. Air emissions from flights during 2012 was 570 tonnes of carbon dioxide, compared with 582 tonnes of carbon dioxide during 2011. Sobi is working to reduce this. Sobi is also working on improving the reporting systems to be able to gather data from subsidiaries and generally reduce costs and environmental impacts.

GRI reporting

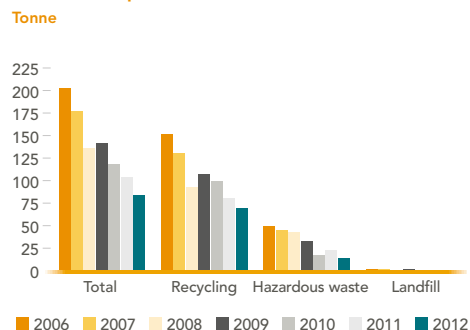
Sobi is applying level C in accordance with the Global Reporting Initiative (GRI) guidelines for reporting on sustainability. The company's GRI report is available at www.sobi.com.

Resource consumption (Stockholm and Umeå facilities)

	2012	2011
Electricity (MWh)	6,742	9,442
District heating (MWh)	4,288	4,887
District cooling (MWh)	3,562	4,622
Steam (MWh)*	3,253	–
Total energy (MWh)	17,845	18,951
Water consumption (m ³)	105,809	162,956

* From 2012 Steam will be reported separately.

Waste disposal 2006–2012





Focus on paediatric indications

“ A key theme across our Development Programmes is our resolute commitment to making novel biological products available to children with debilitating, often life-threatening conditions. This evolving focus on paediatric indications is a key component of our vision for the future.



Significant developments in late-stage pipeline

Sobi's Pipeline Programmes are focused on recombinant proteins for Haemophilia and Neonatology, two of our key Therapeutic Areas. The company's development expertise is highly focused on late preclinical and clinical biologics, as well as on protein manufacturing and process scale-up.

Sobi is passionate about developing products for children with serious conditions, a commitment which began with the development of Orfadin for Hereditary Tyrosinemia type 1 (HT-1) in the early 1990s. We aim to build on this legacy with our Development Programmes to improve the lives of children with rare diseases.

Our innovation model is based on a legacy of biologics expertise dating back to our roots in Kabi in the late 1970s, which we now apply to late preclinical programmes for candidates in rare disease indications. We believe we can efficiently develop innovative programmes through a balance of our own and partnered programmes, with the conviction that the innovation model of the future will see greater leverage for companies who can work together in seamless and nimble collaborations that make the most of each others' expertise.

Sobi's Pipeline Programmes reflect our focus on innovative biological medicines for rare disease indications. Global phase III paediatric clinical trials of long-lasting recombinant clotting factors are underway with our partner Biogen Idec in haemophilia A and haemophilia B, and in Kiobrina we are developing a novel recombinant enzyme replacement therapy to improve growth in pre-term infants.

Key milestones in 2012

















Several key milestones were achieved during the year in the late-stage programmes:

- Positive top-line results from B-LONG, a phase III study investigating long-lasting recombinant factor IXFc fusion protein (rFIXFc) in haemophilia B, conducted by our partner Biogen Idec. A global phase III paediatric clinical trial was initiated of rFIXFc in haemophilia B – Kids-B-LONG.
- Positive top-line results from A-LONG, a phase III study investigating long-lasting recombinant factor VIII Fc fusion protein (rFVIII Fc) in haemophilia A, conducted by our partner Biogen Idec. A global phase III paediatric clinical trial was initiated of rFVIII Fc in haemophilia A – Kids-A-LONG.
- Substantial progress in enrollment of our European phase III LAIF study of Kiobrina.

New licensing agreement for neonatology treatment

In January 2012, Sobi signed a global licensing agreement with the French company Only for Children Pharmaceuticals (O4CP) regarding bumetanide reformulated for treatment of diuresis and seizures in neonates. The new drug is currently in clinical phase II under the EU-financed NEMO project. O4CP will be responsible for development and manufacturing of drug product and for obtaining marketing authorisations. Sobi will be accountable for the commercialisation of the product on a global basis. If approved, this programme will become a complement to the Kiobrina programme within the neonatal area.


Pipeline Programmes

Indication	Product/Project	Partner	Phase I	Phase II	Phase III	Reg phase
Haemophilia A ¹	rFVIII-Fc	Biogen Idec				
Haemophilia B ¹	rFIX-Fc	Biogen Idec				
Improve growth in preterm infants	Kiobrina	–				
Diuresis and seizures in neonates	Reformulated bumetanide	Only For Children Pharmaceuticals (O4CP)				

¹ Positive readout from global registrational studies of rFVIII-Fc and rFIX-Fc in previously-treated patients with severe haemophilia A and B aged 12 years and over occurred during 2012. Two global paediatric clinical trials of rFVIII-Fc and rFIX-Fc in haemophilia A and B, required prior to filing with the EMA, were initiated during 2012 and are on-going.

Life cycle management

Indication	Product/Project
CAPS	Kineret
Hereditary Tyrosinemia type 1	Orfadin, liquid formulation



Haemophilia patients

“ We are committed to making novel biological products available to children with debilitating diseases. Our evolving focus on paediatric therapies is underlined by two global paediatric clinical trials of rFVIII-Fc (Kids A-LONG) and rFIX-Fc (Kids B-LONG) in haemophilia A and haemophilia B, respectively.

Laying the foundation for a major step forward for people with haemophilia



In the second half of 2012 Sobi and Biogen Idec announced positive top-line results from A-LONG and B-LONG, two phase III clinical studies of the companies long-lasting recombinant factor VIII Fc and recombinant factor IX Fc, for the treatment of haemophilia A and B, respectively. The two programmes were run by Sobi's partner Biogen Idec. The primary efficacy and safety objectives of both trials were met.

Both rFVIII Fc and rFIX Fc have the potential to be the first long-lasting products to reach the market and the findings could represent a significant step forward for the haemophilia community. Haemophilia is one of Sobi's key Therapeutic Areas and the haemophilia programmes represent a major commercial opportunity within Sobi's territories and a strong platform for Sobi's long-term organic growth. Over the medium-term, we will focus on investing to ensure that the appropriate infrastructure and resources are in place to support the commercial launch of the haemophilia products in Sobi's territories.

Haemophilia market – USD 3.7 billion¹ in Sobi territories

The total market for haemophilia A and B within Sobi's territories today is estimated at USD 3.7 billion. Globally, over the past decade there has been a gradual transition from factor concentrates based on plasma to recombinant factors, and from episodic treatment to a prophylaxis or preventative treatment paradigm.

Phase III pivotal studies

The A-LONG (rFVIII Fc) and B-LONG (rFIX Fc) phase III studies were open-label, multicentre studies designed to evaluate safety, pharmacokinetics and efficacy in the prevention and treatment of bleeding in previously treated patients with severe haemophilia A and B respectively. The studies included prophylactic and episodic treatment as well as surgery.

Treatment requires frequent injections

Haemophilia A and B are rare inherited disorders that impair blood coagulation.

In haemophilia, the blood does not clot due to a deficit or complete lack of coagulation factors. Patients with haemophilia, therefore require intravenous injections of coagulation factor to stop or prevent bleeding that could otherwise lead to pain, permanent joint damage or life threatening haemorrhages. Treatment is either episodic when bleeding, or prophylactically administered. Current commercially available clotting factors require frequent injections, which, in the case of prophylaxis, means 2–4 injections per week or even more often. This can be very demanding, particularly for a small child, and makes the prospect of long-lasting factor VIII and factor IX therapies very exciting. Also in the case of acute treatment there is often a need for more than one injection to control a bleed.

Long-lasting factors – high unmet medical need

Clotting factors that last longer in the body may have several advantages such as improved protection against bleeds, improved adherence to prophylaxis and reduced frequency of injections, thus reducing the treatment burden. Research that Sobi has conducted among haemophilia healthcare professionals in Europe shows that long-lasting agents are ranked as the most appealing improvement compared to existing therapies.

¹ The Marketing Research Bureau. Ref MRB_WW_coag2011.

Proprietary technology

Recombinant factor VIII Fc and recombinant factor IX Fc are clotting factors developed using Biogen Idec's novel and proprietary monomeric Fc fusion technology, which makes use of a naturally occurring pathway that delays the breakdown of factor in the body and cycles it back into the bloodstream, enabling it to remain in the body longer following an injection. The recombinant coagulation factors are produced without addition of human or animal protein.

Major step forward for the haemophilia community

In the B-LONG study the prophylactic regimens resulted in low single-digit median annualised bleeding rates. Similarly, in the A-LONG study, individualised and weekly prophylactic regimens resulted in low single-digit median annualised bleeding rates. These results point to a substantial reduction in the number of injections needed annually, potentially 50–100 injections fewer per year for a patient on prophylaxis treatment.

Top-line results from the A-LONG study indicate that some patients may be able to achieve dosing intervals better than two times per week.

Furthermore, in A-LONG 98% of bleeding episodes were controlled with one or two injections of rFVIII Fc; and in B-LONG greater than 90% of bleeding episodes were controlled by a single injection of rFIX Fc.

These top-line results clearly demonstrate that rFVIII Fc and rFIX Fc have the potential to enhance the care of people living with haemophilia A and B respectively, and may offer long-lasting protection from bleeding with significantly reduced treatment burden.

Next steps

Consistent with guidelines published by the European Medicines Agency (EMA) that require a study in children

Summary of top-line results from A-LONG and B-LONG

The top-line results from A-LONG and B-LONG studies showed that rFVIII Fc and rFIX Fc are effective in the control and prevention of bleeding, routine prophylaxis, and perioperative management in patients with haemophilia A and B, respectively. Both rFVIII Fc and rFIX Fc were generally well-tolerated.

A-LONG

- Individualised and weekly prophylactic regimens resulted in low single-digit median annualised bleeding rates.
- Median dosing interval was 3.5 days in the individualised prophylaxis arm.
- For 112 subjects with greater than or equal to 6 months on study, approximately 30% achieved a mean dosing interval of greater than or equal to 5 days during the last three months on study.
- 98% of bleeding episodes were controlled with one or two injections of rFVIII Fc.
- No patients developed inhibitors to rFVIII Fc.
- The most common adverse events (incidence of at least 5%) occurring outside of the perioperative management period were nasopharyngitis, arthralgia, headache and upper respiratory tract infection.
- No serious adverse events were assessed to be related to the therapy.

B-LONG

- Prophylactic regimens resulted in low single-digit median annualised bleeding rates.
- Median dosing interval was 14 days in the individualised interval prophylaxis arm during the last 6 months on study, for the 26 subjects who were on study for at least nine months.
- Greater than 90% of bleeding episodes were controlled by one single injection of rFIX Fc.
- No patients developed inhibitors to rFIX Fc.
- The most common adverse events (incidence of at least 5%) occurring outside of the perioperative management period were nasopharyngitis, influenza, arthralgia (joint pain), upper respiratory tract infection, hypertension and headache.
- One serious adverse event, obstructive uropathy in the setting of hematuria, was possibly assessed to be related to therapy. The patient continued rFIX Fc treatment and the event resolved with medical management.

less than 12 years of age prior to filing for marketing authorisation, in July 2012 Biogen Idec and Sobi announced the initiation of two global paediatric clinical trials of rFVIII-Fc (Kids A-LONG) and rFIX-Fc (Kids B-LONG) in haemophilia A and haemophilia B, respectively.

Sobi expects the total Development Programmes, including regulatory review, to be completed within approximately 2 years. This means that 2016 will likely be the first year of significant revenues in Sobi territories.

Biogen Idec's Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for rFVIII-Fc for use in patients with haemophilia A was filed in the first quarter of 2013. Its BLA for rFIX-Fc for use in patients with haemophilia B was submitted in the fourth quarter of 2012.

Additional analyses of the A-LONG and B-LONG studies are on-going and the companies anticipate presenting detailed results at a future scientific meeting.

Partnership with Biogen Idec

Sobi's collaboration with Biogen Idec goes back to 2007 when Biogen Idec acquired Syntonix, a company with whom Biovitrum had a partnership for the development of a drug for the treatment of haemophilia B. In this partnership Biovitrum had initiated the process development work that was then transferred to Biogen Idec following the acquisition.

Terms of the agreement

The agreement with Biogen Idec regarding the haemophilia projects was restructured in 2010. Under the new agreement, Biogen Idec assumed full responsibility for development and development costs, as well as manufacturing rights. In addition, the cross-royalty rates were reduced and commercial rights for certain territories were changed.



Brian O'Mahony

President, European Haemophilia Consortium (EHC)

“ We very much value the partnership, dialogue and level of understanding that exists between Sobi and the European Haemophilia Consortium. In terms of development of and improvement in therapies and standards of care for people with haemophilia, it is important that companies are not only innovative and inventive in their products; but also in the way that they work with us to understand the real needs of the patient community. There is little value in developing a product for which there is no real patient demand.

The companies also play their role, in turn, in helping patients understand the drug development process, so that they can work in partnership to ensure that any meaningful therapeutic developments are available to patients as soon as possible. Sobi is a company which sets an example in both of these respects – listening to and sharing their perspectives with the haemophilia community.”

Subject to the exercise of an option right, Sobi will have commercial rights in Europe, Russia, Turkey and certain countries in the Middle East (the Sobi territory). Biogen Idec has commercialisation rights in North America (the Biogen Idec territory) and all other regions excluding the Sobi territory (the Biogen Direct territory and the Biogen Distribution territory).

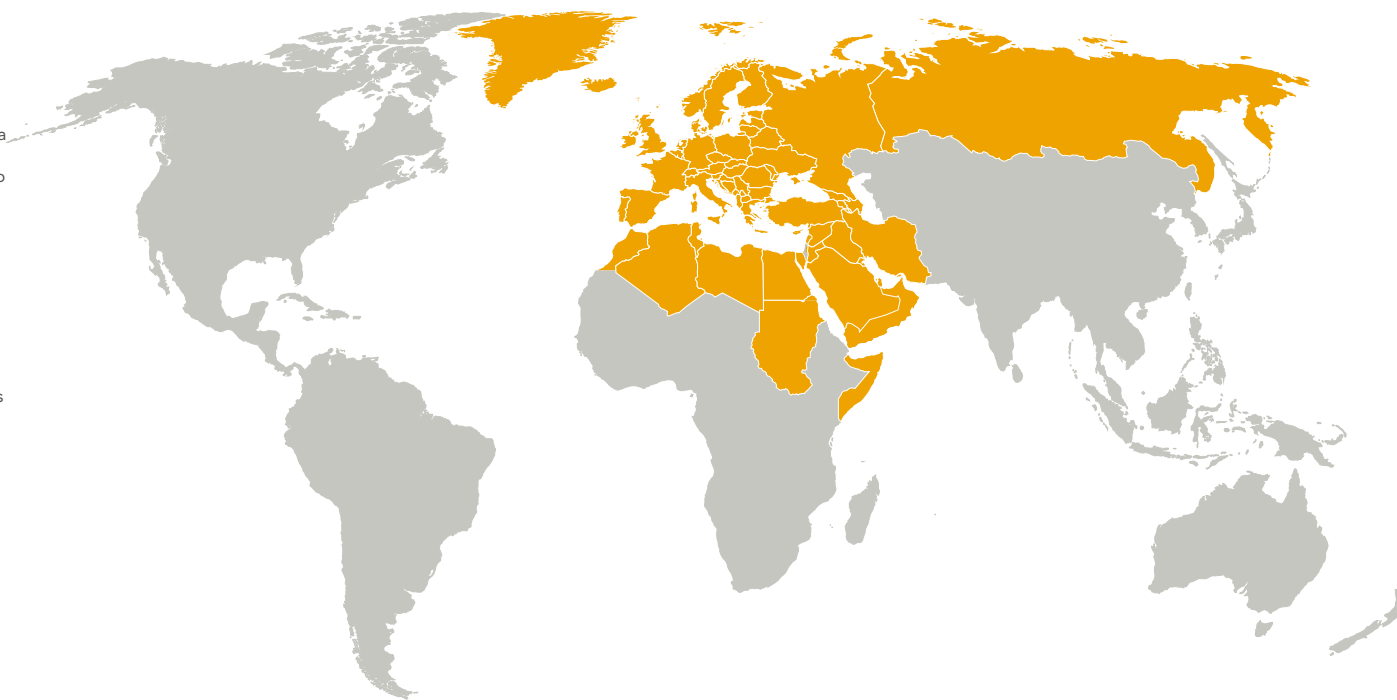
Under the terms of the option right and following

Biogen Idec's submission of a marketing authorisation application to the EMA for each programme, Sobi may opt to take over final regulatory approval, pre-launch and commercialisation activities in the Sobi territory by making a payment into escrow of USD 10.0 M per programme. Upon EMA regulatory approval of each programme, Sobi will be liable to reimburse Biogen Idec 50% of the sum of all shared manufacturing and develop-

ment expenses incurred by Biogen Idec from 1 October 2009 through the date on which Sobi is registered as the marketing authorisation holder, as well as 100% of certain development expenses incurred exclusively for the benefit of the Sobi territory. To effect Sobi's reimbursement to Biogen Idec for each programme, the cross-royalty structure for direct sales in each company's respective territories will be adjusted until the consideration is paid in full.

Sobi territory

Albania	Iceland	Romania
Algeria	Iran	Russia
Andorra	Iraq	San Marino
Armenia	Ireland	Saudi Arabia
Austria	Italy	Serbia & Montenegro
Azerbaijan	Jordan	Slovakia
Bahrain	Kuwait	Slovenia
Belarus	Latvia	Somalia
Belgium	Lebanon	Spain
Bosnia – Herzegovina	Libya	Sudan
Bulgaria	Liechtenstein	Sweden
Croatia	Lithuania	Switzerland
Cyprus	Luxembourg	Syria
Czech Republic	Malta	The Netherlands
Denmark	Mauritania	Tunisia
Djibouti	Moldova	Turkey
Egypt	Monaco	UAE
Estonia	Morocco	Ukraine
Finland	Norway	United Kingdom
France	Oman	Vatican City
Georgia	Poland	Yemen
Germany	Portugal	
Greece	Qatar	
Hungary	Republic of Macedonia	



Sobi
territories

Biogen Idec
territories



*Kiobrina – an Investigational Therapy
in Neonatology*

“ Kiobrina represents an exciting new field in Nutrition and Neonatology. Sobi is committed to innovations in the paediatric and neonatal areas where there remains a high degree of unmet need for medicines specifically developed for these patients.



Kiobrina – a unique project in Neonatology

Kiobrina, our late-stage Neonatology programme, is a recombinant human bile salt stimulated lipase (rhBSSL) developed by Sobi as an enzyme replacement therapy to improve growth in preterm infants who receive pasteurised breast milk or infant formula.

Kiobrina is a unique project in neonatal care and represents an opportunity to fill a substantial medical need – supporting preterm infants in their growth and development. Kiobrina is an important programme for Sobi and represents our commitment to the continued development of innovations in the paediatric and neonatal areas, where there is a high degree of unmet need for new treatments.

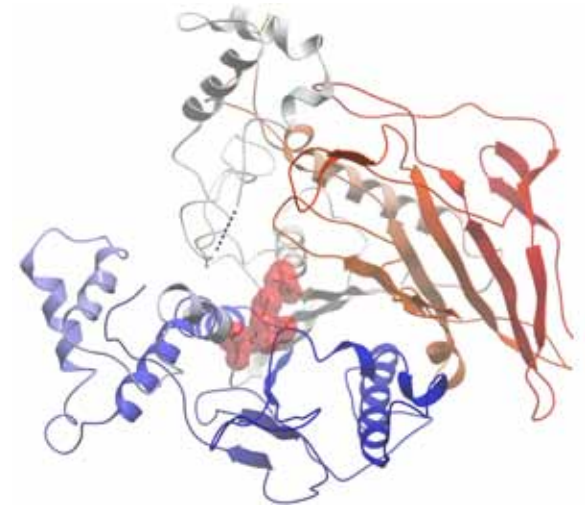
The programme is currently in phase III clinical study and actively recruiting patients. The data from the study is expected in 2014. Sobi owns the global rights to Kiobrina and continues to anticipate a potential launch for Kiobrina in late 2015.

Data from two phase II studies showed that Kiobrina significantly improved growth after only one week of treatment. The data also showed increased absorption of the fatty acids omega-3 (DHA) and omega-6 (ARA).

BSSL is a natural component of mother's milk

Growth in preterm infants fed on pasteurised breast milk or infant formula is often inadequate despite efforts to optimise nutrition. One of the key issues is the need for improvement in uptake of energy and essential fatty acids. Energy uptake is important for growth and early maturation, and long-chain polyunsaturated fatty acids (LCPUFAs) are critical for the development of the brain¹.

Preterm infants who catch up to normal growth in the first year of their life are more likely to have optimal outcomes in health and long-term development². BSSL is a natural enzyme which in early infancy is supplied to the infant through the mother's milk. BSSL is vital for the digestion and absorption of fatty acids and for the infant's ability to grow. Studies have shown that lack of BSSL is correlated with slower growth³.



The picture is based on the coordinates of the protein in PDB 1JMY.

¹ Innis S.M. Fatty acids and early human development. *Early Human development* 83, 761-766, 2007.

² Pilling et al. Growth patterns in the growth-retarded premature infant. *Best Practice & Research Clinical Endocrinology & Metabolism* vol 22, No3, 447-462, 2008.

³ Lindqvist S and Hernell O. Lipid digestion and absorption in early life: an update. *Current Opinion in Clinical Nutrition & Metabolic Care* 13:314-320, 2010.

Many infants do not receive breast milk

Every year there are more than 600,000⁴ infants born before week 32 of gestation. About half of them do not receive fresh breast milk due to the mother's medical condition or as a result of infections, cultural traditions or other reasons. BSSL is a natural bioactive component of fresh breast milk that is not present in formula and inactivated by heating, hence lacking in pasteurised milk³.

Significant medical need

The rate of growth is the single most important determinant of the length of stay in the Neonatal Intensive Care Unit (NICU)⁵. The cost per week for one patient in a NICU could range from EUR 9,500 to 28,000.

Restoring growth in preterm infants may reduce morbidity and NICU stay, and improve neurological development. Kiobrina thus has the potential to contribute both to improved health of preterm infants and substantially reduced costs in the neonatal care.

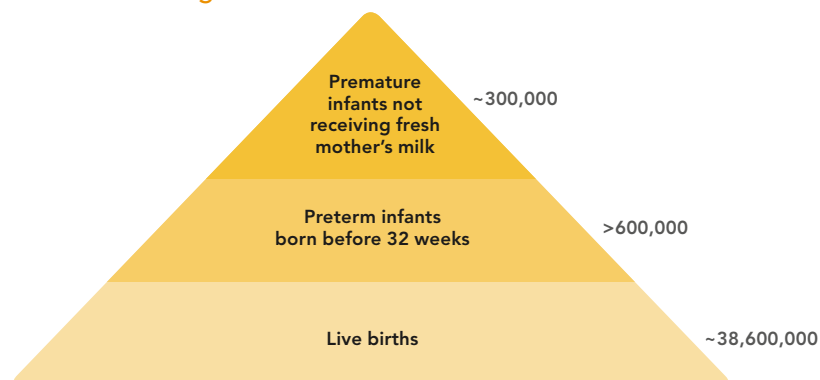
⁴ EU, Russia, US, Canada, Australia, China, Korea. MENA: Saudi Arabia, Iran, Israel, Egypt, Turkey. Latin America: Brazil, Mexico, Argentina, Venezuela.

⁵ American Academy of Pediatrics Committee on Fetus and Newborn. Hospital Discharge of the High-Risk Neonate. Pediatrics. 2008.



Every year there are more than 600,000 infants born before week 32 of gestation. About half of them do not receive fresh breast milk due to the mother's medical condition or as a result of infections, cultural traditions or other reasons.

Number of patients* not receiving fresh mother's milk



* EU, Russia, US, Canada, Australia, China, Korea. MENA: Saudi Arabia, Iran, Israel, Egypt, Turkey. Latin America: Brazil, Mexico, Argentina, Venezuela.



Dr Charlotte Casper

Investigator and European coordinator on Kiobrina phase III clinical trial

“My work with Sobi is in quite a new field in Nutrition and Neonatology. We know that good growth in premature infants is connected to good developmental outcome and early home discharge, so it is important to have good growth after birth when you are dealing with premature babies. But until now we have been focused on how many calories we give infants in order to achieve optimal growth. What is new with Kiobrina is that we are focusing on biological activity of the milk; it is a very exciting development in Neonatology and Nutrition.

Sobi have been a very open and understanding partner. Neonatology is a very difficult area for research and clinical trial development and we are dealing with a very new area of Neonatology and Nutrition. Sobi understand that, they listen and adapt and are flexible in their approach to this area.”

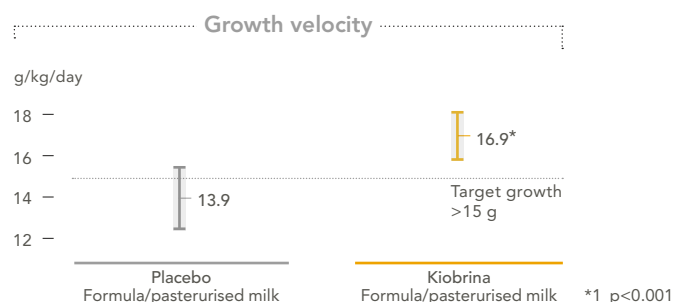
Positive phase II data

The phase II Kiobrina programme was designed as two parallel prospective randomised double-blind crossover studies where Kiobrina, or placebo, was administered in pasteurised milk, or preterm infant formula, during one week of treatment. All infants were born before week 32 of gestational age. As shown in the graph below, a statistically significant improvement in growth velocity was observed. The mean increase in growth velocity was 20% greater with Kiobrina (rhBSSL) than with placebo. The safety profile was comparable to placebo⁶.

Pivotal phase III study

The on-going phase III study is designed to evaluate the efficacy, safety and tolerability of Kiobrina. The primary endpoint is growth velocity after 4 weeks. First patients were enrolled in July 2011 and the last patient is expected to be enrolled in the study in the first half of 2013, with a follow-up period of twelve months. The study is expected to enroll patients in approximately 70 centres across 10 European countries.

Positive phase II data



The phase II Kiobrina programme was designed as two parallel prospective randomised double-blind crossover studies where Kiobrina, or placebo, was administered in pasteurised milk, or preterm infant formula, during one week of treatment. All infants were born before week 32 of gestational age. As shown in the graph above, the infants that were given Kiobrina grew 20% more than preterms on placebo.

⁶ Carnielli VP et al. A combined analysis of data from two studies comparing rhBSSL (recombinant human bile salt stimulated lipase) and placebo added to infant formula or pasteurised breast milk in preterm infants. Pediatric Academic Societies, Abstract, 2011.

Core Products in key Therapeutic Areas: Inflammation and Genetics



Core Products are proprietary products for which Sobi has global or regional rights and all are products with high unmet medical needs. Currently, Sobi's Core Products are concentrated across two of the company's key Therapeutic Areas: Kineret within Inflammation and Orfadin, Ammonaps and Ammonul within Genetics.

Kineret and Orfadin are Sobi's two largest products in terms of revenue and both reflect Sobi's commitment to developing new products and to expanding existing products to address paediatric indications. In 2012, sales of Kineret for the full year increased by 15%, and sales of Orfadin for the full year increased by 13%. These products accounted for approximately 44% of the company's total revenues. Overall revenues for Core Products in 2012 were up 14% to SEK 925.1 M (812.3).

Focus on growth

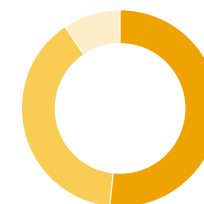
Sobi's near-term focus is to maintain growth in the operating business driven by the Core Products in our key Therapeutic Areas. There are opportunities to grow in existing markets as well as to further establish these products in newer markets including the US, Russia, Central and Eastern Europe and in the Middle East. Increased life-cycle management activities are also expected to drive growth for both Kineret and Orfadin going forward.

Core Products

SEK M	2012	2011	2010
Kineret	484.7	422.0	422.3
Orfadin	356.7	315.7	321.8
Other products	83.7	74.6	76.8
Total	925.1	812.3	820.9

Revenues by product, 2012

%



■ Kineret, 52% ■ Orfadin, 39% ■ Other products, 9%



Inflammation: Kineret

Kineret is a recombinant protein drug first approved in 2001 for the reduction of signs and symptoms, and to slow the progression of structural damage in moderately to severely active Rheumatoid Arthritis (RA), in adult patients who have failed one or more disease modifying antirheumatic drugs (DMARDs).

Kineret blocks the biologic activity of IL-1 α and IL-1 β by competitively blocking Interleukin-1 (IL-1) binding to the Interleukin-1 type 1 (IL-R1) receptor, which is expressed in a wide variety of tissues and organs. IL-1 is a key mediator of inflammation and plays a prominent role in autoinflammatory diseases in both adults and children. Kineret is also increasingly being prescribed on a named patient basis as a leading treatment for several rare diseases within both the paediatric and adult inflammatory segments. Sobi acquired the global marketing rights to Kineret from Amgen in 2008.

Evolving focus on paediatric indications

Sobi is focused on expanding the indication for Kineret to include certain paediatric, orphan indications. Sobi announced the filing for an extended label for Kineret in the US to include the Neonatal-Onset Multisystem Inflammatory Disease (NOMID) indication in children and adults, which was subsequently approved by the US Food and Drug Administration (FDA) in December 2012, following a priority review. Kineret is the first and only FDA-approved treatment for NOMID, the most severe form of Cryopyrin-Associated Periodic Syndromes (CAPS). Kineret was approved under an Orphan Drug designation. In March 2012 the European Medicines Agency (EMA) adopted the Paediatric Investigation Plan (PIP) for Kineret including both CAPS and Systemic Juvenile Idiopathic Arthritis (SJIA), another autoinflammatory disease responsive to IL-1 blockade.

In November 2012, Sobi filed an application with the EMA for an expanded label for Kineret to include the CAPS indication in children and adults. Sobi's efforts to expand the label for Kineret to include the CAPS indication are indicative of our growing commitment of making innovative products available to children with debilitating and often life-threatening illnesses.

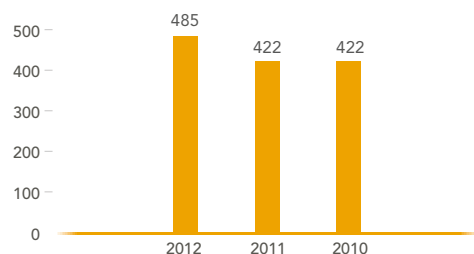
Market potential

RA affects about 1% of the population in the EU and the US. Epidemiological forecasts indicate that the number of patients with RA in the seven largest markets¹ will increase to 5.2 million in 2019, from approximately 4.7 million in 2010. It is more common in women than in men by about a two-to-three ratio. Generally RA occurs between the ages of 40 and 60. Today, 60% of the patients are diagnosed and about 30% of them, i.e. approximately

¹ Source: Datamonitor; France, Germany, Italy, Spain, Japan, US and Great Britain.

Revenues, Kineret 2010–2012

SEK M



Total reported sales of Kineret increased by 15% to SEK 484.7 M (422.0) and with 14% in constant exchange rates.

800,000 patients are treated with biological therapies. In up to 25% of high-risk RA patients with co-morbidities and who have taken other medications for their RA that have not worked, Kineret is a possible option.

CAPS are a group of rare autoinflammatory diseases with an incidence estimated to be 1:1,000,000 worldwide.

Growing interest in the role of IL-1

There is a growing awareness across research and clinical communities of the mechanism behind inflammation and of the role of IL-1. IL-1 has been shown to be a major contributor in both localised and systemic inflammation in the body.

Diseases due to chronic inflammation may result in loss of function in one organ, a specific tissue or

throughout large parts of the body. These diseases range from very rare autoinflammatory conditions such as CAPS or TNF α Receptor-Associated Periodic Syndromes (TRAPS), to rheumatoid conditions such as RA, Still's disease, osteoarthritis and myopathies. Recently more common disorders such as gout, diabetes and atherosclerosis have also been associated with IL-1-related chronic inflammation².

Transfer of production

The transfer of production of Kineret from Amgen in the US to a contract manufacturer in Europe was initiated in 2010. This transfer will lead to lower production costs from mid-2013 and beyond.

² www.nature.com/reprintcollections/interleukin-1



A patient presenting with fever, rash, and inflammatory symptoms is not rare, but a diagnosis of NOMID. Kineret is now the first and only FDA-approved treatment for NOMID, the most severe form of CAPS. CAPS is very rare, found in about one in a million people. Sobi is committed to improve the lives of rare disease patients and their families.

Kineret

Indication 1: In the EU Kineret is indicated for the treatment of the signs and symptoms of Rheumatoid Arthritis (RA) in combination with methotrexate in adults with an inadequate response to methotrexate. In the US Kineret is indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active RA, in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs).

RA is a chronic inflammation disease caused by the immune system and resulting in chronic and disabling pain and stiffness in the joints. The disease affects about 1% of the population in the EU and US.

Indication 2: In the US Kineret is indicated for the treatment of people with the severe form of Cryopyrin-Associated Periodic Syndromes (CAPS) called Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

In the EU, Sobi has filed an application with the European Medicines Agency (EMA) for an expanded label for Kineret to include the CAPS indication in children and adults.

CAPS are a group of rare inherited autoinflammatory diseases caused by autosomal dominant mutations in a gene called NLRP3. CAPS are characterised by uncontrolled overproduction of IL-1 β . Interleukin-1 (IL-1) induces a number of inflammatory responses such as

fever, pain sensitisation, bone and cartilage destruction and acute plasma protein responses. In the most severe form, NOMID, it is associated with increased mortality and fever, rash, chronic aseptic meningitis, sensorineural hearing loss, craniofacial abnormalities, and bone lesions. NOMID is also called chronic infantile neurologic cutaneous and arthritis syndrome (CINCA) in Europe.

Product description: Kineret (anakinra) is a recombinant protein drug used for home treatment by patients suffering from NOMID, the most severe form of CAPS, and RA.

Geographic market: Global. Sobi has a global licence for the manufacturing and sales of Kineret.

New research collaboration with Affibody AB within the Interleukin-1 field

In July 2012 Sobi signed a research collaboration and option agreement with the Swedish biotech company Affibody AB for the discovery and development of novel treatments for inflammatory diseases where Interleukin-1 (IL-1) is implicated.

The research will be based on Affibody AB's proprietary technology platforms and includes five different protein targets within the IL-1 field. All targets are key proteins involved in the regulation of human immune and inflammatory processes. One project is a lead candidate for the inhibition of IL-1 beta in the preclinical phase, and the others are in discovery.

The agreement covers an initial 2-year period during which Sobi has an option to enter into a licensing agreement with worldwide exclusive rights to selected development projects.

The collaboration provides a good commercial fit with Sobi's existing work in the IL-1 field, with Kineret, within our key Therapeutic Area of Inflammation, and with the company's strategic biologics development capabilities. The research will be carried out by both companies and will be led by a joint steering committee. Each company will bear their own costs.



David Beijer
CEO, Affibody AB

“ We have two separate agreements with Sobi, the most recent put in place this year – they have really become our partner of choice. We have a nice fit with them; they ideally complement our own core competencies. In terms of our regular interaction with their scientists, we are really pleased – they are a genuine pleasure to work with. In terms of business development and negotiating these collaborations, there was a clear mutual understanding; we both saw the opportunities to collaborate and there was the ability to move quickly. The process throughout was very transparent. Sobi are definitely a strong biopharmaceutical developer in niche indications and biologics.”



Orfadin

“ At Sobi, we are committed to improving the quality of life for children and dedicated to developing and delivering products that will help restore vitality and hope to young lives. Orfadin has saved the lives of hundreds of children with hereditary tyrosinemia type 1 around the globe.



Genetics: Orfadin

Orfadin, an orally administered small molecule drug, is used for the treatment of Hereditary Tyrosinemia type 1 (HT-1), a rare genetic disorder, which can cause liver failure, kidney dysfunction and neurological problems. Orfadin was commercialised by Sobi after its initial development by two Swedish scientists in the early 1990s, and the launch of drug, a lifesaving treatment for patients with HT-1, signalled the beginning of Sobi's commitment to developing innovative therapies for children with lifesaving conditions. Today, Orfadin has saved the lives of hundreds of children around the globe. Before Orfadin was discovered, these patients were severely disabled and 70–90% of them died during the first 10 years of life.

Market potential

Worldwide, HT-1 affects about one newborn child in 100,000, although there are geographical variations. Several countries are beginning to include HT-1 in their

newborn screening programmes. The US has included HT-1 in newborn screening panels in 48 states, and earlier diagnosis of patients and treatment initiation is also gaining ground in Europe where newborn screening for HT-1 is also making progress.

During 2012 all main markets showed strong growth, driven by patient weight growth and identification of new patients. Increased focus and resources in the Middle East, North Africa and Russia has resulted in increased patient access to Orfadin. In Russia new legislation came into effect during the latter part of 2012 granting all HT-1 patients reimbursement for treatment with Orfadin.

Liquid formulation

Sobi is developing a liquid formulation of Orfadin, which will facilitate precise dosing for children and should help to support compliance. At approval the new Orfadin formulation would also extend the orphan designation in Europe through

2017. The European Medicines Agency (EMA) approved Sobi's Paediatric Investigation Plan in March 2012.

A significant step forward for HT-1 patients

During 2012 two significant milestones were achieved for HT-1 patients.

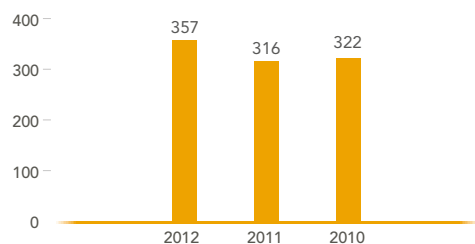
Building real-life evidence of the benefits of rare disease treatments such as Orfadin and sharing best practice and evidence based recommendations is critical to the optimal provision of care for patients with rare diseases.

During the year a clinical study of the outcomes from long term treatment with Orfadin was published, documenting the value of early diagnosis and treatment.

In January 2013, for the first time, a group of international experts on HT-1 published treatment recommendations for the optimal care of the disease. This represents a major support resource for all caregivers, who in many cases treat only a small number of HT-1 patients.

Revenues, Orfadin 2010–2012

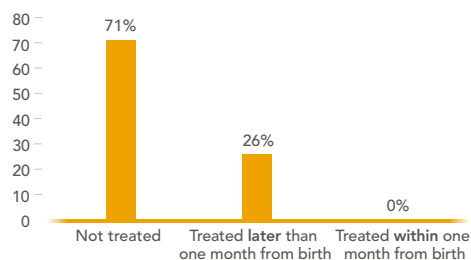
SEK M



Total reported sales of Orfadin increased by 13% to SEK 356.7 M (315.7) and with 14% in constant exchange rates.

The importance of early detection and treatment with Orfadin

% of patients requiring liver transplant for survival



Patients were followed for more than five years to document long-term outcome.

Ref: J. Larochelle et al. / Molecular Genetics and Metabolism 107 (2012) 49–54

Orfadin

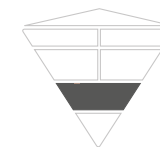
Indication: Hereditary Tyrosinemia type 1 (HT-1).

In the case of Hereditary Tyrosinemia, the body cannot fully break down the amino acid tyrosine. Toxic substances are formed and accumulate in the body, and can cause liver failure, kidney dysfunction and neurological problems. In the most common form of the disease, symptoms arise within the first 6 months of the child's life.

Product description: Orfadin (nitisinone) blocks the breakdown of tyrosine and thereby prevents the toxic substances to form. However, tyrosine remains in the body and the patient must be on a special diet in addition to the Orfadin treatment. The diet includes a low content of tyrosine and phenylalanine.

Geographic market: Global.

Partner Products



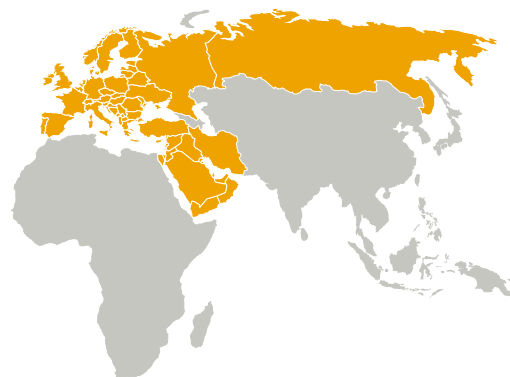
Sobi Partner Products (SPP) is focused on providing mid-sized pharmaceutical and biotech companies with an integrated solution for the commercialisation of their products. Partner Products is specialised in handling a large number of products with smaller revenues in a cost-efficient way. Today Sobi Partner Products has more than 20 partners.

The central purpose of Sobi Partner Products is to create value for our partners and Sobi while at the same time delivering innovative therapies for patients with niche and rare diseases.

The Partner Product vision is “To be the preferred partner to small and mid-size biotech and pharma companies; making speciality medicines available to patients with high unmet medical needs in Europe, Middle East, and Russia.”

Sobi Partner Products – competitive advantage

Sobi has more than 25 years experience in promoting niche and speciality products based on partnerships. Our competitive advantage is the ability to offer a targeted and cost-effective method of delivering lifesaving therapies to patients by leveraging Sobi’s existing infrastructure and specialised knowledge of managing partnership structures in an effective way.



The Partner Product vision is “To be the preferred partner to small and mid-size biotech and pharma companies; making speciality medicines available to patients with high unmet medical needs in Europe, Middle East, and Russia.”

We apply an integrated “go to market” approach within several therapy areas, which address important unmet needs. We can offer services spanning from Named-Patient Use (NPU) programmes, distribution, pricing and market access to marketing and commercialisation.

Sobi’s ability to offer several products for specific segments in this way has become an advantage as it facilitates access to the specialist physicians, nurses and other customers. At the core of our efforts is our belief that every patient must be cared for and provided with optimal treatment for their condition. By providing our partners with a unique distribution platform, we are able to make niche medicines available to patients across Europe.

Areas of therapeutic focus

Our broad networks within our Partner Products areas of therapeutic focus facilitate the introduction of new products into the markets we serve. Our service offering

Partner Products

SEK M	2012	2011	2010
Current portfolio	407.2	373.6	346.0
Co-promotion	12.0	105.0	100.3
Discontinued products	0.0	45.0	118.3
Total	419.2	523.6	564.5



Sobi has a long heritage in promoting niche and speciality products in collaboration with partnerships. Our expertise, gained through over 25 years experience, enables us to offer our partners a targeted and cost effective method of delivering lifesaving therapies to patients.

includes the implementation of strategies for regulatory approval, pricing and reimbursement, unlocking sales potential through our commercial, medical and market access capabilities and preparing the market for delivery of associated and/or follow-on products.

Geographical presence in Europe, Middle East and Russia

We take pride in our ability to offer a nimble and flexible service offering while providing full European coverage and wholly owned subsidiaries in Russia and Middle East. The Nordic countries are Partner Products strongholds, where we are the market leader in providing medicines for niche and rare diseases within a broad range of indications. We have a successful track record also in more challenging areas such as Central and Eastern Europe; Partner Products had strong growth in the Central Eastern European territory during 2012.

Sobi Partner Products offer a broad range of capabilities

- 25 years experience and an excellent track record within the niche pharmaceutical segment in Europe.
- A well-established local pricing and market access competence.
- Well developed Named-Patient Use capabilities.
- An effective and complete logistic network.
- A highly trained and experienced key account managers and sales force across Europe.
- A lean organisational structure, allowing us to act quickly upon opportunities.
- Broad key opinion leaders and customer network within key Therapeutic Areas.
- Local as well as central medical affairs capabilities.

Partner Products' areas of therapeutic focus

- Haematology
- Oncology
- Emergency medicines and antidotes
- Infectious diseases and speciality care

Products by Therapeutic Area (examples)

Haema- tology	Oncology	Emergency medicines and antidotes	Infectious diseases and speciality care
Defibrotide	Aloxi	Cyanokit	Betapred
Erwinase	Kepivance	Fomepizole	Buronil
Ferriprox	Multiferon	ViperaTAb	Mezavant
Willfact	Removab		
	Yondelis		

Our partners' products are important to us and we offer our partners as full and as unwavering commitment to making their products available to the patients who urgently need them in the markets we serve.

2012 developments

Total sales of Partner Products for the full year amounted to SEK 419.2 M (523.6), including co-promotion for ReFacto AF/BeneFIX and discontinued products in the amount of SEK 12 M (150). Adjusted for these items and for currency effects, total revenues increased by 10%.

The Partner Product portfolio was enhanced during the last 12 months with an extension of the Promixin® deal to include the intravenous formulation in Germany. The agreement duration was also prolonged. Sobi also entered a partnership with Gentium, regarding Defibrotide® in the Nordic countries. Furthermore, Sobi and Helsinn Group signed two new partnership deals: the first regarding an oral formulation of Aloxi® for the Nordic countries; and the second related to the future commercialisation of the new Aloxi combo (netupitant-palonosetron) product for the same territory.

The Buronil® cooperation with Lundbeck ended in September 2012, but Sobi have continued to manage the product in our territory on behalf of the new owner, Medilink. Ongoing discussions regarding several new partner deals are ongoing, which hopefully will materialise during the beginning of 2013.

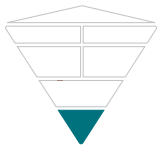


Dr Riccardo Braglia
CEO, the Helsinn Group

“ In 2006 Helsinn Group started the partnership with Sobi, through a licensing agreement granting Sobi the rights for distributing Helsinn's Aloxi, a new generation antiemetic for patients under cancer treatment, in the Nordic countries. The excellent performance achieved with Aloxi resulted in the extension of our partnership and business cooperation in the Cancer Supportive Care franchise with new agreements aimed at improving the quality of life of cancer patients in Northern Europe.”

Some of our partners





ReFacto AF

ReFacto AF/XYNTHA® is a recombinant protein drug for the treatment of haemophilia A. Injections of factor VIII and proper healthcare allow most persons with haemophilia A to live a normal life. ReFacto AF is the trademark for the product in Europe and XYNTHA is the registered trademark in the US, Canada, Australia and other select global markets. BeneFIX is a recombinant protein drug for the treatment of haemophilia B.

Haemophilia is a genetic inherited disorder in which the ability of the blood to coagulate is reduced due to the lack of a specific protein in the blood. The two most common forms are haemophilia A, where there is a lack of coagulation factor VIII, and haemophilia B, where there is a lack of coagulation factor IX.

Long-standing partnership

Since 1998, Sobi has had a long-standing partnership with Pfizer. For the global market Sobi manufactures ReFacto AF/XYNTHA, a treatment for haemophilia A sold worldwide by Pfizer. As the global supplier of the drug substance, Sobi receives manufacturing fees as well as royalties on Pfizer's sales of ReFacto. The active ingredient is produced in Sobi's Good Manufacturing Practice (GMP) biologics facility in Stockholm, Sweden.

Consistent growth

Total ReFacto manufacturing and royalty revenues for the full year amounted to SEK 565.8 M (575.0). Total manufacturing revenues for the full year declined by 3% to SEK 436.0 M (451.7). The figure for 2011 includes valida-

tion batch deliveries to the amount of SEK 42.0 M. Total royalties for the full year increased by 5% to SEK 129.8 M (123.3).

Supply agreement extended to 2020

In February 2012, Sobi announced the extension of the supply agreement with Pfizer through to 2020 with an option to extend further.

At the same time it was also agreed that Sobi would return the co-promotion rights for ReFacto and BeneFIX in the Nordic region as of January 2012 in exchange for a payment of SEK 307.5. The co-promotion rights were due to expire in 2016.

Production improvements

In 2011 Sobi made a significant upgrade to the downstream processing capacity in the Stockholm facility, increasing capacity as well as efficiency in the process. This has been a significant driver of gross margin improvement in the latter half of 2012 and is a component of our long-term capacity efforts in the facility.

ReFacto Manufacturing

SEK M	2012	2011	2010
Manufacturing revenues	436.0	451.7	388.0
Royalty revenues	129.8	123.3	109.7
Total	565.8	575.0	497.7

Summary – Sobi's Product portfolio

	PRODUCT/PROGRAMME	THERAPEUTIC AREA
Core Products		
Proprietary products or products where Sobi has global or regional rights.	Kineret®	Inflammation
	Orfadin®	Genetics & Metabolism
	Ruconest™	
	Ammonaps®	
	Ammonul®	
Partner Products		
Speciality pharmaceuticals, sold through license or distribution agreements with more than 20 partners. Sobi is market leader in the Nordic region and also has a long standing presence in the Baltic States and Central and Eastern Europe.	Willfact®	Haematology
	Erwinase®	
	Ferriprox®	
	Defibrotide®	
	Kepivance®	Oncology
	Yondelis®	
	Aloxi®	
	Multiferon®	
	Removab®	
	ViperaTAb™	Emergency medicines
	Cyanokit®	
	Fomepizole	
	Mezavant®	Other
	Buronil	
	and other products	
ReFacto Manufacturing		
Manufacturing of drug substance for Pfizer and royalties.	ReFacto AF®/XYNTHA®	Haemophilia
Pipeline Programmes		
Research and development focused on recombinant protein drugs in late preclinical and clinical phase for specialist indications.	rFVIII Fc (haemophilia A) in Phase III	Haemophilia
	rFIX Fc (haemophilia B) in Phase III	
	Kiobrina (improves growth in premature infants) in phase III	Neonatology
	Reformulated Bumetanide (diuresis and seizures in neonates) in phase II	

Core Products, share of total revenues, 2012

48%

Partner Products, share of total revenues, 2012

23%

ReFacto Manufacturing and royalties, share of total revenues, 2012

29%

Annual Report 2012

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Directors' report

Highlights 2012

- Total revenues increased to SEK 1,923.2 M (1,910.8). Adjusted for currency effects and discontinued products, revenues increased by 8%.
- Revenues from Core Products increased by 14% adjusted for currency effects.
- Gross margin increased to 54% (51), driven by efficiency gains in production, and completion of technology transfer for Kineret®. Operating expenses declined by 5% reflecting the ongoing streamlining of operations.
- Other operating revenues and expenses, was positively affected by proceeds of SEK 307.5 M from the divestment of the co-promotion rights for ReFacto AF®/ BeneFIX® in the Nordic region back to Pfizer.
- Operating profit (EBITA), before amortization of intangible assets and non-recurring items, was SEK 404,1 M (127,3).
- Profit for the period including write-downs amounted to SEK –100.9 M (17.9), corresponding to earnings per share of SEK –0.38 (0.07). 2011 includes activation of tax carry forward that have been utilized during the year.
- Cash flow from operations amounted to 405.6 M (102.9).
- Sobi issued a 5-year senior bond loan in the amount of SEK 600 M.
- Sobi and Biogen Idec announced positive top-line results from A-LONG and B-LONG phase III clinical studies of the companies' long-lasting recombinant coagulation factors, rFVIII Fc and rFIX Fc. Both were effective in the control and prevention of bleeding, in routine prophylaxis and perioperative management, and were generally well-tolerated.

Key figures

SEK M	2012	2011
Total revenues	1 923.2	1,910.8
Gross profit	1 040.4	974.6
Gross margin	54%	51%
Operating profit before amortisations and non-recurring items (EBITA)	404.1	127.3
Operating profit before non-recurring items (EBIT)	–17.5	–238.2
Profit/loss	–100.9	17.9
Earnings/loss per share, SEK	–0.38	0.07

Please see page 42 for a five year summary overview of revenues, costs and results.

Sobi's operations

Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Inflammation and genetic diseases, with three late stage biological development projects within Haemophilia and Neonatology. We also market a portfolio of specialty and rare disease products for partner companies.

In 2012 the company generated revenues through:

- Production of the drug substance for ReFacto AF®/ XYNTHA® and royalties from Pfizer's global sales of ReFacto AF/XYNTHA; and
- Product sales primarily in Europe and North America. Product sales include proprietary products and products sold through distribution and licensing agreements.

Revenues

Total revenues in 2012 increased to SEK 1,923.2 M (1,910.8). 2011 included revenues from co-promotion for ReFacto AF/ BeneFIX and discontinued products of SEK 150 M. Adjusted for these items and for currency effects, total revenues increased by 8%.

Sales of Core Products increased by 14%, the current Partner Product portfolio by 10%, while growth in ReFacto AF manufacturing and royalties showed a slight decrease of 2% – all after adjustments for currency effect.

SEK M	2012	2011
Core products	925.1	812.3
Partner products	419.2	523.6
ReFacto	565.8	575.0
Other revenues	13.1	0.0
Total revenues	1,923.2	1,910.8

Non-recurring items

Non-recurring items in 2012 amounted to SEK –37.1 M (–80.4) and related mainly to the amended agreement with the sellers of Arexis, signed on 30 March 2012, see note 36 och 37.

Gross margin

The gross margin, adjusted for balance sheet write-downs, increased to 54% (51) as a result of higher utilisation of the plant in Stockholm and of efficiency improvements following the scale-up of the downstream production process for ReFacto AF, and the completion of the technology transfer process for Kineret.

The gross profit for 2012 included one-time costs of SEK 64 M relating to the transfer of Kineret production to Germany, a milestone payment of SEK 13.1 M received for Orfadin® in Japan, and co-promotion revenues of SEK 12.0 M (105.0).

Expenses

Operating expenses decreased by 5% to SEK 941.2 M (994.6). The decrease was the result of conscious cost control.

Sales and administrative expenses increased to SEK 961.2 M (804.4). The increase was driven by investment in commercial infrastructure and geographic expansion. Research and development expenses decreased by 28% to SEK 401.6 M (555.7), with increased expenses in the phase III programme for Kiobrina® that was offset by savings within R&D from the restructuring measures implemented in 2011.

Non-recurring items were SEK –37.1 M (–80.4) for the full year, and include SEK –34 M relating to the amendment in the first quarter of the purchase agreement with the sellers of Arexis.

Other operating revenues and expenses amounted to SEK 304.9 M (147.4) and include proceeds of SEK 307.5 M from the divestment of the co-promotion rights for ReFacto AF/ BeneFIX in the Nordic region to Pfizer as of 15 February 2012.

Profit

Operating profit (EBITA) before amortisation of intangible assets and non-recurring items amounted to SEK 404.1 M (127.3). Amortisation of intangible assets amounted to SEK 421.6 M (368.1). The increase relates to the fact that the company has evaluated the future potential of Multiferon®, and the management decided to write down the tangible and intangible asset value of SEK 162 M. Operating profit (EBIT) amounted to SEK –54.6 M (–318.6).

Net financial items

Net financial items for the full year 2012 amounted to SEK –50.5 M (–52.2). Financial income of SEK 7.3 M (10.5) is primarily as a result of gains related to currency fluctuations and interest income from cash balances. Financial expenses of SEK 57.8 M (62.7) are mostly related to interest related expenses.

Taxes

Sobi has continued to utilise its tax loss carry forward. The company's tax rate therefore deviates from the Swedish tax rate. In due to the changed tax rate (22%) from 2013 the deferred tax are affected with SEK 77.6 M. The tax expense for the year was SEK –18.9 (5.9) and deferred tax amounted to SEK 23.2 M (394.7).

Other comprehensive income and expenses

Net other comprehensive income and expenses amounted to SEK 5.7 M (0.2) and consist mostly of the one-time currency loss when rolling the Amgen milestone of USD 55M.

Cash flow and investments

Cash flow from operations amounted to SEK 405.6 M (102.9). Net non-cash items amounted to SEK 468.6 M (100.4) and were mainly attributable to amortisation and write-downs of product rights and licences, only slightly offset by reversal of deferred taxes.

Cash flow from investing activities amounted to SEK –67.3 M (–43.7) and was mostly attributable to investments in intangible assets.

Key figures – 5 years

SEK M	2012	2011	2010	Proforma 2009 ²	2009	2008
Total revenues	1,923.2	1,910.8	1,906.7	2,065.6	1,297.0	1,140.6
Adjusted profit/loss for the period	–63.8	98.3	–16.7	–	32.4	60.4
Cost of goods and services sold	–882.8	–936.3	–685.7	–664.3	–375.7	–264.7
Research and development expenses	–401.6	–555.7	–558.8	–603.1	–569.4	–670.6
Operating profit/loss	–54.6	–318.6	–10.3	72	16.2	–386.2
Financial items – net	–50.5	–52.2	–82.2	–	16.3	20.2
Profit/loss for the period	–100.9	17.9	–104.5	–	32.4	–335.4
Earnings/loss per share ¹ , SEK	–0.38	0.07	–0.47	–	0.29	–3.28
Earnings/loss per share after full dilution ¹ , SEK	–0.38	0.07	–0.47	–	0.29	–3.28
Number of shares	265,227	265,227	212,181	–	50,396	49,815
Equity ratio	76.6%	74.1%	61.4%	–	48.2%	49.8%

¹ Earning per share have been adjusted for the rights issue in June 2011.

² Proforma figures due to the acquisition of Swedish Orphan.

A decrease in working capital had a positive impact on cash flow of SEK 37.9 M (–15.4 M). Inventories declined, mainly for ReFacto AF and Kineret, and this was offset by a reduction in current liabilities, mainly trade payables, which had a negative impact on working capital.

Financial position

Cash and cash equivalents as of 31 December 2012 amounted to SEK 457.0 M (219.1).

The remaining bank loans were replaced by a 5-year SEK 600 M senior bond with maturity in 2017 issued on 26 June 2012. When issued, the bond had a floating interest of 3 months Stibor + 500 bps, which was swapped to a fixed rate of 6.9%. The bond has replaced Sobi's existing term facility and has improved the company's financial flexibility, as well as extended the maturity profile of Sobi's debt. The loan is listed on NASDAQ OMX Stockholm.

Net debt as of 31 December 2012 amounted to SEK 143 M, compared to SEK 481 M per 31 December 2011.

Equity

Consolidated shareholders' equity as of 31 December 2012 amounted to SEK 4,837.9 M, compared to SEK 4,963.4 M as of 31 December 2011.

The Parent company

Revenues for the Parent company in 2012 amounted to SEK 1,640.5 M (1,170.1). Operating profit was SEK 265.4 M (523.3). Net profit was SEK 31.6 M (546.2). The main variance between

the years is driven by discrete actions: in 2011, the result was positively affected by an internal transfer of business. In 2012, the driver was the proceeds from the sale of the Nordic co-promotion rights for SEK 307.5 M to Pfizer.

Cash and cash equivalents and short-term investments as of 31 December 2012 amounted to SEK 276.5 M (175.0). Shareholders' equity as of 31 December 2012 amounted to SEK 5,607.4 M (5,530.0), the variance being driven by the profit for the year as well as effect of completed mergers.

Sales by business area and geographical region

Core Products

The Core Product portfolio (Kineret, Orfadin, Ammonaps®, Ammonul® and Ruconest®) showed a 14% increase to SEK 925.1 M (812.3). The positive top-line growth was achieved by a combination of volume and value gains, and was primarily driven by the sales momentum in Kineret and Orfadin.

Total sales of Kineret increased by 15% to SEK 484.7 M (422.0) as a result of growth in both North America and Europe.

Total sales of Orfadin increased by 13% to SEK 356.7 M (315.7). Sales were driven by growth in North America and most European markets, and by accelerated growth in the Middle East, Russia and North Africa. However, the 2012 sales are, in part, the result of some phasing effects from the fourth quarter of 2011 to the first quarter of 2012, that contributed to the very strong growth rate for the 2012 fiscal year.

Currency fluctuations for the full year were negligible for Kineret as well as for Orfadin, as the negative impact on EUR-based sales was offset by a positive impact from USD-based sales.

Partner Products

Total sales of Partner Products amounted to SEK 419.2 M (523.6). The Partner Product portfolio has undergone significant changes and refocus during 2011 and 2012, making a comparison on a year-on-year basis of the portfolio irrelevant. Total sales for Partner Products in 2012 included co-promotion revenues of SEK 12.0 M (105.0) and no revenues from discontinued products (45.0). Adjusted for these items and for currency effects, total revenues in the Partner Product portfolio increased by 10%. The key growth drivers in the portfolio were Aloxi®, Mezavant® and Defibrotide®.

Total sales of Kepivance® increased by 6% to SEK 82.3 M (77.9). The geographic expansion of Kepivance continued and the product was launched in Canada 2012. Total sales of Yondelis® increased by 12% to SEK 55.4 M (49.4).

The Partner Product portfolio was expanded 2012 with new agreements for Promixin® in the Nordic countries, Germany and Central and Eastern Europe, for Buronil® in the Baltic States,

Austria, the Czech Republic and Portugal, and for a new product based on netupitant-palonosetron in the Nordic countries.

ReFacto AF

Total ReFacto AF manufacturing and royalty revenues amounted to SEK 565.8 M (575.0). Total manufacturing revenues declined by 3% to SEK 436.0 M (451.7). The revenue for 2011 included validation batch deliveries in the amount of SEK 42 M, even adjusting for the validation batches, revenues from manufacturing, excluding royalties, grew by 6% during 2012.

Total royalties increased by 5% to SEK 129.8 M (123.3). In February 2012, Sobi and Pfizer extended their supply agreement for ReFacto AF/XYNTHA until 31 December 2020, with an option to further renew.

Geographical region

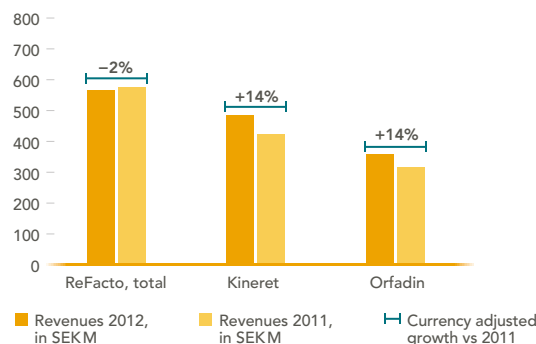
Revenues in the Nordic region (excluding ReFacto manufacturing and related royalty revenues) have decreased by 29% to SEK 304.3 M (427.9).

The decrease was primarily driven by changes in the Partner Product portfolio, i.e., the:

- Sale of co-promotion revenues of Mimpara® that were sold back to Amgen 2011; and
- Sale of co-promotion revenues of ReFacto AF/BeneFIX sold back to Pfizer in 2012;
- Expiration of the distribution contract with Shire in 2011 (affecting Xagrid, Fosrenol and Equasym) as a result of Shire's intention to establish a marketing and sales organisation in the Nordic.

Revenues in Europe and North America have increased driven by strong sales growth for Kineret and Orfadin, in particular.

Revenues by key product



Product sales by region

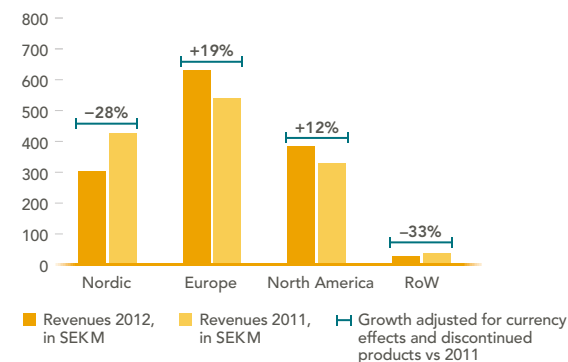
(Excluding ReFacto manufacturing and royalty revenues)

SEK M	2012	2011	Change
Nordic	304.3	427.9	-29%
Europe	630.1	540.9	16%
North America	383.1	328.2	17%
RoW	26.8	38.8	-31%
Sum	1,344.3	1,335.8	1%

Sales by key product

SEK M	2012	2011
Kineret	484.7	422.0
Orfadin	356.7	315.7
Other core products	83.7	74.6
Core Products	925.1	812.3
Current portfolio	407.2	373.6
Discontinued products	0.0	45.0
Co-promotion revenues	12.0	105.0
Partner Products	419.2	523.6
Manufacturing revenues	436.0	451.7
Royalty revenues	129.8	123.3
ReFacto	565.8	575.0
Other revenues	13.1	0.0
Total revenues	1,923.2	1,910.8

Revenues by region



Products per business line

Core Products	Partner Products	ReFacto
Inflammation	ReFacto AF	Manufacturing
Kineret	co-promotion	Royalty
Ruconest	Kepivance	
Genetics	Yondelis	
Orfadin	Ferriprox	
Ammonaps	Betapred	
Ammonul	Buronil	
	Aloxi	
	Willfact	
	Other	

Development

Sobi's development projects include three phase III programmes: rFIXFc and rFVIIIc within Haemophilia and Kiobrina within Neonatology. There are also preclinical and life-cycle management projects.

Positive top-line results from two phase III haemophilia studies

In the second half of 2012 Sobi and Biogen Idec announced positive top-line results from A-LONG and B-LONG, two phase III clinical studies of the companies' long-lasting recombinant coagulation factors, rFVIIIc and rFIXFc, for the treatment of haemophilia A and B, respectively. Both haemophilia A and B are rare, inherited disorders that impair blood coagulation.

The top-line results showed that both rFVIIIc and rFIXFc were effective in the control and prevention of bleeding and in routine prophylaxis and perioperative management, and were generally well-tolerated.

The A-LONG study results showed that:

- Individualised and weekly prophylactic regimens resulted in low single-digit median annualised bleeding rates.
- Median dosing interval was 3.5 days in the individualised prophylaxis arm.
- For 112 subjects with greater than or equal to 6 months on study, approximately 30% achieved a mean dosing interval of greater than or equal to 5 days during the last three months on study.
- 98% of bleeding episodes were controlled with one or two injections of rFVIIIc.
- No patients developed inhibitors to rFVIIIc.
- The most common adverse events (incidence of at least 5%) occurring outside of the perioperative management period were nasopharyngitis, arthralgia (joint pain), headache and upper respiratory tract infection.
- No serious adverse events were assessed to be related to the therapy.

The B-LONG study results showed that:

- Prophylactic regimens resulted in low single-digit median annualised bleeding rates.
- Median dosing interval was 14 days in the individualised interval prophylaxis arm during the last 6 months on study, for 26 subjects who were on study for at least nine months.
- Greater than 90% of bleeding episodes were controlled by a single injection of rFIXFc.
- No patients developed inhibitors to rFIXFc.
- The most common adverse events (incidence of at least 5%) occurring outside of the perioperative management period were nasopharyngitis, influenza, arthralgia, upper respiratory infection, hypertension and headache.
- One serious adverse event, obstructive uropathy in the setting of hematuria, was assessed to be possibly related to therapy. The patient continued rFIXFc treatment and the event resolved with medical management.

The primary efficacy and safety objectives were met in both studies. Biogen Idec's Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for rFVIIIc for use in patients with haemophilia A was filed in the first quarter of 2013. Its BLA for rFIXFc for use in patients with haemophilia B was submitted in the fourth quarter of 2012.

In 2012 Biogen Idec and Sobi also initiated two global paediatric clinical trials, Kids A-LONG and Kids B-LONG, for the study of treatment of children with haemophilia A and B, respectively.

For a summary of key data from A-LONG and B-LONG, see the table Hemophilia programmes.

Haemophilia programmes	rFIXFc	rFVIIIc
	Haemophilia B	Haemophilia A
Phase I/IIa data	July 2010	July 2011
Phase III studies	B-LONG	A-LONG
No. of patients	105	150
Start date	Dec 2009	Nov 2010
Phase III data	H2 2012	H2 2012
Start of pediatric trials in previously treated patients	H1 2012	H1 2012
	USA and Europe	USA and Europe
Orphan Drug designation		

No. of patients required in European studies

	rFIXFc	rFVIIIc
Previously treated patients ≥12 years	20	50
Previously treated patients 6 – <12 years	10	25
Previously treated patients <6 years	10	25

Ref. European Medicines Agency (EMA)

Enrolment in Europe continues for phase III registrational study for Kiobrina

Kiobrina is a recombinant human bile salt stimulated lipase (rhBSSL) being developed by Sobi as an oral enzyme replacement therapy to improve growth in preterm infants who receive pasteurised breast milk or infant formula. The on-going phase III study is designed to evaluate the efficacy, safety and tolerability of Kiobrina. The primary endpoint is growth velocity after 4 weeks. The first patients were enrolled in July 2011 and the last patient is expected to be enrolled in the study in first half of 2013, with a follow-up period of 12 months. The trial is expected to enrol patients in approximately 70 centres across 10 European countries. The company continues to anticipate a potential launch for Kiobrina in late 2015.

Kiobrina, Phase III study

Placebo-controlled, double blind study
4 weeks treatment
430 patients, born before pregnancy week 32
10 countries, 70 sites

Kiobrina, Phase III observational study

24 months
All LAIF patients are entitled to participate

Paediatric Investigation Plans for Orfadin and Kineret

Sobi has received formal agreements from (EMA) Paediatric Committee on its Paediatric Investigation Plan (PIP) for Orfadin and Kineret.

FDA approves Kineret for the treatment of NOMID

Sobi's application for Kineret for the indication of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) in the US, filed in July 2012, was granted a priority review by the FDA and was approved by the authority in December 2012. Kineret is the first and only FDA-approved therapy for NOMID.

In November 2012, Sobi filed an application for an EU Marketing Authorisation with the European Medicines Agency (EMA) for Kineret for the indication of Cryopyrin Associated Periodic Syndromes (CAPS).

Outlook for 2013

- Total revenues for the full year 2013 are expected to be in the range of SEK 2,000 to 2,200 M.
- Revenues for
 - Core Products are expected to show high single-digit growth;
 - Partner Products portfolio is expected to grow by about one third; and
 - ReFacto AF manufacturing and royalty are expected to show low single-digit growth.
- Gross margin is expected to be in the range of 57–59%.

Other information

New and amended partnership agreements during the year

Terms of agreement with Biogen Idec

Further details on the restructured agreement with Biogen Idec for the development and commercialisation of the long-lasting recombinant factor VIII and factor IX haemophilia programmes were disclosed in February 2012. See note 36.

Agreement with Gentium

In January 2012 an agreement was signed with Italy-based Gentium S.p.A. regarding exclusive distribution rights for 10 years for Defibrotide in the Nordic and Baltic regions. Defibrotide is a drug for the treatment of hepatic veno-occlusive disease (VOD)¹. Sobi will be responsible for obtaining pricing and reimbursement approvals and for sales, marketing and local medical affairs in the defined markets.

Only for Children Pharmaceuticals

A global licensing agreement with the French company Only for Children Pharmaceuticals (O4CP) was signed in January 2012 regarding bumetanide reformulated for treatment of diuresis and seizures in neonates. The new drug is currently in clinical phase II in the EU-financed NEMO project.

Pfizer

In February 2012 Sobi and Pfizer extended their supply agreement for ReFacto AF/XYNTHA until 31 December 2020, with an option to renew. Sobi will continue to be the global supplier of the drug substance for ReFacto AF/XYNTHA, which is produced at the company's plant in Stockholm. In a separate agreement, Sobi and Pfizer agreed that Sobi should return the

co-promotion rights for ReFacto AF and BeneFIX in the Nordic region to Pfizer as of 15 February 2012 in exchange for a payment to Sobi in the amount of SEK 307.5 M.

Affibody

In July 2012 Sobi signed a research collaboration and option agreement with the Swedish biotech company Affibody AB, for the discovery and development of novel treatments for inflammatory diseases where Interleukin-1 (IL-1) is implicated. The agreement covers an initial 2-year period during which Sobi has an option to enter into a licensing agreement with worldwide exclusive rights to selected development projects.

Ruconest

In August 2012, Sobi's geographical rights for the distribution of Ruconest were expanded to include the entire EU region, Iceland, Norway and Switzerland, as well as the Balkans, North Africa and the Middle East. Ruconest received its marketing authorisation in Europe in October 2010. It is used to treat the rare disease Hereditary Angioedema (HAE).

Expanded Kineret label to include NOMID

In December 2012, the FDA-approved Kineret (anakinra) for the treatment of children and adults with NOMID. Kineret is the first and only FDA-approved therapy for NOMID, the most severe form of CAPS. This is the first approval allowing the use of Kineret in children (approved for NOMID under an Orphan Drug Designation).

Bond loan issue

On 26 June 2012 Sobi issued a 5-year senior bond loan in the total amount of SEK 600 M. Sobi applied for a listing of the bond loan on NASDAQ OMX Stockholm. After approval by the Swedish Financial Supervisory Authority, the bond loan was listed on NASDAQ OMX Stockholm on 16 November 2012.

Transfer of Kineret production

The transfer of production of Kineret from Amgen in the US to a contract manufacturer in Europe was initiated in 2010. In June 2012 the transfer of the drug product process was approved by the EMA and the FDA as well as the Australian authority Therapeutic Goods Administration (TGA). This transfer will lead to lower production costs.

Subsidiaries in the US and Dubai

Sobi's subsidiary in the US, Sobi Inc., became fully operational at the beginning of 2012. A new subsidiary in Dubai, Sobi Middle East FZ, was established in the second quarter.

Strengthened leadership team

The senior leadership team was strengthened significantly with the appointment of Alan Raffensperger as Chief Operating Officer, Birgitte Volck as Chief Medical Officer and Wills Hughes-Wilson as Chief Patient Access Officer.

Legal issues

Arexis

On 29 March 2012, Sobi amended its share purchase agreement regarding the acquisition in 2005 of the pharmaceutical company Arexis AB. As stated in Sobi's annual and quarterly reports, the sellers of Arexis initiated arbitration as well as an expert determination procedure in 2011 regarding certain claims related to the share purchase agreement. Both proceedings have been withdrawn as a consequence of the amended share purchase agreement. According to the amended agreement, Sobi has no remaining development obligations towards the sellers. Under the amended agreement, Sobi will pay the sellers a total of SEK 77 M. Sobi has paid SEK 36 M when the agreement was signed and will pay SEK 20 M in 2013 and SEK 21 M in 2014.

Paradisat 14

In 2004 the real estate Paradiset 14 was transferred to a substantially foreign-owned limited liability partnership, Nya Paradiset KB, whereupon the participating interests in Nya Paradiset KB were sold to an external party at market price. On 3 March 2011 the Administrative Court ruled in favour of the Tax Agency's request, explaining that, based on the above transfer and subsequent sale, Sobi will, under the tax law, be charged an amount of SEK 232.2 M as revenue in the 2005 tax year. The company appealed to the Administrative Court of Appeal. A stay of proceedings was issued in the case while awaiting the Supreme Administrative Court's (SAC) verdict on another, separate tax law case, known as the "Cyprus case". On 30 May 2012 the SAC delivered its verdict in the "Cyprus case" and Sobi's tax case was taken up for continued consideration by the Administrative Court of Appeal. Sobi will have the opportunity to supplement and strengthen its legal submission. During the period,

¹ VOD is a serious, and potentially fatal complication of hematopoietic stem-cell transplantation (HSCT).

there have been no relevant developments in the proceedings. For further background, see note 37. The tax loss carry forward has been decreased by the disputed amount. Therefore, the amount is not included in capitalised tax losses.

Environmental information

Sobi's environmental management system is based on the ISO 14001 standard, although the company is not certified. Management has established an environmental policy to further underscore the importance of environmental work. The policy is available on the company's website, www.sobi.com.

The production facilities in Stockholm and Umeå have permits for hazardous operations in compliance with the Swedish Environmental Code. Compliance with the terms of the permit is reported annually in environmental reports prepared for the local supervisory authorities. The company also has operations in Solna that are subject to a reporting obligation according to the same regulations. In 2012 no violations were reported from any sites.

Sobi has a permit from the Swedish Work Environment Authority for the handling of thioacetamide. The company also has an import licence from the Swedish Board of Agriculture for animal by-products and a licence to handle flammable goods. Sobi also has a licence from the Swedish Radiation Safety Authority to work with radioactive substances. In 2012 no such work was performed.

Adjustment to the current regulations has so far not negatively affected Sobi's competitiveness or operations. The company cannot, however, predict the effects of future regulations.

Significant events after the reporting period

Distribution agreement signed with Valeant/PharmaSwiss

Sobi entered into an exclusive distribution agreement with Valeant/PharmaSwiss for the products Megace®, Monopril®, Cefzil® and Duricef® for the treatment of indications within the oncology, cardiovascular and anti-infective therapy areas.

Under the terms of the agreement, Sobi will have exclusive distribution rights in Ireland, the United Kingdom, France, Italy, Germany, Spain, Finland, Sweden, Denmark, Norway, Austria, Belgium, Liechtenstein, Netherlands, Portugal and Luxembourg. The portfolio has current revenues of approximately SEK 120 M in the Sobi territory.

Savient co-promotion

Sobi has entered into an exclusive agreement with Savient for the co-promotion of Kineret (anakinra) in the US. Kineret is indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active Rheumatoid Arthritis (RA) in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs). Kineret is also indicated in the US for the treatment of children and adults with NOMID. Savient will market and promote Kineret beginning 1 April 2013. Sobi will remain responsible for all Kineret commercial drug manufacturing, supply and regulatory activities.

Distribution agreement with Exelixis

In February 2013, Sobi entered into a three-year agreement to support the distribution and commercialization of Cometriq™ for metastatic medullary thyroid cancer (MTC) in the European Union (EU) and potentially other countries. No other indication is covered by this agreement, and Exelixis maintains full commercial rights for Cometriq in MTC outside the covered territory and for all other indications on a global basis. On November 29, 2012, Exelixis announced that the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for Cometriq for the proposed indication of treatment of progressive, unresectable, locally advanced, or metastatic MTC.

New bond amounting to SEK 200 M

Sobi has issued a further SEK 200 M under the current bond loan, to ensure that Sobi can take advantage from the opportunities presented by the pace and scale of our haemophilia programmes.

Return of the rights for Willfact

On 1 January 2013 Sobi returned the rights in Germany for Willfact® to LFB, but will retain the rights for the Nordic markets.

Amgen

A milestone payment to Amgen at USD 55 M was paid during the first quarter 2013. The payment was dependent on sales volumes for Kineret, which were achieved during the fourth quarter 2012.

Employees

The average number of employees in 2012 was 514 (517), of which 385 (412) were in Sweden. Salaries and other remuneration amounted to SEK 353.4 M (356.3), of which SEK 243.1 M (253.5) was paid in Sweden (Parent company).

Salaries and benefits

Competitive terms of employment are a prerequisite in order to recruit and retain qualified employees. Salaries are determined on an individual basis and are differentiated and adapted to salary criteria agreed upon locally.

Diversity and equal opportunity

Of the total number of employees in 2012, 40% were men and 60% were women.

All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

Work environment

Sobi strives to fully comply with all work environment related laws and regulations and, therefore, systematic environmental initiatives are integrated into the work environment and quality assurance work. The company's environmental policy is available at www.sobi.com. The formal work environment responsibility is delegated down the line. Each restricted area has an environmental group coordinator. The coordinators work with managers, safety officers and other employees to compile environmental action plans. Risk inventories and safety inspections focusing on ergonomics, chemicals, GMMs, electrical safety and radiation protection are performed regularly in restricted areas. There were no workplace accidents to report to the Swedish Work Environment Authority in 2012.

Respect for labour market regulations

Sobi complies with and respects labour market regulations and the agreements reached between the parties in the labour market. The company works constructively with trade unions and employer organisations and has good relationships with these bodies.

Proposal for guidelines for remuneration to senior executives

For information on staff cost and remuneration of directors and senior executives, see note 14. Management in this context

refers to Sobi's CEO and the executives who report to him at any given time and who are part of the company's management team, as well as members of the Board of Directors to the extent they have entered into consulting agreements.

Motives

Sobi shall offer a total remuneration in line with market conditions to enable the company to recruit and retain competent personnel. The remuneration to management may consist of fixed salary, variable salary, pension and other compensation. Long-term incentive programmes 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 company's and the member's, respectively, performance in relation to objectives determined in advance.

Fixed salary

The fixed salary for the CEO 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 CEO and the other members of the management is revised once every year, as per 1 January. 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 CEO 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 company's/the group's long-term development, value creation and financial growth and shall be designed in a way that does not encourage an excessive risktaking. The variable salary may not amount to more than 50% of the annual gross salary (including pension) for the CEO and not more than 20–50% of the fixed annual salary (excluding pension, or in specific cases, including pension) for the other members of the management.

Long-term incentive programmes

Long-term incentive programmes may constitute a complement to the fixed salary and the variable salary. The participants in the programme 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 with having long-term incentive programmes shall be to create a long-term commitment to Sobi, to offer the participants to take part in the company'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 on the current incentive programmes, see note 14.

Other remuneration and terms of employment

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

Fixed salary during notice periods and severance payment, including payments for any restrictions on competition, shall in aggregate not exceed an amount equivalent to the fixed salary for two years. The total severance payment shall for all members of the management be limited to the existing monthly salary for the remaining months up to the age of 65.

The CEO may, in case of a change of control of the company, meaning that more than 50% of the shares in the company are owned by one shareholder, (i) be entitled to a retention bonus corresponding to maximum 6 monthly gross salaries (including pension) provided that notice of termination of the CEO's employment has not been given 6 months after the change of control, alternatively (ii) in case of a material change of the CEO's employment conditions, be entitled to terminate the employment with a right to severance payment in accordance with the above. Upon a material change in the business, other executives may (i) be entitled to a retention bonus corresponding to maximum 6 monthly fixed salaries (excluding pension, or in specific cases, including pension), provided that notice of termination of employment has not been given 6 months after such change, alternatively (ii) under certain circumstances, be entitled to terminate the employment with a right to severance payment, however, corresponding to maximum 12 monthly

fixed salaries (excluding pension, or in specific cases, including pension), to be paid in addition to the salary during the notice period.

Other compensation may consist of other customary benefits, such as healthcare insurance, which shall not constitute a material portion of the total remuneration.

In addition, additional compensation may be paid out in extraordinary circumstances, provided that such arrangement is made for management recruitment or retention purposes and is agreed on an individual basis. Such extraordinary arrangements may for example include a one-time cash payment, or a support package including relocation support, tax filing support, or similar.

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.

Guidelines and remuneration 2012

Guidelines and other terms of employment approved by the Annual General Meeting in 2011 can be found in note 14.

Share and option programmes

Sobi currently has four share programmes. All programmes are described in detail in note 14.

Proposed appropriation of profit

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

SEK	
Share premium reserve	4,109,365,935
Retained earnings	518,271,254
Profit/loss for the year	31,584,616
Total	4,659,221,805

The Board of Directors and the Chief Executive Officer propose that the funds at their disposal, SEK 4 659 221 805, be carried forward.

Risk management



The overall risk management structure consists of eight interrelated components:

1. Internal environment
2. Objective setting
3. Event identification
4. Risk assessment
5. Risk response
6. Control activities
7. Information and communication
8. Monitoring, including follow-up and evaluation.

All business activities involve risks. Our approach to risk management is to ensure that risks are proactively identified, assessed and mitigated. Creating awareness of such risks enables them to be limited, controlled and managed, while business opportunities can be utilised in the interest of value creation.

The Sobi Risk Management Committee is responsible on behalf of management to establish a common organisational approach to risk management and to ensure consistent and efficient risk identification, assessment and control. The Com-

mittee has regular meetings throughout the year and includes the heads of the major functions and *ad hoc* members on an agenda-driven basis.

The Chairman of the Committee is Sobi's General Counsel and the Risk manager is the Secretary. Reports are presented on a quarterly basis to the Executive Leadership Team, to the Audit committee and a review of the work is annually presented to the Board of Directors.

The risk management processes follow the established Committee of Sponsoring Organizations of the Treadway Commission – Enterprise Risk Management Integrated Frame-

work (COSO – ERM), which forms the foundation for Sobi's Risk Management Policy.

Sobi also has a Crisis Management Policy and a Crisis Management Team in place, with the objective of developing effective management and preventative measures in the event of a crisis.

This preparation is an important part of the company's efforts to optimally handle any potential crisis. The Crisis Management Team meets on a regular basis for planning and training purposes.

Objective and definitions

Sobi work to ensure that sound risk management is integrated on a day-to-day basis and that a common organisational approach to risk management is implemented. This allows us to identify and assess events that may affect the company's ability to achieve its objectives.

Risk assessment allows Management to consider the extent to which potential events may have an impact on the achievement of the company's objectives. Management assesses events from two perspectives – likelihood and impact – and normally uses a combination of qualitative and quantitative methods to evaluate both elements.

Based on this, the judgment of risk responses falls within the following categories: Avoidance, Reduction, Sharing or Acceptance.

Key risk areas

The research and development of new drugs and the regulations regarding research and development, manufacturing, testing, and marketing and sales of pharmaceutical products is complex and may change over time. Below is a summary of the main risks that may affect the company's operations. The risk areas are not ranked but are categorised and described.

Development risks

Bringing new drugs to the market

Sobi currently has a number of projects in clinical development and several projects in preclinical development. To develop a new biopharmaceutical product up to and including market launch is a capital-intensive, complex and risky process. The likelihood of successfully reaching the market increases as the project advances in the development process, however, the risks remain substantial even up to and including Phase III clinical development, while the costs increase at a growing pace as the project progresses into the later clinical phases.

Before the company can get approval to launch any of its biopharmaceutical products it must demonstrate that they are of high quality, safe and efficacious through sufficient, well-controlled preclinical studies and clinical trials. The number of pre-clinical studies and clinical trials required varies depending on the candidate drug, indications, preclinical and clinical results and the regulations that apply for the specific candidate drug.

Preclinical and clinical development is a time-consuming and costly process that is affected by numerous factors, including factors beyond the company's control such as changes in

requirements from the authorities. During clinical development it may emerge that the biopharmaceutical candidates are not sufficiently effective or they may prove to have undesirable or unintended side effects, toxicities or other properties. This may disrupt, delay or stop clinical development and prevent or limit the commercial application of the candidate drug.

Difficulties of obtaining and maintaining regulatory approvals for new products

Before the launch of any of Sobi's biopharmaceutical products is initiated, the company and its partners must demonstrate that the biopharmaceutical product meets the rigorous demands for quality, safety and efficacy expected by the authorities in the countries or regions in which Sobi plans to market the therapy.

Even if the company's biopharmaceutical product meets the criteria for safety and efficacy in clinical trials, the authorities may have a different opinion regarding how the data from pre-clinical studies and clinical trials is interpreted. Authorities may also approve a candidate drug for fewer indications than applied for or make the approval conditional upon post-marketing authorisation studies being conducted. The US authority, the FDA; the European authority, the EMA; and other regulatory authorities, may delay or limit new approvals.

If any of Sobi's product portfolio receives marketing authorisation, this does not confirm that these products would gain price approval and reimbursement status within the national or regional healthcare systems; nor acceptance in the market among physicians, patients, procurement organisations and the medical community. The degree of market acceptance for each of the company's biopharmaceutical product depends on a number of factors. Many of these are beyond the company's control and depend on external decision-making processes and bodies.

Challenges in collaborations and partnerships

Part of Sobi's strategy is to enter into various partnership agreements, e.g., joint development and/or authorisations with other pharmaceutical and biotechnology companies for the development and launch of some of Sobi's products. Partnerships might also be with patients' organisations, academic institutions or other relevant groups. The success of such partnerships will largely depend on the work of Sobi's partners or licensees, since these still have considerable right of determination over the work and resources that will be put into the projects, depending on the nature of the agreement between the different parties.

Risks relating to intellectual property rights and patent risks

Sobi's success will largely depend on the company's, or its licensors', ability to obtain protection in the US, the EU and other countries or regions for the intellectual property rights for the products the company develops, manufactures, markets and sells. The patent situation within the area of biotechnology and pharmaceuticals involves complex legal and scientific issues. Even if a patent is granted, it may be opposed, declared void, or circumvented, which would limit the company's ability to prevent competitors from marketing similar products and reduce the period during which the company obtains patent protection for its products. Sobi has a number of technology licences that are important for the business, and the company is expected to be able to obtain further licences in the future.

In addition to patented products and technologies, Sobi uses its own technology, processes and knowhow not protected by patents. The company's objective is to protect such information through confidentiality agreements with employees, consultants and partners.

The technologies that Sobi uses in its research or that are included in target products or candidate drugs that the company is working to develop and eventually commercialise, may infringe patents or patent applications owned or controlled by other companies. In this case, Sobi works with the other party or parties, to seek agreed solutions in order to allow the work to progress.

Manufacturing of biopharmaceuticals and quality risks

Sobi manufactures proteins- and recombinant protein biopharmaceutical products and is dependent on the company's production facilities in Stockholm and Umeå, Sweden, being maintained and readily available. Sobi also collaborates on manufacturing pharmaceuticals with other pharmaceutical companies, as both a supplier and a customer.

The manufacture of proteins and recombinant protein biopharmaceuticals requires precise and high-quality manufacturing processes and controls, therefore the company must ensure that all manufacturing processes and methods and all equipment meet the Good Manufacturing Practice (GMP) requirements. Slight deviations in any part of the manufacturing process may result in delays or batch failure.

GMP requirements regulate all aspects of the manufacturing of pharmaceuticals, including quality control and quality assurance, manufacturing processes and documentation. Furthermore, Sobi must perform extensive audits of its distributors,

contract laboratories and suppliers who are also covered by these requirements.

To be compliant with these GMP requirements, Sobi and its distributors, contract laboratories and suppliers need to maintain high-quality manufacturing processes and quality controls that are sufficient to guarantee that the products meet the current specifications and other requirements.

Sobi's production facilities may be inspected at any time by the authorities and by the company's customers.

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.

Sales and market risks

Competitors and marketing regulations

The market for specialist pharmaceuticals is characterised by significant competition and rapid technology development. Sobi's competitors include international pharmaceutical, biotechnology and specialist pharmaceutical companies. Some competitors have significant financial, technical and human resources as well as large manufacturing, distribution, sales and marketing capabilities.

Each significant reduction in revenues from its key products could have a significantly negative effect on Sobi's business, results and financial position. This could be the case regardless of whether the reduction is due to a fall in demand, an increase in competition or other reasons, such as changes in regulations for state subsidies for pharmaceuticals.

Furthermore, there is always a risk that the company's products in development will be exposed to competition from similar products or entirely new concepts which prove to be of greater value. Sobi, therefore, initiates collaborations with external research groups at the forefront of medical development in order to increase the chances of gaining access to target proteins that can be developed into competitive medical treatments. To ensure best possible protection against competition, Sobi focuses on strong intellectual property rights.

The market in which Sobi operates is increasingly affected by price pressure. The increased cost of healthcare in many countries leads to governments and other payers becoming more aware of the costs, which in turn leads to strong price pressure. In most markets where Sobi is active, governments exercise a certain degree of control over the price of pharmaceuticals.

This control and its effects vary from country to country, and various methods are being used on both the supply and the demand side to control pharmaceutical costs.

Sobi's success is dependent on the products developed by the company. Sobi's products are covered by, and entitled to, reimbursement/payment through private or state payment systems within the healthcare sector. Legislation and regulatory proposals in various European countries and in the US include measures that could restrict or prevent payment for treatment with certain pharmaceuticals. In certain cases, such legislation has also resulted in the prices of pharmaceuticals being subject to increased state price controls or mandatory price cuts, which can create price differences between countries and increase parallel importation and distribution. The use of pharmaceuticals may also be affected by guidelines, recommendations and studies published by authorities and organisations.

Parallel imports

It cannot be ruled out that differences in pharmaceutical prices in the markets where Sobi operates could lead to an increase in parallel imports. This means that Sobi's products could be purchased less expensively in certain markets and potentially compete with Sobi's sales in other markets.

Product counterfeiting

Furthermore, the supply of prescription pharmaceuticals is facing an increasing challenge in that certain distribution channels are vulnerable to counterfeit pharmaceutical products in a greater number of markets, as well as via the internet. Counterfeit products may contain the wrong dose of the pharmaceutical ingredient or no ingredient at all; they may also contain harmful substances.

Financial risks

The company's business is exposed to currency risk. The majority of the company's expenses are incurred in SEK, while a significant proportion of its revenues are in other currencies. As a result of the company's international expansion, a reduction in the exchange rate of US dollars and the Euro, in particular; or other foreign currencies in which revenues are earned relative to SEK, could have a negative impact on Sobi's results and financial position. More information about financial risks can be found in note 3.

Ethical and compliance risks

In order to ensure compliance, respect human rights, promote fair employment, safe working conditions, environmental responsibility and high ethical business standard, the Code of Conduct & Ethics is applicable globally in the production, supply and support of all Sobi products and services. The Code is effective from 2013.

The Sobi share

Sobi's shares have been listed on NASDAQ OMX Stockholm under the company name Swedish Orphan Biovitrum since June 2010 (ticker SOBI, ISIN SE0000872095). The Biovitrum share was originally listed in September 2006.

Share performance and turnover

The total turnover of Sobi's shares in 2012 was 89 million shares for a total value of SEK 1,438 M (1,575).

The share price rose in 2012 by 142%, from SEK 15.10 at the beginning of the year to SEK 36.60 at the end of the year. The highest price paid was SEK 45.50 (31 October 2012) and the lowest was SEK 14.95 (2 January 2012). The last price paid in 2012 was SEK 36.60. Sobi's shares are included in the OMX Stockholm Pharmaceuticals & Biotechnology PI Index, which rose by 3.83% during the same period.

The market capitalisation at the end of the year was SEK 9.87 billion.

Shareholders

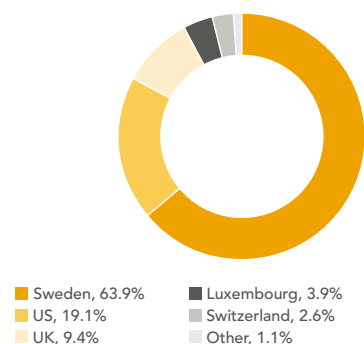
At the end of the year Sobi had a total of 8,006 shareholders (8,013). Investor AB was the largest owner with 39.9% of the capital and 40.5% of the votes. The 15 largest shareholders accounted for a total of 75.2% of the capital and 76.6% of the votes. Approximately 61% of the shares were owned by Swedish legal entities, such as institutions and funds.

Largest shareholders as of 28 December 2012*

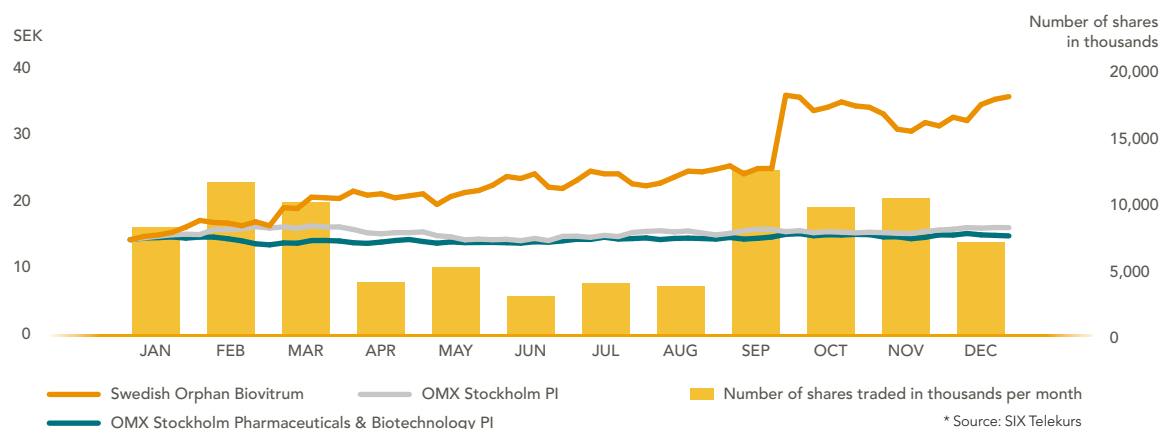
Shareholder	Number of shares	Share capital, %	Share votes, %
Investor AB	107,594,165	39.9	40.5
Swedbank Robur fonder	11,850,576	4.4	4.5
Omnibus Account W FD: OM80	11,023,737	4.1	4.2
JPM Chase NA	10,426,244	3.8	3.9
MPM Bioventures II-QP, LP.	9,147,730	3.4	3.4
Bo Jesper Hansen	8,893,846	3.3	3.4
Handelsbanken Fonder AB	7,786,548	2.9	2.9
SIX SIS AG, W8IMY	6,830,786	2.5	2.6
Livförsäkringsaktiebolaget Skandia	6,293,935	2.3	2.4
Goldman Sachs & Co, W9	5,130,856	1.9	1.9
Lannebo fonder	4,097,000	1.5	1.5
SSB CL OMNIBUS AC OM07 (15PCT)	3,665,997	1.4	1.4
Gladiator	3,622,001	1.3	1.4
Skandia fonder	3,524,537	1.3	1.3
Catella fonder	3,375,703	1.2	1.3
Total	194,369,815	75.2	76.6
Other	70,856,783	23.2	23.2
Swedish Orphan Biovitrum AB C-aktier, voting rights 1/10	4,408,260	1.6	0.2
Total	269,634,858	100.0	100.0

* Source: Share register at Euroclear Sweden AB and Sobi

Shareholders by country



Sobi share price and trading volume during 2012*



Share capital

The share capital at the end of the year amounted to SEK 147,947,800 distributed between 269,634,858 shares, with a quota value of approximately SEK 0.55, of which 265,226,598 are ordinary shares and 4,408,260 are class C shares. The ordinary shares carry one vote per share and the class C shares carry 1/10 of a vote per share.

All class C shares are treasury shares and were issued in connection with the long-term incentive programmes: Share Programme 2010, Share Programme 2011 and Share Programme 2012. The class C shares only entitle the holder to a dividend on the company's distributable profit in an amount equivalent to 10% of the share's quota value. All shares carry equal rights to the company's assets and any surplus in the event of liquidation.

Development of share capital and number of shares

	No. of shares	Share capital SEK
December 2011	267,295,132	146,664,000
June 2012 Rights issue of class C shares	684,590	375,632
September 2012 Rights issue of class C shares	1,655,136	908,168
December 2012	269,634,858	147,947,800

Analyst coverage

ABG Sundal Collier	Peter Hugrefte
Carnegie	Kristofer Liljeberg
Danske Bank	Mattias Häggblom
Handelsbanken	Peter Sehested
Nordea	Erik Hultgård
SEB/Skandinaviska Enskilda Banken	Lars Hevren
Swedbank	Johan Unnerus
Pareto Öhman AB	Yilmaz Mahshid

Short facts Sobi share

Listing	NASDAQ OMX Stockholm
Number of shares	269,634,858
Market capitalization	SEK 9.87 billion
Ticker	SOBI
ISIN	SE0000872095

Corporate governance report

Major external regulations

- Swedish Companies Act
- Swedish and International accounting law
- NASDAQ OMX Stockholm regulations
- Swedish Corporate Governance Code

Major internal regulations

- Articles of Association
- Board of Directors' working procedures
- Instructions to the CEO
- Policy documents



① Annual General Meeting

Sobi's highest decision-making body is the Annual General Meeting (AGM), at which all shareholders have the right to elect members to the Board. The AGM also elects the Auditor. The AGM must be held within 6 months of the end of the financial year, in order to decide on whether to adopt the income statement and balance sheet and decide on the appropriation of profits or losses.

② Nomination Committee

The Nomination Committee represents the shareholders and has the sole task of preparing resolutions on election and compensation issues for the AGM.

③ Board of Directors

The Board's responsibility for the Group's organisation and administration entails satisfactory monitoring of accounting, fund management and financial circumstances in general. The Board also decides on overall objectives, strategies, financial structure, policies, appointment of the Chief Executive Officer (CEO) and executive compensation, acquisitions, disposals and major investments. The Board approves and adopts the Annual Report and interim reports, and is responsible for proposing a dividend, if any, at the AGM. The Board bases its work on the workplan for the Board, the instructions to the CEO and the principles governing the division of duties among the CEO, Chairman, Board and various working committees that the Board has established. The Board's workplan and the instructions to the CEO are revised and updated once a year.

The Chairman of the Board leads the Board's work, monitors the company's development and ensures that important issues are addressed as needed and that all important decisions are preceded by active and constructive discussions. The Chairman is employed by the company as executive chairman.

④ Audit Committee

The Audit Committee's main duties are to handle the company's accounting, financial, reporting and audit matters, as well as matters relating to internal control within 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 auditors regarding compliance with laws and regulations involving financial matters; and annually examining remuneration to the auditors.

⑤ Compensation & Benefits Committee

The task of the Compensation & Benefits Committee is to propose guidelines and principles for the company's remuneration programmes. This responsibility includes oversight and proposals for remuneration to senior executives and proposals for long-term incentive programmes, pension plans and other issues relating to remuneration to the company's employees.

⑥ Scientific Committee

The Scientific 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.

⑦ CEO/Executive Leadership Team

The company has a functional organisation and the Executive Leadership Team consists of the CEO and the heads of the most important functions. The Executive Leadership Team comprises a broad composition of people with deep and extensive experience in R&D, as well as the production and sale of pharmaceuticals. In addition, Executive Leadership Team members also possess the requisite skills in finance and business, law, human resources and communications. The operative management is based on the decision-making procedure established by the Board, as reflected in the organisational and management model on which Sobi works and is governed. At Board Meetings, the CEO and, when necessary, the Chief Financial Officer (CFO), General Counsel and other senior executives in the management present information on matters that require the attention of the Board.

⑧ Auditors

The company's Auditor, elected at the AGM, audits the consolidated financial statements, as well as the annual accounts of the Parent company and subsidiaries, and also provides an audit report.

Swedish Orphan Biovitrum AB (Sobi) is a Swedish public limited liability company with its registered office in Stockholm. The company is listed on NASDAQ OMX Stockholm. In addition to the rules stipulated by law or other statute, the company applies the Swedish Corporate Governance Code.

The company does not deviate from the code. This corporate governance report refers to the 2012 financial year. The report comprises a part of the formal Annual Report and has been reviewed by the company's auditors.

Shareholders, share capital, the share and voting rights

On 31 December 2012, Sobi had a total of 8,006 (8,013) shareholders. Investor AB was the largest shareholder, holding 39.9% (40.3) of the share capital and 40.5% (40.5) of the voting rights. The 15 (15) largest shareholders accounted for 75.2% (76.9) of the share capital and 76.6% (77.5) of the voting rights. No owner other than Investor AB has a direct or indirect shareholding that represents at least one tenth of the voting rights of all shares in the company. Sobi's Articles of Association contain no restrictions on how many votes each shareholder may cast at a general meeting.

The 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 Sobi to finance the continued development and expansion of operations. The Board does not intend to propose any dividend within the foreseeable future.

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 (AGM) be held in Stockholm. Sobi has not found that the composition of the body of shareholders motivates any particular measures for shareholders being able to follow the AGM remotely.

Annual General Meeting 2012

At the Annual General Meeting (AGM) on 26 April 2012, directors Bo Jesper Hansen, who was also re-elected as Chairman, Adine Grate Axén, Lennart Johansson, Helena Saxon, Hans GCP Schikan and Hans Wigzell were re-elected to serve until the 2013 AGM. Matthew Gantz was elected as a new director.

The AGM resolved on remuneration to the Chairman of the Board and the directors elected by the AGM, see note 14.

The AGM also resolved on a new performance-based long-term share programme as well as resolutions on a directed issue of C-shares and authorisation for the Board to repurchase issued C-shares. In addition, the AGM resolved to approve the Board's resolution on transfer of own shares.

The minutes of the 2012 AGM are available at www.sobi.com.

Annual General Meeting 2013

The AGM will be held on Friday 26 April 2013, in the Wallenberg Auditorium at the Royal Academy of Engineering Sciences (IVA), see the last page in the Annual Report.

Nomination Committee

According to the instructions and rules adopted by the AGM on 26 April 2012, the Nomination Committee shall consist of four members, three of whom shall represent the three largest shareholders of the company as of the last banking day of August according to statistics from Euroclear Sweden AB. The fourth person shall be the Chairman of the Board, as stipulated in the same resolution. The composition of the Nomination Committee shall be announced at least 6 months before the AGM.

The members of the Nomination Committee for the AGM 2013: Petra Hedengran, Investor AB (Nomination Committee chair)
Roger Johanson, Skandia Liv
Åsa Nisell, Swedbank Robur Fonder AB
Bo Jesper Hansen, Chairman of the Board, Swedish Orphan Biovitrum AB

The Nomination Committee has held three meetings.

Board

Composition of the Board

During the fiscal year 2012 the Board consisted of seven members elected at the AGM on 26 April 2012, as well as two employee representatives and two deputies appointed by the trade unions. Three members were women, including the employee representatives. For further details on the Board, see pages 58–59.

Sobi is a speciality pharmaceutical company with a focus on marketing, development, and production of pharmaceutical products to treat rare diseases. The portfolio contains products that are both marketed and at all stages of clinical development. It is therefore crucial that the members of the Board have

extensive, in-depth experience of marketing and research in the pharmaceutical industry, as well as financial qualifications.

Chairman of the Board

The duties of the Chairman of the Board, 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 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.

The Chairman of the Board is employed by the company as executive chairman. As such, his duties also include representing the company with partners and other stakeholders in the pharmaceutical field, as instructed by the CEO.

Independence

The company complies with the independence requirements in the Swedish Corporate Governance Code such that the majority of the Board members elected at the AGM are independent from the company and management, and that at least two of them are independent in relation to the larger shareholders.

The table on page 55 shows the independence of the directors at the time of publication of this report.

Number of meetings

The Board meets at least five times a year, usually in conjunction with publication of the interim and annual financial statements and the AGM. Additional meetings or telephone conferences are scheduled as necessary. The Board carries out an in-depth strategic review of operations during at least one Board Meeting each year.

The Board has scheduled a total of five meetings and four teleconferences for 2013.

The Board's work in 2012

The Board held 24 meetings in 2012. The statutory Board Meeting was held on 26 April 2012. Sobi's General Counsel has been secretary at the meetings. Other Sobi employees have presented reports. The Board met more times than planned due to the issue of the bond loan, the announcement of clinical results from the haemophilia programmes and several matters regarding commercial agreements.

Major issues during 2012

- Issuance of bond loan
- Strategic focus of the company
- Proposals for potential acquisitions and collaborations
- Evaluation and amendment to commercial agreements
- Development of project portfolio
- Announcement of clinical results from haemophilia programmes

Committees

Audit Committee

Sobi's Audit Committee consists of three members who are independent of management: Lennart Johansson (Chairman), Adine Grate Axén and Helena Saxon.

The Committee met 11 times during the year. The table below shows the attendance of each director. The company's elected auditors also attended four of the meetings. Discussion topics at these meetings included the Auditors' planning of the audit, their observations and review of the company and compensation to the Auditors and the company's interim reports. The large number of meetings during the year was mainly related to the personnel and organisational changes within the finance department, the renegotiation of the company's credit facilities and the issuance of the bond loan.

For information on remuneration to the company's auditors, see note 15.

Compensation & Benefits Committee

Sobi's Compensation & Benefits Committee consists of three members: Bo Jesper Hansen (Chairman), Hans GCP Schikan and Helena Saxon. Hans GCP Schikan and Helena Saxon are independent in relation to senior management. The head of human resources serves as secretary to the committee, but is not a member.

The Compensation & Benefits Committee met five times during the year. The table below shows the attendance and status (independent/dependent) of each director. At these meetings, the Committee discussed and followed up on annual salary revision and bonuses for the CEO and senior management, and made proposals for guidelines, nominations, and allocation in the long-term incentive programme. Proposals for guidelines for remuneration to the CEO and senior management will be presented at the AGM in April 2013, for the approval of the shareholders.

For information about salaries and benefits for the CEO and senior management, see note 14.

Scientific Committee

The Scientific Committee consists of three members, two of whom are independent of management: Hans Wigzell (Chairman) and Hans GCP Schikan. The third member, Bo Jesper Hansen, is not independent of management. The Committee's work in 2012 included advising on acquisitions and licensing of new research projects. The Committee convened two times

during the year, with all three members present at one meeting and with two members present at the other.

Remuneration to Board members

The AGM held on 26 April 2012 resolved that for the period up until the next AGM, a Board remuneration of SEK 1,890,000¹ shall be paid of which SEK 250,000 shall be paid to each director elected by the AGM with the exception of the Chairman of the Board, who will not receive any remuneration for work on the Board or on its committees. For work on the Audit Committee, a fee of SEK 90,000 will be paid to the Chairman of the committee and SEK 50,000 to each of the other committee members. For work on the Compensation and Benefits Committee, a fee will be paid amounting to SEK 50,000 to the Chairman of the committee and SEK 25,000 to each of the other committee members. 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 of the other committee members. It was further resolved that for each meeting of the Board, a fee of EUR 1,000, corresponding to SEK 8,900 using the exchange rate at the time of the notice to the AGM, is paid to the members of the Board that reside inside Europe but outside the Nordic countries, and a fee of EUR 2,000, corresponding to SEK 17,800 using the exchange rate at the time of the notice to the AGM, is paid to the members of the Board that reside outside Europe.

For a specification of remuneration to the Board, see note 14.

¹ Compensation of the Board has been paid with SEK 1,815,000 as a result of the fact that the Board chairman neither received compensation for his work in the committees.

	Independent	Attendance ⁴			Shareholding as of 31 Dec 2012
		Board	Audit Committee	Comp. & Ben. Committee	
Bo Jesper Hansen	1	23/24	–	5/5	8,893,846
Hans Wigzell	●	22/24	–	–	200,000
Lennart Johansson	2	23/24	10/11	–	20,000
Helena Saxon	2	23/24	11/11	5/5	15,500
Adine Grate Axén	●	20/24	9/11	–	32,000
Hans Schikan	●	23/24	–	5/5	–
Matthew Gantz as from 26/4	●	16/24	–	–	–
Catarina Larsson	3	23/24	–	–	750
Bo-Gunnar Rosenbrand	3	22/24	–	–	2,500

¹ Member to be regarded as dependent to both the company and its management.

² Member to be regarded as dependent to larger principal shareholders.

³ Employee representative.

⁴ Table figures show the total meeting attendance.

Changes in the Board

The AGM in April 2012 elected Matthew Gantz as new Board member.

Executive Leadership Team

Each year, the Board establishes the distribution of work between the Board, the chairman of the Board, and the CEO. The Executive Leadership Team consists of the heads of the most important functions and will meet at least every second month.

During 2012, the Executive Leadership Team met once every month and at year-end 2012, it consisted of 12 members.

For further details on the Executive Leadership Team, see pages 60–61.

Remuneration to senior management

In order to attract and keep competent employees, Sobi has established long-term incentive programmes. The CEO, the Executive Leadership Team, all managers and a number of other key persons receive a fixed salary and a variable salary. The variable salary, which is in accordance with a system adopted by the Board, is based on both overall company goals and individual goals. The variable salary may amount to a maximum of 20–50% of annual salary. For more information, see note 14.

System for internal control and risk management over the financial reporting

The Board is responsible for internal control in accordance with the Swedish Companies Act and the Swedish Corporate Governance Code. Below, the Board presents the most important features of the system for internal control and risk management with regards to financial reporting. During 2012, efforts to streamline and develop the processes in the accounting department have continued.

The internal control environment at Sobi follows the established framework, Internal Control – Integrated Framework of The Committee of Sponsoring Organizations (COSO). It consists of the following five components:

1. Control Environment
2. Risk Assessment
3. Control Activities
4. Information and Communication
5. Follow-up

1. Control Environment

The control environment constitutes the basis of the company's internal controls. The control environment mainly comprises the culture on which the Board and management base their work and communication. 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 of the control environment, which includes organisation, 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 Sobi's business activities can be found on the company's intranet.

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

2. Risk assessment

Effective risk assessment unites Sobi'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 a) identify the important risks that affect the internal controls with regard to financial reporting and b) identify where these risks are, i.e., at what level in the company. Risk management is intended to minimise the number of risk factors within financial reporting, and to ensure that the opportunities available within the company are used in the best possible way.

The operating units carry out risk analyses regarding financial reporting to identify and assess risks in the various accounting and reporting processes. Work in 2012 included monitoring the units' work with process-based control, monitoring and reporting on internal governance and control. Risk work is reported quarterly to the Executive Leadership Team, Audit Committee and Board.

3. Control activities

After identifying risks relating to financial reporting, Sobi has developed several control activities. These activities are implemented in all areas that affect financial reporting. The purpose of the control activities is to prevent, detect and correct errors and irregularities. Activities include analytical monitoring and comparison of financial performance or entries, account reconciliation, monitoring, checking Board decisions and the Board's established policies and procedures, approval and reporting of business transactions and agreements, mandate and authorisation instructions, as well as accounting and valuation principles.

The Controllers' responsibility for maintaining internal controls within each area is developed and managed within the company. They follow-up activities through a variety of controls, such as forecasting and budgets follow-up, income and balance sheet analysis, reconciliations, as well as trend analysis and business intelligence. The result of this work is reported to the management of each business area, as well as to the Executive Management and Board.

Independent Swedish and foreign authorities perform regular tests and checks of Sobi's production environment. These inspections primarily focus on production-related procedures. The outcome of these controls and inspections is followed up by Sobi's Executive Leadership Team.

4. Information and communication

Sobi has information and communication channels aimed at ensuring efficient and accurate information services relating to financial reporting. Guidelines for financial reporting are communicated to employees through policies and are made accessible through the company's intranet. Meetings are held within the company at management level, then at the level that each department head considers appropriate, as well as several large meetings in which all employees participate.

The Board receives regular financial updates relating to the Group's financial position and performance.

Procedures for providing external information aim to provide the market with relevant, reliable and correct information concerning Sobi's development and financial position. Sobi has a communications policy meeting the requirements for a listed company.

To assess the materiality of information and ensure timely communication of important information to the market, a Disclosure Committee has been formed that includes the CEO, Chief Operating Officer (COO), CFO, General Counsel, VP

External Affairs, covering internal and external communications, and VP Investor Relations.

Financial information is regularly presented in the form of:

- Interim reports and full-year reports, published as press releases.
- The Annual Report.
- Press releases on all matters which could materially affect the valuation of the company and the share price.
- Presentations and telephone conferences for financial analysts, investors and media representatives on the day of publication of full-year and quarterly results and in conjunction with the release of important news.
- Meetings with financial analysts and investors.

All reports, presentations and press releases are published at www.sobi.com at the same time as they are communicated to the market.

5. Follow-up

The Board and the Audit Committee decide on the arrangements for monitoring of internal controls. Sobi's CFO is responsible for ensuring compliance with the internal controls in compliance with the resolution of the Board. Follow-up is done on various levels in the Group.

The Board deals with all quarterly financial statements and the annual report before publication, and monitors auditing of internal controls, especially those carried out by external auditors, through the Audit Committee. The information provided is evaluated regularly. The company's auditors personally report their observations and assessment of internal controls to the Audit Committee.

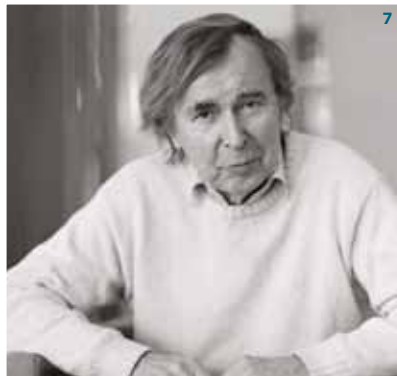
Internal audit

Sobi does not have a separate internal audit function, but has chosen to carry out the follow-up and the annual evaluation of the compliance of the internal control over the financial reporting through the existing organisation. The Board and the Audit Committee regularly reconsider the question of the establishment of an internal audit function.

Violation

The company has not violated any of the rules of the stock exchange where the company's shares are listed or any good practices of the Swedish stock market.

Board of Directors



1 Bo Jesper Hansen

Born 1958.

Chairman and Board member since 2010.

M.D. with a Ph.D. from Copenhagen University.

Other appointments: Board member of Hyperion Therapeutics Inc., GenSpera Inc., Topotarget A/S, MipSalus ApS, Zymenex A/S, Orphazyme ApS, Reapplix ApS and CMC Kontrast AB.

Previous appointments: Various positions in Swedish Orphan International AB since 1993 including CEO from 1998–2010. Medical advisor for Synthelabo, Pfizer, Pharmacia and Yamanouchi. Founder of Scandinavian Medical Research.

Shares: 8,893,846

2 Adine Grate Axén

Born 1961.

Board member since 2010.

M.Sc. from Stockholm School of Economics, Harvard AMP.

Other appointments: Chairman of Nasdaq OMX Stockholm's Listing Committee and Alhanko & Johnson AB. Vice Chairman of Sjunde AP-fonden. Advisor and working Board member of HI3GS Holding AB. Board member of Sampo OY, 3G Infrastructure Services AB, HI3G Denmark ApS and Swedavia AB.

Previous appointments: Member of the Commission for the sale of shares in companies with state ownership. Board member of Gambro AB, OMX AB 1994–2007, various senior management positions and Board assignments within Investor AB and member of the management group 1999–2007. Board member of Acne Studios Holding AB, EDB Ergo Group AS and Carnegie Investment Bank AB.

Shares: 32,000

3 Matthew Gantz

Born 1965.

Board member since 2012.

BA Princeton University and MBA from Harvard Business School.

Other appointments: US Executive Vice President of BTG, an international specialist healthcare company.

Previous appointments: Founder and previously CEO of Acureon Pharmaceuticals, President and CEO of Hydrabiosciences Inc., Vice President Europe for Chiron's Biopharmaceutical Division and General Manager for PathoGenesis Europe. Prior to Chiron/PathoGenesis, a variety of US sales and marketing roles at Abbott Laboratories Diagnostic Division.

Shares: 0

4 Lennart Johansson

Born 1955.

Board member since 2010.

M.Sc. from Stockholm School of Economics.

Other appointments: Member of the management team and Head of Financial Investments at Investor AB. Board member of HI3G and Lindorff group.

Previous appointments: CEO in b-business partners and Emerging Technologies AB. Board member of SAAB AB, IBX Group AB, Gambro Holding AB and Mölnlycke Health Care.

Shares: 20,000

5 Helena Saxon

Born 1970.

Board member since 2011.

M.Sc. from Stockholm School of Economics.

Other appointments: Investment Manager at Investor AB, Board member of Aleris, Gambro and Mölnlycke Health Care.

Previous appointments: CFO of Hallvarsson & Halvarsson, Vice President of Investor AB and financial analyst at Goldman Sachs.

Shares: 15,500

6 Hans GCP Schikan

Born 1958.

Board member since 2011.

Pharm.D, Utrecht University.

Other appointments: CEO of Prosensa, The Netherlands. Board member of Top Institute Pharma. Member of the Advisory Board of BioScience Park Leiden. Member of Core Team Dutch Top Sector Life Sciences & Health.

Previous appointments: Chairman of Dutch Association of the Innovative Pharmaceutical Industry, Nefarma. Various senior management positions within previous Organon and Genzyme.

Shares: 0

7 Hans Wigzell

Born 1938.

Board member since 2005.

M.D., D.Sc., Professor of Immunology.

Other appointments: Chairman of Karolinska Development AB and Rhenman & Partners Asset Management AB. Board member of RaySearch Laboratories AB (publ), Intercell AG (publ), Sarepta Therapeutics Inc and AB Wigzell produktion. Member of the Royal Swedish Academy of Sciences and the Royal Swedish Academy of Engineering Sciences.

Previous appointments: President of Karolinska Institutet. Board member of NeoDynamics AB, PROBI AB and Diamyd Medical AB.

Shares: 200,000

8 Catarina Larsson

Born 1952.

Employee Representative.

Laboratory engineer.

Board member since 2001.

Representative of Federation of Salaried Employees in Industry and Services.

Shares: 750

9 Bo-Gunnar Rosenbrand

Born 1963.

Employee Representative.

Laboratory engineer.

Deputy Board member 2001–2005. Board member since 2006.

Representative of Federation of Salaried Employees in Industry and Services.

Shares: 2,500

Mikael Winkvist

Authorised Public Accountant

PricewaterhouseCoopers AB

Executive Leadership Team



1 Geoffrey McDonough

Born 1970.

Chief Executive Officer.

Employed since 2011.

M.D., Harvard Medical School, B.Sc. Biology and B.A. Philosophy from University of North Carolina.

Previous positions: Various senior positions within Genzyme Corporation since 2002, most recently as President of Europe, Middle East and Africa 2010–2011. SVP and General Manager, Personalized Genetic Health 2008–2010, Global Business Leader, LSD Therapeutics. US 2005–2008. Before Genzyme he was working as an Internist and Paediatrician in the US.

Shares: 218,779

2 Alan Raffensperger

Born 1960.

Chief Operating Officer.

Employed since January 2012.

B.Sc. in Health Service Management, University of Maryland, Baltimore, US

Other appointments: Chairman of the Board, Pharmanest AB

Previous positions: CEO of Benechill Inc., Executive Director, Head of Nephrology at Amgen International 2008–2010, General Manager of the Nordic and Baltic Region at Amgen 2005–2008, Sales and Marketing Director at Roche Pharmaceuticals 1999–2004, Vice President, Global Marketing Diabetes Care, Roche Diagnostics 1996–1998, Business Director Europe, Diabetes Care at Boehringer Mannheim 1994–1996. Leading positions within Pharmacia in Sweden and the US

Shares: 31,497

3 Birgitte Volck

Born 1962.

Senior Vice President Development, Chief Medical Officer.

Employed since August 2012.

M.D., Ph.D., University of Copenhagen, Denmark.

Previous positions: Various senior positions within Amgen since 2007, most recently Executive Development Director, Bone, Neuroscience & Inflammation, International R&D at Amgen Limited in Uxbridge, UK. Nordic Medical Director & Project Director at Genzyme A/S 2004–2007, Vice President, Clinical Development & Medical Affairs at Pharmexa A/S 2001–2004. Various clinical and scientific assignments 1991–2000.

Shares: 54,748

4 Wills Hughes-Wilson

Born 1971.

Vice President External Affairs, Chief Patient Access Officer.

Employed since February 2012.

Honours graduate in Law from the University of Durham, UK.

Previous positions: Vice President Health/Market Access Policy EMEA at Genzyme Corporation, now part of the French Sanofi Group. Executive Director of Emerging Biopharmaceutical Enterprises (EBE), a specialised group of the European Federation of Pharmaceuticals Industries & Associations (EFPIA). Government affairs lead within the European animal health/veterinary medicines industry and Ernst & Young Consulting.

Shares: 13,761*

5 Fredrik Berg

Born 1955.

Vice President, General Counsel and Head of Legal & Intellectual Property, Risk- Safety and Environment Management.

Employed since 2001.

Master of Law.

Previous positions: Head of Legal/Intellectual Property at Pharmacia AB and General Counsel for Pharmacia Europe, Middle East, and Africa 1997–2001. Law firm Lindahl 1996–1997. Procordia, Kabi Pharmacia, Pharmacia & Upjohn and various positions as company lawyer and head of legal services at KabiVitrum 1988–1996. Law firm Tisell & Co 1984–1988.

Shares: 61,544

6 Maria Berggren

Born 1961.

Vice President, Head of Human Resources.

Employed since 2005.

Behavioural science degree.

Previous positions: People Relationship Manager for Technology Services at Cap Gemini Sverige AB, People Relationship Manager for the Nordic activities within Cap Gemini, Ernst & Young, Telecom & Media and various senior human resources positions within Ericsson AB. Consultant in human resources and management development.

Shares: 12,441

7 Anders Edvell

Born 1969.

Vice President, Head of Sobi Partner Products.

Employed since 2006.

M.D., Ph.D., MBA from Stockholm School of Economics, degree in launch strategies from SIMI (Copenhagen) and degree in pharmaceutical medicine from ECPM University, Basel.

Other appointments: Board member of LFF Service AB

Previous positions: Country Manager in Swedish Orphan International, Northern European Regional Director at Sobi and a number of international and national positions within Swedish and foreign pharmaceutical companies.

Shares: 11,450

8 Stefan Fraenkel

Born 1972.

Vice President, Head of Corporate Development.

Employed since 2009.

Ph.D. in International Economics & Management, MBA from Copenhagen Business School and a B.Sc. engineering degree from Chalmers University of Technology.

Previous positions: Various international senior commercial and business development positions within Wyeth 2001–2009. Before Wyeth, worked as a management consultant.

Shares: 12,741*

9 Cecilia Förberg

Born 1956.

Vice President, Head of Project and Portfolio Management.

Employed since 2001.

M.Sc. in Chemical Engineering and Ph.D. in Biochemical Engineering from the Royal Institute of Technology in Stockholm.

Previous positions: Joined Kabi Pharmacia in 1989 and has held various project leader and management positions, primarily within biopharmaceutical process development in Kabi Pharmacia, Pharmacia and Pharmacia Upjohn.

Shares: 6,824

10 Stephen James

Born 1966.

Vice President. Head of Drug Design and Development.

Employed since 2001.

Ph.D. in Biochemistry and Cell Biology, University of Leeds, UK. BSc (Hons) in Biochemistry and Microbiology, University of St. Andrews, UK.

Previous positions: A number of management positions in Research and Preclinical Development in Pharmacia & Upjohn, Pharmacia AB and Biovitrum AB. Prior to this, University of Dundee Research Fellow, UK.

Shares: 5,722

11 Lena Nyström

Born 1956.

Vice President, Head of Manufacturing Operations.

Employed since 2001.

M.Sc. in Chemistry at KTH in Stockholm.

Previous positions: Joined Kabi Vitrum in 1984. From 1995 various management positions within process development and manufacturing in Kabi Pharmacia AB, Pharmacia AB and Pharmacia Upjohn.

Shares: 7,373

12 Annika Muskantor

Born 1966.

Acting Chief Financial Officer as of September 2012.

B.A. in Economics and German Studies, Northwestern University; MBA, Kellogg Graduate School of Management, both Chicago, US.

Previous positions: Interim CFO of a variety of companies including eBay, Turner Broadcasting/MMG, and Zodiak Television. Independent consultant with previous focus on change management, M&A, valuations and transactions. Prior to this, consultant at McKinsey & Company and financial analyst at Harris Trust & Savings bank/Bank of Montreal in Chicago.

Shares: 0

* Includes holding by related natural and legal persons.

Group's statement of comprehensive income

SEK THOUSAND	Note	2012	2011
	1-4		
Total revenues	6-7	1,923,161	1,910,834
Cost of goods and services sold		-882,782	-936,264
Gross profit		1,040,379	974,570
Sales and administration expenses	15	-961,144	-804,462
Research and development expenses		-401,645	-555,719
Non-recurring items	8	-37,095	-80,404
Other operating revenue	10	345,869	201,055
Other operating expenses	11	-40,970	-53,656
Operating profit/loss	9, 12, 14, 16, 19, 31	-54,606	-318,616
Financial income	17	7,314	10,504
Financial expenses	18	-57,800	-62,733
Financial items – net		-50,486	-52,229
Profit/loss before tax		-105,092	-370,845
Income tax expense	20	4,209	388,772
Profit/loss for the year		-100,883	17,927
Other comprehensive income ¹			
Cashflowhedge		-6,494	-
Actuarial loss		-1,200	-
Translation difference		2,021	-244
Comprehensive income for the year		-106,556	17,683
Earnings/loss per share (SEK) ²		-0.38	0.07
Earnings/loss per share after full dilution (SEK) ²		-0.38	0.07
Number of shares (ordinary)		265,226,598	265,226,598
Average number of shares		265,226,598	242,119,185
Outstanding warrants		-	300,000
Number of shares after full dilution		265,226,598	265,226,598
Average number of shares after full dilution		265,226,598	242,119,185

¹ 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.

² For calculation, see disclosure "Changes in Equity". Earnings per share have been adjusted for the rights issue completed in June 2011.

Group balance sheet

SEK THOUSAND	Note	2012-12-31	2011-12-31
ASSETS	1-4		
Fixed assets			
Intangible fixed assets	21	4,533,366	4,885,077
Tangible fixed assets	22	125,585	155,941
Financial fixed assets	24	4,381	11,410
Total fixed assets		4,663,332	5,052,428
Current assets			
Inventories	26	700,368	893,819
Accounts receivable, trade	27, 30	343,244	309,631
Other receivables	27	40,480	49,885
Prepaid expenses and accrued income	28	114,051	174,727
Liquid funds	29, 30	456,951	219,043
Total current assets		1,655,094	1,647,105
TOTAL ASSETS		6,318,426	6,699,533

SEK THOUSAND	Note	2012-12-31	2011-12-31
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital		147,948	146,664
Other capital contribution		4,822,888	4,841,762
Other reserves		-29,731	-29,731
Retained Earnings		-2,225	-12,951
Net result		-100,883	17,683
Shareholders' equity referring to the owners of the Parent company		4,837,997	4,963,427
Liabilities			
<i>Long-term liabilities</i>			
Deferred income tax liabilities	25	318,281	352,684
Other liabilities	32	622,115	700,000
Provisions for other liabilities and charges	33	31,233	6,719
Total long-term liabilities		971,629	1,059,403
<i>Short-term liabilities</i>			
Accounts payable		104,488	287,971
Current tax liabilities		4,060	13,088
Other liabilities		104,765	41,878
Accrued expenses and prepaid revenues	34	295,487	333,766
Total short-term liabilities		508,800	676,703
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		6,318,426	6,699,533
Pledged assets			
– Parent company			
Pledged assets	35	200,000	3,975,588
Contingent liability	36	–	–

Group statement of changes in equity

SEK THOUSAND	Share capital	Other capital contribution	Other reserves	Profit/loss carried forward	Total shareholders' equity
Shareholders' equity, 1 January 2011	117,559	4,267,494	-29,487	-13,195	4,342,371
Comprehensive income					
Net profit/loss for the year	-	-	-	17,927	17,927
Comprehensive income	-	-	-	17,927	17,927
Other comprehensive income					
Translation differences	-	-	-244	-	-244
Sum other comprehensive income	-	-	-244	17,927	17,683
Transactions with shareholders					
Share based compensation	-	9,329	-	-	9,329
Issue of shares	29,105	564,939	-	-	594,044
Sum transactions with shareholders	29,105	574,268	-	-	603,373
Shareholders' equity, 31 Dec 2011	146,664	4,841,762	-29,731	4,732	4,963,427
Shareholders' equity, 1 January 2012	146,664	4,841,762	-29,731	4,732	4,963,427
Changed accounting principals	-	-	-24,744	-	-24,744
Comprehensive income					
Net profit/loss for the year	-	-	-	-100,883	-100,883
Other comprehensive income					
Cashflowhedge	-	-	-6,494	-	-6,494
Actuarial loss	-	-	-1,200	-	-1,200
Translation differences	-	-	2,021	-	2,021
Total comprehensive income	-	-	-5,673	-100,883	-106,556
Transactions with shareholders					
Issue of shares	1,284	-	-	-1,284	-
Share based compensation	-	5,870	-	-	5,870
Sum transactions with shareholders	1,284	5,870	-	-1,284	5,870
Shareholders' equity, Dec 31 2012	147,948	4,847,632	-60,148	-97,435	4,837,997

Swedish Orphan Biovitrum's share capital at year-end was SEK 147,947,800 shared between 269,634,858 shares with a par value of around SEK 0.55. The issued shares break down as 265,226,598 ordinary shares and 4,408,260 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. These shares represent 0.8% of the total number of shares in the company. The issue of shares was based on the long-term share programme.

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 redeemed shares.

	2012	2011
Net profit/loss referable to shareholders of the Parent company	-100,883	17,927
Average number outstanding ordinary shares (thousands)	265,227	242,119
Earnings per share before dilution (SEK per share)	-0.38	0.07

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.

	2012	2011
Net profit/loss referable to shareholders of the Parent company	-100,883	17,927
Average number outstanding ordinary shares for calculation of earnings per share after dilution (thousands)	265,227	242,119
Earnings per share after dilution (SEK per share)	-0.38	0.07

Group cash flow statement

SEK THOUSAND	2012	2011
Operations		
Profit/loss for the year	-100,883	17,927
Adjustment for items not affecting cash flow	468,614	100,396
Cash flow from operations before change in working capital	367,731	118,323
Change in working capital		
Decrease (+) / Increase (-) in inventories	193,351	86,522
Decrease (+) / Increase (-) in operating receivables	32,876	-99,138
Increase (+) / Decrease (-) in operating liabilities	-188,485	-2,777
Cash flow from operations	405,473	102,930
Investment activities		
Investment in operation	-	-29,768
Investment in intangible fixed assets	-62,847	-7,641
Investment in tangible fixed assets	-5,456	-7,664
Divestment tangible fixed assets	4,547	1,320
Divestment of short term financial assets	-600	-
Divestment of short term assets	-2,899	-
Cash flow from investment activities	-67,255	-43,753
Financing activities		
Issue of bond	600,000	-
Loans – Raising/Amortization	-	14,286
Issue of shares	-	594,044
Repayment of bank loan	-700,000	-486,763
Cash flow from financing activities	-100,000	121,567
Net change in liquid funds	238,318	180,744
Liquid funds at beginning of year	219,043	38,469
Exchange rate differences in liquid funds	-310	-170
Liquid funds at end of year	456,951	219,043

Supplementary data to the Cash flow statement – Group

SEK THOUSAND	2012	2011
Interest paid and received		
Interest received	2,329	2,856
Interest paid	42,247	51,509
Adjustments for items not affecting cash flow		
Amortization/depreciation and write down of assets	454,298	276,026
Write-down of financial asset	3,000	-4,888
Write-down of inventory and accounts receivable	-	117,990
Capital gain/loss from divestment of tangible fixed assets	925	177,025
Revaluation of present value of long-term liability	-	3,051
Revaluation of financial fixed assets	-	75
Pensions	55	6,594
Cost share programmes	5,870	9,329
Arexis, see note 36	34,000	-
Deferred tax	-23,160	-394,725
Additional purchase price Multiferon	-	-148,730
Restructuring costs	-	67,685
Other items	-6 374	-9,036
	468,614	100,396

Parent company income statement

SEK THOUSAND	Note	2012	2011
	1-4		
Total revenues	6-7	1,640,506	1,170,073
Cost of goods and services sold		-813,252	-647,222
Gross profit		827,254	522,851
Sales and administration expenses	15	-446,006	-380,091
Research and development expenses		-390,362	-534,725
Non-recurring items	8	-37,095	-77,898
Other operating revenues	10	347,018	1,022,998
Other operating expenses	11	-35,375	-29,865
Operating profit/loss	9, 12, 14, 16, 19, 31	265,434	523,270
Result from participation in Group companies	13	1,065	-538
Financial income	17	37,648	11,077
Financial expenses	18	-52,072	-64,987
Financial items – net		-13,359	-54,448
Untaxed reserves	5	-73,373	-
Profit/loss before tax		178,702	468,822
Income tax expense	20	-147,116	77,406
Profit/loss for the year		31,586	546,228

Parent company statement of comprehensive income

SEK THOUSAND	2012	2011
Profit/loss for the year	31,586	546,228
Cashflow hedge	-6,494	-
Comprehensive income for the year	25,092	546,228

Parent company balance sheet

SEK THOUSAND	Note	2012-12-31	2011-12-31
ASSETS	1–4		
Fixed assets			
Intangible fixed assets	21	638,543	665,872
Tangible fixed assets	22	119,953	143,494
Shares in Group companies	23	4,058,305	4,015,630
Financial fixed assets	24	3,110	141,313
Deferred tax	25	2,317	–
Total fixed assets		4,822,228	4,966,309
Current assets			
Inventories	26	617,942	716,845
Accounts receivable	27	184,365	68,682
Current receivables	27	31,356	58,160
Receivables from Group companies		955,346	805,664
Prepaid expenses and accrued revenues	28	108,530	169,145
Cash and bank balances	29	276,462	175,025
Total current assets		2,174,001	1,993,521
TOTAL ASSETS		6,996,229	6,959,830

SEK THOUSAND	Note	2012-12-31	2011-12-31
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
<i>Restricted equity</i>			
Share capital		147,948	146,664
Statutory reserve		800,257	800,257
Total restricted equity		948,205	946,921
<i>Non-restricted equity</i>			
Share premium reserve		4,109,366	4,104,780
Profit/loss carried forward		518,269	–67,903
Net profit/loss for the year		31,586	546,228
Total unrestricted equity		4,659,221	4,583,105
Total shareholders' equity		5,607,426	5,530,026
<i>Untaxed reserves</i>			
Tax allocation	5	1,101	–
Total untaxed reserves		1,101	–
Liabilities			
<i>Long-term liabilities</i>			
Other liabilities	32	619,750	700,000
Total long-term liabilities		619,750	700,000
<i>Current liabilities</i>			
Accounts payable		90,153	193,132
Liabilities to Group companies		336,983	256,253
Tax liabilities		1,771	–
Other liabilities		94,743	6,567
Accrued expenses and prepaid revenues	34	244,302	273,852
Other provisions	33	–	–
Total current liabilities		767,952	729,804
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		6,996,229	6,959,830
Pledged assets			
– Parent company			
Pledged assets	35	200,000	3,655,588
Contingent liabilities		–	–

Parent company change in shareholders' equity

SEK THOUSAND	RESTRICTED EQUITY		UNRESTRICTED EQUITY		Total share- holders' equity
	Share capital	Statutory reserve	Share premium reserve	Profit/loss carried forward	
Shareholders' equity, 1 Jan 2011	117,559	800,257	3,530,512	-72,433	4,375,895
Issue of shares	29,105	–	564,939	–	594,044
Redemption of shares	–	–	–	4,530	4,530
Share based compensation	–	–	9,329	–	9,329
Comprehensive income for the year	–	–	–	546,228	546,228
Shareholders' equity, 31 Dec 2011	146,664	800,257	4,104,780	478,325	5,530,026
Shareholders' equity, 1 Jan 2012	146,664	800,257	4,104,780	478,325	5,530,026
Cashflow hedge	–	–	–	-6,494	-6,494
Fusion	–	–	–	46,438	46,438
Issue of shares	1,284	–	-1,284	–	–
Share based compensation	–	–	5,870	–	5,870
Comprehensive income for the year	–	–	–	31,586	31,586
Shareholders' equity, 31 Dec 2012	147,948	800,257	4,109,366	549,855	5,607,426

Sobi's share capital at year-end was SEK 147,947,800 shared between 269,634,858 shares with a par value of around SEK 0.55. The issued shares break down as 265,226,598 ordinary shares and 4,408,260 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 THOUSAND	2012	2011
Operations		
Loss for the year	31,586	546,228
Adjustment for items not affecting cash flow	272,529	-658,793
	304,115	-112,565
Tax paid	-	-
Cash flow from operations before change in working capital	304,115	-112,565
Change in working capital		
Decrease (+) / Increase (-) in inventories	98,903	120,529
Decrease (+) / Increase (-) in operating receivables	-138,001	-140,001
Increase (+) / Decrease (-) in operating liabilities	23,148	67,509
Cash flow from operations	288,165	-64,528
Investment activities		
Acquisition of subsidiaries ¹	-43,139	-29,785
Fusion and liquidation of subsidiaries	464	-
Investments in intangible fixed assets	-28,485	-5,975
Investments in tangible fixed assets	-16,040	-5,522
Divestment of short-term financial assets	472	-
Cash flow from investment activities	-86,728	-41,282
Financing activities		
Loan – Raising	600,000	14,286
Issue of shares	-	594,044
Amortization of loans	-700,000	-336,739
Cash flow from financing activities	-100,000	271,591
Net change in liquid funds	101,437	165,781
Liquid funds at beginning of year	175,025	9,083
Cash added due to merger	-	161
Liquid funds at end of year	276,462	175,025

¹ Acquisition of subsidiaries during 2012 is mainly related to the amended purchase agreement of Arexis SEK 43 M.

Supplementary disclosures to the Cash flow statement – Parent company

SEK THOUSAND	2012	2011
Interest paid and received		
Interest received	1,800	2,287
Interest paid	36,519	51,358
Adjustments for items not affecting cash flow		
Amortization/depreciation and write down of assets	85,668	374,278
Revaluation of present value of long-term liabilities	-	3,083
Capital gain/loss from divestment of fixed assets	422	-
Revaluation of deferred tax	135,202	-135,773
Cost share programmes	5,870	9,329
Accrued interest group loaning	-	7,603
Internal transfers of factor IX	-	-985,000
Arexis, see note 36	34,000	-
Restructuring costs	-	67,685
Other items	11,367	2
	272,529	-658,793

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 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 15 September 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, 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 liabilities (including derivative instruments) measured at fair value through profit and loss.

Standards, amendments and interpretations that went into effect in 2012

By the standards (IFRS and IFRIC) that took effect in 2012 is not deemed to have any effect on the Group.

New standards, amendments and interpretations to existing standards which have not been previously applied by the Group.

Amendments have been introduced to IAS 1 "Presentation of Financial Statements" regarding the reporting of Other comprehensive income. The most significant change to the amended IAS 1 is the requirement that the items reported under "Other comprehensive income" are to be classified according to two categories. This classification is based on whether or not the items can be reclassified to an item in the income statement (reclassification adjustments). The change does not address the matter of which items are to be included in "Other comprehensive income".

IAS 19 "Employee Benefits" was amended in June 2011 and shall apply not later than for fiscal years beginning 1 January 2013. The change means that it will no longer be permitted to apply the corridor approach and instead recognises actuarial gains and losses in other comprehensive income as incurred. Cost of past service will be reported immediately. Interest cost and expected return on plan assets will be replaced by a net interest calculated using the discount rate, based on the net surplus or net deficit in the defined benefit plan. From 1 January 2012, the Group has stopped applying the "corridor method" in the current IAS 19 and instead recognises all actuarial gains and losses in other comprehensive income as incurred. Previous years' unrecognised actuarial losses, SEK 27.8 M before tax, have been reported as a change in accounting principle, directly against the opening balance of equity for 2012. This means that the introduction of the new IAS 19 will only have a limited effect on the consolidated results of operations.

IFRS 9 "Financial instruments" deals with the classification, valuation and reporting of financial liabilities and assets and replaces parts of IAS 39. IFRS 9 requires that financial assets be classified into two different categories and determined at initial recognition. For financial liabilities there are smaller changes which refer to liabilities that are designated at fair value. The Group intends to apply the new standard by the financial year beginning 1 January 2015 and has not yet evaluated the effects. The standard has not yet been endorsed by the EU.

IFRS 13 "Fair Value Measurement" provides a precise definition and a single source of fair value measurement and disclosures and guidance on the application when other IFRSs already require or permit fair value measurement. The Group has not yet evaluated the full impact of IFRS 13 on the financial statements. The Group intends to apply the new standard to the financial year beginning 1 January 2013. The introduction of the standard will only have a limited effect on the consolidated

results of operations. The standard has not yet been endorsed by the EU.

None of the other IFRS and IFRIC interpretations that have not yet entered into force, are expected to have a material impact 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 Sobi 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 acquisition is comprised of the sum total of the fair value of the assets transferred as compensation, equity instruments issued and liabilities incurred or assumed from the previous owner of the acquired company on the transfer date. Each conditional payment is reported at fair value on the acquisition date. Subsequent changes to the fair value of any conditional purchase price classified as a provision are reported in the statement of comprehensive income. All transaction costs attributable to an acquisition are expensed. Identifiable assets acquired, as well as liabilities and contingent liabilities assumed through a business combination are valued at fair value on the acquisition date.

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 recorded as goodwill. When an acquisition occurs 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 occurs 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 amortised 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 of the acquired subsidiary are assumed, the difference is recognised directly in the income statement.

>> Note 2, cont.

Intra-group transactions, balances and unrealised gains on transactions between Group companies are eliminated. Any unrealised 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 reporting. The basis for identifying reportable segments is the internal reporting as reported to and followed up by the highest decision-making executive. For Sobi, 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 recognised in the income statement. Items relating to operations are reported within operating profit, while other items are reported as financial income or expense.

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 Sobi'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 risks and benefits have been transferred to the buyer, which normally occurs when the goods have been delivered from the company's consignment inventory to the end customer.

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.

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

The Group's revenues include revenue from licensing agreements, such as out-licensing 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. Depending on the contract, the initial licensing fee is either recognised up front or 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 are considered to belong to a separate completed part of the agreement. This portion of the revenue is recognised as soon as it is received, i.e. when the terms of the agreement have been met.

Revenue from service assignments is recognised 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 recognised as work is carried out. Revenue from research collaboration is recognised in the period in which it is carried out.

Government grants

Government grants are recognised when the company fulfils the requirements associated with the grant and when it can be established with certainty that the subsidy will be received. Grants received are recognised 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. Sobi receives government grants mainly in the form of research grants from the EU. A minor part of Sobi 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 Sobi's 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 represents operating income before amortisation 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 Sobi, 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.

>> Note 2, cont.

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 amortisation over their estimated useful lives (5 to 20 years). Depreciation is adapted to the expected earnings for each product right.

Research and development costs

Expenditure for a development project is recognised as an intangible asset if the company can prove that it is technically possible to complete and profitably commercialise the results, and only if the expenditure for the project can be reliably measured. Amortisation 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 expenditures are recognised as incurred.

Acquired R&D

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

Software and IT projects in progress

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

Costs associated with developing or maintaining software are recognised as expenses as incurred. Costs directly associated with identifiable software products developed specifically for Sobi and which are controlled by the Group and are likely to generate economic benefits exceeding costs beyond one year are recognised as intangible fixed assets. Direct costs include the software development employee costs and a reasonable portion of relevant overhead.

Expenditures to enhance the performance of software or extend its useful life (development costs) beyond the original plan are capitalised and added to the initial cost of the software.

Amortisation according to plan for computer programmes that have been recognised as fixed assets is done using the straight-line method over the programme's useful life up to a maximum of three years.

Tangible fixed assets

Tangible fixed assets are recognised 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 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 are classified in the consolidated accounts either as finance or operating leases. Leased fixed assets where Sobi 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

Goodwill, with an indeterminable useful life, and intangible assets not yet taken into operation, are not depreciated but are instead tested annually for impairment. Product rights are depreciated, but are still tested annually for impairment since the book value is significant for the Group. Other assets that are subject to amortisation 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 realisable value and its value in use. When calculating the recoverable amount a discount rate corresponding to the company's weighted average cost of capital (WACC) is used.

When testing for impairment, assets are grouped at the lowest levels at which there are separate identifiable cash flows. Since Sobi 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 recognised, less depreciation, if no write-down had been performed. Impairment losses on goodwill are not reversed. Impairment testing of goodwill and capitalised research and development projects are described in note 21.

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.

Purchases and sales of financial assets are recognised on the trading date, i.e. the date on which the Group commits to purchase or sell the asset. Financial instruments are initially recognised 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 are initially recognised 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 recognised in the statement of comprehensive income.

>> Note 2, cont.

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 and interest rate derivatives are stated either as assets or liabilities, depending on whether the fair value is positive or negative.

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 instead 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 amortised 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 and interest swap contracts used initially to hedge the risk of exchange rate fluctuations and, secondarily, to cover interest risks in the company's financing. All derivatives are assigned a market value and the market val-

ues 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.

Sobi'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 recognised in the balance sheet at fair value. When hedge accounting is not done the change in value is recognised in the consolidated statement of comprehensive income. Changes in value are reported directly in the income statement. The hedged flows may be both contracted and forecast transactions. This year there has been a hedge on milestone payment to Amgen of USD 55 M that fell due in the first quarter of 2013.

Borrowing

Borrowing transactions are initially reported at fair value, net after transaction costs. Borrowing is thereafter reported at amortised 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 for a period of at least 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 either cost or net realisable value, whichever is less. Cost is calculated using the first in, first out principle (FIFO). The net realisable 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 amortised 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 recognised 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 recognised in the balance sheet when Sobi 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 fulfil the obligation. It must also be possible to make a reliable estimate of the amount. Provisions are recognised in the amount corresponding to the best estimate of the payment required to fulfil 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 recognised at its present value. The discount rate corresponds with the market rate before tax, and the risks associated with the liability. Provisions are recognised in the balance sheet under other short-term and non-current liabilities.

Provisions for restructuring which substantially change the way in which the Swedish Orphan Biovitrum Group works are recognised 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 recognised 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

>> Note 2, cont.

other cost of withdrawal. Such estimates are based on the relevant situation in negotiations with the affected parties and/or their representatives. Salaries relating to periods following the termination of duty to work are expensed when the decision is made and communicated.

Liabilities

Financial liabilities are measured at fair value less any transaction costs. After the date of acquisition, loans are measured at amortised 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 recognised in the statement of comprehensive income 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.

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 assets relating to deductible temporary differences and losses carried forward are reported to the extent it is likely that they will be able to be utilised. The value of deferred tax assets is reduced when it is no longer considered likely that they can be utilised. 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

Pensions

Sobi 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 obli-

gation 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.

Sobi primarily has defined contribution pension commitments and these commitments are insured through Skandia, Alecta and one pension fund. 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 utilise 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 mortgage 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. Actuarial gains and losses are recognized in other comprehensive income in the period in which they arise.

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 2005–2012 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.

Long-term incentive programmes

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, Sobi has established long-term incentive programmes. 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 programme 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 programme, the costs of which are recognised over the vesting period. Valuation of the Employee option programmes and Share programmes are based on commonly accepted models. The Black and Scholes model has been used for the valuation of the warrants in the employee option programmes and Monte Carlo simulation has been used to calculate the value of the Performance shares in the Share programmes.

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.

>> Note 2, cont.

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, calculation of the defined-benefit commitment based on current salary levels without consideration to future increases, and recognition of all actuarial gains and losses in the income statement as they occur. See further in note 14 regarding the incentive programme.

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 recognised as revenue. Transaction costs in connection with acquisitions of companies are recognised in the income statement. Contingent consideration is recognised as part of the cost if they are likely to fall out. If, in subsequent periods it turns out that the initial assessment needs to be revised, the acquisition cost should be adjusted. In 2012, the revision of conditional purchase price attributable to the acquisition of Arexis reduced the cost by SEK 34 M.

Group contributions

The principles of how a listed parent company should report group contributions changed in 2013 and is effective for annual reports beginning on 1 January 2013 or later; early adoption is permitted. Either the principal rule or the alternative rule can be applied. However, whichever rule is chosen must be applied consistently for all group contributions received/provided and for all financial years. Sobi applies the alternative rule as of 2012 and, consequently, reports all group contributions received/provided as appropriations.

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 2011.

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. Sobi'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 Sobi's development and how the company manages them to minimise 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. Sobi 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 emphasises a low level of risk. The aim is to minimise 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. 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.
- Sobi CEO and CFO are authorised to risk hedge net exposure to foreign currency as follows:

Expected time period	Permitted hedging
1–3 months	0–70%
4–6 months	0–50%
7–9 months	0–40%
10–12 months	0–30%

>> Note 3, cont.

In case of net exposure to foreign currency with an expected duration of more than 12 months, the hedging must be approved by the Board.

Translation exposure

The Group's results are affected by exchange rate fluctuations when the foreign subsidiaries' results are translated into SEK.

Interest risk

The Group's financing sources consist primarily of equity, cash flow from operations and borrowings. In the case of borrowings which are interest bearing, the Group is exposed to interest rate risk. Interest rate risk is the risk that changes in general interest rates will negatively affect the Group's earnings. Fixed interest period mostly affects the cash flow risk. The Group's long-term financing was restructured during the second quarter 2012, implying that the previous outstanding bank liabilities were replaced with a bond loan maturing 26 June 2017 with a coupon rate of Stibor 3 months + 5.00%. The company has hedged the interest rate risk with an interest swap maturing 26 June 2015, in which the flows are matched with the bond.

In order to limit the effect of a change in interest rates the CFO has the authority to extend the fixed interest period of by to 12 months and the CEO up to 24 months. Interest terms over 24 months require Board-approval. Since the interest rate duration is short, changes in interest rates directly affect the Group's net interest income and cash flow. The Group's interest-bearing liabilities on 31 December 2012 amounted to SEK 640 M.

Credit risk

Credit risk is the risk that customers do not fulfill their commitments; i.e. that the Group does not receive payment for their claims. The credit risk in the Group is primarily related to accounts receivable. At the closing date, these amounted to SEK 343.2 M, of which SEK 150.0 M are overdue. See note 27 for information regarding overdue accounts receivable. Sobi's customers are primarily hospitals and government, which means that the states provide a substantial portion of their financing. If the company deems that a claim will not be honoured the asset must be written down. On 31 December 2012, the Group made provisions for bad debts amounting to SEK 5.1 M. Normally there is no collateral for the credit risk in accounts receivable.

Credit reports are taken up both in the distribution agreement and at single business, when the customer is not previously known or when other circumstances cause uncertainty regarding credit worthiness. Credit reports should be obtained from a market recognised rating agency.

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. The company has a loan facility amounting to SEK 135 M (see further note 32). Group finance follows the rolling forecasts of the group liquidity reserve to ensure that the Group has sufficient cash to meet the needs of current operation while maintaining enough space for maintaining liquidity to meet hedging Q1 2013 and the repayment of the bond debt maturing in 2017. 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 the contractual, non-discounted cash flows from the Group's financial liabilities, classified according to the time remaining to the contractual maturity date as per the balance sheet date.

Debt maturity

	Less than 1 year	1–2 year	2–5 year	More than 5 year
As per 31 December 2012				
Bond ¹	41,400	41,400	703,500	–
Derivatives	11,077	–	–	–
Liabilities – long term	–	–	–	–
Accounts payable	104,488	–	–	–
Other liabilities	400,252	22,115	–	–
As per 31 December 2011				
Bond	–	–	–	–
Liabilities – long term	–	175,000	525,000	–
Accounts payable	287,971	–	–	–
Other liabilities	379,175	–	–	–

¹ The interest rate is calculated based on an interest rate of 6.9%, the interest rate are non discounted.

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%. The equity ratio as of 31 December 2012 was as follows:

	2012	2011
Shareholders' equity	4,837,997	4,963,427
Total assets	6,318,426	6,699,533
Equity ratio	76,6%	74,1%

Contingent liabilities

See note 36.

Note 4

Important estimates and assumptions for accounting purpose

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

Intangible assets

Intangible assets at Sobi 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, see below and note 21.

Goodwill

The Group periodically assesses for impairment of goodwill in accordance with the policy described in note 2. The recoverable amount of the cash-generating unit is determined by a calculation of value in use. When calculating the value of use certain estimates must be made (see note 21). On 31 December 2012, Sobi's goodwill amounted to SEK 1,605 M (1,605). The impairment tests carried out did not show any impairment loss.

>> Note 4, cont.

Development projects

The Group assesses periodically for impairment of capitalised research projects in accordance with the policy described in note 2. The evaluation of impairment requires that certain estimates must be made (see note 21).

Product rights

Product rights have a limited useful life and depreciation is employed to spread the cost over this period. The amortisation period is in the range 5–20 years and is adapted to the expected earnings in the case of each product right. Where the booked value of these product rights is very significant for the Group, these are tested annually for impairment. The assumption that has the greatest impact on the future value is the projected sales growth. It is based on assumption related to the underlying growth, future product development, and expanded uses of the drug. In the event that the company's assumptions regarding product development and the expansion of the applicable areas for a pharmaceutical prove to be incorrect, this may imply that the impairment of this product right is required. Other assumptions made in conjunction with testing for impairment are stated in note 21.

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®, Orfadinand®, and Kineret®, as well as finished stock for other products. For this inventory no provision for obsolescence is made. Stock levels for Kineret® and Kepivance® are estimated to last for several years. The stocked prod-

uct 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 results in 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 Multi-feron®, production of ReFacto® cultivation and purification. If a certain portion of the stock is not approved by the quality department of Sobi and/or Pfizer, Sobi will do an obsolescence assessment of the batch that was not approved, based on historical obsolescence. Sobi 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. 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 recognised as other current liabilities until they are earned.

The Group also recognises deferred revenue from licensing agreements. According to the milestone method, successive milestones are considered as separate from the initial licensing fee. Initial licensing fees can be reported in two ways, depending on the formulation of the licensing agreement. One such way is that the revenue is recognized directly in conjunction with the receipt of the license fee, while the alternative is that the revenue is distributed over the estimated duration of the agreement, as no separate earnings period is deemed to have been completed when the license fee is received. Subsequent milestone payments are considered to belong to a separate, completed part of the agreement. This portion of the revenue can, therefore, be recognized as soon as it is received, i.e. when the terms of the agreement have been met.

Taxes and legal disputes

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. In accordance with current tax regulations, loss carry-forwards never mature. At 31 December 2012 the activated tax losses amounts to SEK 0.2 M (37.9).

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 amortisation only starts when the project has reached the commercialisation 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 fulfil 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 capitalised and amortised on a straight-line basis from the time the company can prove that it is technically possible to fulfil and profitably commercialise the results.

Payments concerning the projects and substances in agreements with third parties, which are generally defined as prepaid payment and conditional payments, are capitalised and amortised according to plan from the time the product can be commercialised.

For a sensitivity analysis, see note 21.

Note 5

Tax allocation

PARENT COMPANY	2012	2011
Tax allocation 2008	920	–
Tax allocation 2009	181	–
	1,101	–

The tax allocations are the result of a fusion of subsidiaries during the year. Tax allocation 2007 has been reversed during the year.

Note 6

Distribution of revenues

GROUP	2012	2011
Total revenues by major type of income		
Product sales	1,332,160	1,230,887
Co-promotion revenues	12,021	104,953
Manufacturing and contract development	436,033	451,683
Royalty revenues	129,798	123,311
Licensing and milestone revenues	13,149	–
	1,923,161	1,910,834
PARENT COMPANY	2012	2011
Total revenues by major type of income		
Product sales	1,049,505	490,126
Co-promotion revenues	12,021	104,953
Manufacturing and contract development	436,033	451,683
Royalty revenues	129,798	123,311
Licensing and milestone revenues	13,149	–
	1,640,506	1,170,073

Revenues by regions

GROUP	2012	2011
Nordic ¹	434,238	487,150
Europe	1,066,173	986,796
North America	383,121	398,080
Other	39,629	38,808
Total revenues	1,923,161	1,910,834
PARENT COMPANY	2012	2011
Nordic ²	337,833	220,953
Europe	804,789	606,044
North America	465,116	339,762
Other	32,768	3,314
Total revenues	1,640,506	1,170,073

¹ Net sales in Sweden totaled SEK 115 M (185).

² Net sales in Sweden totaled SEK 78 M (108).

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. Sobi reports revenue distributed by geographical segments. See note 6 for more information regarding the distribution of revenues of major type of revenue and geographical areas.

Sobi's single largest customer is Pfizer, with net sales of SEK 436 M (452), corresponding to 23% (24%) of the company's total revenues. Sobi has not had any other customer for which revenue exceeds 10% of the company's total revenues in 2011 and 2012. The majority of fixed assets are in Sweden; no fixed assets amounting to any material value are abroad.

Note 8

Non-recurring items

GROUP	2012	2011
Personnel	–	–25,600
Premises	–	–52,200
Other	–37,095	–2,604
	–37,095	–80,404
PARENT COMPANY	2012	2011
Personnel	–	–25,600
Premises	–	–52,200
Other	–37,095	–98
	–37,095	–77,898

Of expenses for 2012, SEK 34 M refers to the supplementary agreement entered into with the sellers of Arexis on 30 March 2012.

Note 9

Depreciation/amortisation and write-down of intangible and tangible fixed assets

GROUP	2012	2011
Depreciation according to plan by type of asset		
Capitalised software expenses	-3,380	-3,890
Patents and licenses	-56,142	-34,028
Product rights	-211,272	-190,713
Land and buildings	-1,798	-336
Plant and machinery	-3,880	-17,355
Equipment, tools, fixtures and fittings	-14,875	-28,515
Cars	-682	-644
	-292,029	-275,481
Depreciation according to plan by function		
Cost of goods and services sold	-21,117	-24,911
Sales and administration expenses	-268,829	-241,675
Research and development expenses	-2,083	-8,895
	-292,029	-275,481
Write-downs by type of asset		
Capitalised software expenses	-	-12,600
Patents and licenses	-150,764	-
Research and development	-	-126,932
Equipment, tools, fixtures and fittings	-11,505	-38,066
	-162,269	-177,598
Write-downs by function		
Sales and administration expenses	-162,269	-44,943
Research and development expenses	-	-126,932
Other operating expenses	-	-3,123
Non-recurring items	-	-2,600
	-162,269	-177,598

PARENT COMPANY	2012	2011
Depreciation according to plan by type of asset		
Capitalised software expenses	-3,444	-3,858
Patents and licenses	-2,055	-1,010
Product rights	-48,891	-48,671
Land and buildings	-1,798	-
Plant and machinery	-3,880	-16,650
Equipment, tools, fixtures and fittings	-25,600	-27,486
	-85,668	-97,675
Depreciation according to plan by function		
Cost of goods and services sold	-21,117	-23,869
Sales and administration expenses	-62,468	-65,069
Research and development expenses	-2,083	-8,737
	-85,668	-97,675
Write-downs by type of asset		
Capitalised software expenses	-	-10,000
Research and development expenses	-	-126,932
Equipment, tools, fixtures and fittings	-	-38,066
	-	-174,998
Write-downs by function		
Sales and administration expenses	-	-44,943
Research and development expenses	-	-126,932
Other operating expenses	-	-3,123
	-	-174,998

Note 10

Other operating revenues

GROUP	2012	2011
Divestment real estate property	8,821	3,623
Rental income	-	3
Exchange rate gains on operating receivables/liabilities	20,980	45,301
Divestment of the co-promotion rights	307,480	-
EU contribution received	-	128
Disposal of intangible assets	-	1,864
Additional purchase price for Multiferon	-	148,730
Other	8,588	1,405
	345,869	201,055
PARENT COMPANY	2012	2011
Rental income	-	3
Exchange rate gains on operating receivables/liabilities	20,980	24,207
Furthermore invoiced costs to partners	8,821	1,110
Furthermore Invoiced costs to subsidiaries	-	10,714
Transfers of operation	-	986,864
Divestment of the co-promotion rights	307,480	-
EU contribution received	-	100
Other	9,737	-
	347,018	1,022,998

Note 11

Other operating expenses

GROUP	2012	2011
Exchange rate losses on operating receivables/liabilities	-39,578	-48,822
Scrapping costs	-	-3,577
Cost related to divestment of business	-	-538
Reimbursed foreign VAT	20	-318
Other	-1,412	-401
	-40,970	-53,656
PARENT COMPANY	2012	2011
Exchange rate losses on operating receivables/liabilities	-35,395	-26,451
Scrapping costs	-	-3,124
Reimbursed foreign VAT	20	-290
	-35,375	-29,865

Note 12

Expenses for operational leasing

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

	GROUP		PARENT COMPANY	
	2012	2011	2012	2011
Within 1 year	2,898	5,246	113	340
Between 1 and 5 years	5,023	5,710	727	1,262
	7,921	10,956	840	1,602
Leasing costs for the year:	5,218	8,325	651	3,507

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

	GROUP		PARENT COMPANY	
	2012	2011	2012	2011
Within 1 year	56,917	89,821	54,220	84,698
Between 1 and 5 years	284,593	296,675	282,602	286,355
Later than 5 years	179,320	263,195	179,320	263,195
	520,830	649,691	516,142	634,248
Leasing costs for the year:	88,810	88,664	85,379	76,585

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. SOBI 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.

Note 13

Result from participation in Group companies

PARENT COMPANY	2012	2011
Dividends from subsidiaries	1,368	-
Write-down of shares in subsidiaries	-303	-
Capital gain from divestment of subsidiaries	-	-538
	1,065	-538

Note 14

Personnel, personnel costs and remuneration to Board members and executive management

Average number of employees

GROUP	2012	of which men	2011	of which men
Sweden	385	40%	412	40%
Denmark	11	19%	10	18%
Finland/Balticum	11	36%	9	50%
Norway	9	44%	10	50%
United Kingdom	16	69%	14	71%
France	18	39%	16	53%
Germany	17	47%	16	39%
Italy	11	36%	10	40%
Spain	11	45%	7	45%
Russia	3	33%	2	0%
Central Eastern Europe	14	36%	10	36%
USA*	8	59%	0	0%
Dubai**	0	100%	0	0%
Total	514	40%	517	40%

* Employed as of July 2012

** Employed as of October 2012

Salaries, other remunerations and social security expenses

GROUP AND PARENT COMPANY	2012		2011	
	Salaries and remunerations	Social security costs	Salaries and remunerations	Social security costs
Parent company	243,143	126,689	253,524	136,964
(of which pension cost ¹)		(40,831)		(53,919)
Subsidiary	110,259	31,053	102,838	39,733
(of which pension cost		(11,013)		(13,278)
Group total	353,402	157,742	356,362	176,697
(of which pension cost ¹)		(51,844)		(67,197)

¹ Of the Group's and Parent company's pensions costs, SEK 1 M (0.9) pertain to the Board and CEO. The Group's outstanding pension commitments for the Board and CEO amount to SEK 0 M (0).

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

	2012		2011	
	Board and CEO	Other employee	Board and CEO	Other employee
Parent company				
Salaries and benefits	16,059	227,084	23,358	230,166
(of which bonuses, etc.)	(6,026)	(11,899)	(10,685)	(6,932)
Subsidiaries				
Salaries and benefits	10,209	100,050	12,080	90,758
(of which bonuses, etc.)	(818)	(6,665)	(767)	(6,557)
Group total	26,268	327,134	35,438	320,924
(of which bonuses, etc.)	(6,844)	(18,564)	(11,452)	(13,489)

Remuneration policy 2011

The remuneration policy approved at the 2012 Annual General Meeting states that Sobi 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 incentives may be offered as a supplement to the above and will then be submitted for approval at the 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 pre-determined targets.

The full guidelines are described in the Directors' Report on page 46–47.

Remuneration to the CEO

Geoffrey McDonough took up the position as Chief Executive Officer and President of Sobi on 15 August 2011.

In 2012 Geoffrey McDonough received SEK 4 M in annual gross salary (which includes pension). The CEO's salary is reviewed annually on 1 January by the Board and the company's Compensation & Benefits Committee. Besides fixed salary, a variable salary of no more than 50% of the annual gross salary including pension is paid. The variable salary adheres to a system approved by the Board and is based on comprehensive company objectives. The 2012 variable salary amounted to SEK 838 thousand.

The notice period for both the company and the CEO is three months. The CEO is entitled to 21 months severance pay based on gross salary at termination. Severance pay is applicable if the employment is terminated by the company. The CEO is entitled to additional compensation equivalent to six months' salary if the CEO is still employed 6 months after major changes in ownership structure based on gross salary at the end of the 6 months.

Sobi pays a contribution of 25% of annual gross salary for Geoffrey McDonough's future pension benefits. Pensionable salary in 2012 was SEK 4 M annually and the retirement age is 65.

The CEO participates in a special benefits package that includes, a housing contribution, relocation assistance, and tax declaration, among other benefits, as well as various benefits that follow rules on tax relief for payments to foreign experts, researchers and other key personnel.

>> Note 14, cont.

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 comprised of two components: 70% of which is company objectives and 30% individual goals. The maximum individual levels are between 20 and 50% of basic salary.

For other executives and key employees, the variable salary is based 50% on company objectives and 50% on individual goals. Variable salary levels for these individuals are between 10 and 30% 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

Sobi pays a contribution of 25% of Geoffrey McDonough's pensionable salary at the agreed premium based direct retirement solution. The contribution is paid through a distribution of Geoffrey McDonough's annual gross salary of SEK 4 M which, according to the employment contract, includes pension contributions. The pension is paid to the CEO on retirement.

Sobi's pension plan for executive management is principally a defined contribution plan. This means that Sobi makes contributions equal to 27% 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 maximised 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%. This applies to one individual who has contributions of 30%, and in this case, 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, three individuals have a defined benefit or ITP. Members of management who are employed abroad are covered by different pension plans, depending of the country of employment.

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

	Basic pay/ fees	Variable remunera- tion	Pension cost	Other benefits	Financial instrument	Other remunera- tion	Total
2012							
Chairman of the Board ¹	854	–	–	–	–	7,937	8,791
Other board members ²							
Helena Saxon	313	–	–	–	–	–	313
Hans Schikan	318	–	–	–	–	–	318
Adine Grate Axén	297	–	–	–	–	–	297
Lennart Johansson	335	–	–	–	–	–	335
Hans Wigzell	300	–	–	–	–	–	300
Matthew Gantz ³	220	–	–	–	–	–	220
Chief Executive Officer							
Geoffrey McDonough	3,000	838	1,000	218	1,364	–	6,420
Other senior management ⁴	19,406	2,387	6,702	371	2,154	2,801	33,821
	25,043	3,225	7,702	589	3,518	10,738	50,815

¹ The purchase agreement relating to Swedish Orphan included a commitment by Bo Jesper Hansen not to compete with Swedish Orphan Biovitrum and its subsidiaries until 2012. Bo Jesper Hansen was also employed in the company, and received monthly compensation amounting to about DKK 565 thousand, which is entirely deducted from the compensation in the same amount that Bo Jesper Hansen is entitled to in accordance with the acquisition agreement. During 2012 an amount of SEK 854 thousand was expensed. The amount refers to accrued vacation pay for 2009 ie the period before the acquisition of Swedish Orphan Holding AB (in his former role as CEO), which previously has not been settled.

² Information regarding the directors fees can be found in the Corporate Governance Report.

³ Matthew Gantz has been a member of the Board since the Annual General Meeting 2012. Compensation relates to work carried out during this period.

⁴ "Other senior executives" refers to Swedish Orphan Biovitrum's management team consisting of 11 persons other than the CEO as of 31 December 2012. The CFO is currently employed only in an acting capacity, and the compensation paid to him/her is reported under fees.

>> Note 14, cont.

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

	Basic pay/ fees	Variable remunera- tion	Pension cost	Other benefits	Financial instrument	Other remunera- tion	Total
2011							
Chairman of the Board ¹	–	–	–	–	–	8,226	8,226
Other Board members ²							
Helena Saxon ³	193	–	–	–	–	–	193
Hans Schikan ³	183	–	–	–	–	–	183
Adine Grate Axén	290	–	–	–	–	–	290
Lennart Johansson	325	–	–	–	–	–	325
Wenche Rolfsen ⁴	91	–	–	–	–	–	91
Michael Steinmetz ⁴	100	–	–	–	–	–	100
Hans Wigzell	291	–	–	–	–	–	291
Hans Glemstedt ⁴	97	–	–	–	–	–	97
Chief Executive Officer							
Kennet Rooth ⁶	1,575	590	577	36	–	–	2,778
Geoffrey McDonough ⁶	1,125	754	375	105	429	8,300	11,088
Other senior management ⁵	15,922	1,372	5,323	174	3,154	–	25,945
	20,192	2,716	6,275	315	3,583	16,526	49,607

¹ The purchase agreement relating to Swedish Orphan included a commitment by Bo Jesper Hansen not to compete with Swedish Orphan Biovitrum and its subsidiaries until 2012. Bo Jesper Hansen was also employed in the company, and received monthly compensation amounting to about DKK 565 thousand, which is entirely deducted from the compensation in the same amount that Bo Jesper Hansen is entitled to in accordance with the acquisition agreement.

² Information regarding the directors fees can be found in the Corporate Governance Report.

³ Helena Saxon and Hans Schikan have been members of the Board since the Annual General Meeting 2011. Compensation relates to work carried out during this period.

⁴ Wenche Rolfsen, Michael Steinmetz and Hans Glemstedt resigned from the Board at the Annual General Meeting 2011.

⁵ "Other senior executives" refers to Swedish Orphan Biovitrum's management team consisting of 12 persons other than the CEO as of 31 December 2011.

⁶ Geoffrey McDonough took up the position as CEO on 15 August 2011. Compensation relates to work carried out during this period. Kennet Rooth resigned as CEO on 15 August 2011 and the compensation relates to work during the period between 1 January 2011 until 15 August 2011.

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

	2012	2011
Parent company and subsidiaries		
Parent company		
Salaries and remunerations	42,618	39,655
(of which bonuses etc)	(6,026)	(10,685)
Pension cost	7,597	5,619
Number of persons (excl. union representatives)	15	17
Subsidiaries		
Salaries and remunerations	10,769	14,008
(of which bonuses etc)	(818)	(1,017)
Pension cost	1,142	1,862
Number of persons	10	11
Group		
Salaries and remunerations	53,387	53,663
(of which bonuses etc)	(6,844)	(11,702)
Pension cost	8,739	7,480
Number of persons (excl. union representatives)	25	28

Long-term incentive programmes

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

Employee option programme 2007/2012

This programme expired 1 April 2012. No options were returned or awarded under this programme.

>> Note 14, cont.

Employee option programme 2009

This programme expired 9 June 2012. No shares were awarded under this programme.

Share programme 2010 and Share programme 2011

At the 2010 and 2011 Annual General Meetings, respectively, decisions were made to introduce performance-based, long-term share programmes. The programmes cover managers and key employees 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 periods of three years for the respective programmes. 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 programme 2010 and the Share programme 2011 ("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 programme (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 these programmes.

Performance Condition 1: For any allotment of common shares to be possible under Share programme 2010, the total shareholder return for the Sobi 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 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% of the maximum number of common shares will be carried out, in accordance with what has been described previously. 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 Sobi 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 (programme 2010) and 13.93 (programme 2011) on the allotment date, volatility of 32.8% (programme 2010) and 37.0% (programme 2011) and a risk free interest rate of 2.06% (programme 2010) and 1.82 % (programme 2011).

Share programme 2010

	Number of Performance shares	Number of Matching shares	Value	Purchase price	Benefit
Other senior management, 6	79,677	14,414	2,169,904	–	2,169,904
Sum	79,677	14,414	2,169,904	–	2,169,904

Share programme 2011

	Number of Performance shares	Number of Matching shares	Value	Purchase price	Benefit
Other senior management, 7	250,772	41,022	2,234,055	–	2,234,055
Sum	250,772	41,022	2,234,055	–	2,234,055

Long-term incentive programme for CEO Geoffrey McDonough

Extraordinary General Meeting 24 August 2011 approved the Board's proposal for the introduction of a performance based long term incentive programme for the newly appointed CEO Geoffrey McDonough. The programme is based on a personal investment in Sobi-shares in the market and the assignment requires, inter alia, that certain performance requirements related to the development of Sobi's share price are met.

Allotted Performance shares shall be received free of charge. The number of Performance shares that may be received by the Participant is dependent on the fulfilment of certain performance Condition, which relate to targets for value creation based on the development of the share price during the period 22 June 2011 until 15 August 2014 ("trading days").

The calculation of the development of the Share price shall be based on a comparison of the volume weighted average purchase price for the Share as noted on NASDAQ OMX Stockholm's official list during a period of nine trading days prior to and including the first day of the Performance period (i.e. during the period 10–22 June 2011) and the volume weighted average purchase price for the Share as noted on NASDAQ OMX Stockholm's official list during the last ten trading days of the Performance period.

The 500,000 Performance shares shall be allotted based on the following conditions:

Pro-rata allotment of 400,000 Performance shares

- For any allotment of Performance shares to be possible the share price must have increased by more than 15% during the Performance period (i.e. the volume weighted average Share price during the last ten trading days of the Performance period shall amount to more than SEK 25.77).
- For the maximum allotment of 400,000 Performance shares, the volume weighted average Share price during the last ten trading days of the Performance period shall amount to at least SEK 45.00.
- If the volume weighted average Share price during the ten last trading days of the Performance period is between the thresholds set out in item a and item b above, the portion of the 400,000 Performance shares to be allotted shall be calculated on a pro-rata basis (i.e. the calculation shall be linear).

>> Note 14, cont.

Threshold allotment 1 of 30,000 Performance shares

- d) In addition to the pro-rata allotment of Performance shares pursuant to items a-c above, the participant shall be allotted 30,000 Performance shares if the volume weighted average share price during the last ten trading days of the Performance period amounts to at least SEK 30.00.

Threshold allotment 2 of 70,000 Performance shares

- e) In addition to the pro-rata allotment and the threshold allotment 1 of Performance shares pursuant to items a-d above, the participant shall be allotted 70,000 Performance shares if the volume weighted average Share price during the last ten trading days of the Performance period amounts to at least SEK 35.00. For the avoidance of doubt, none of the 70,000 Performance shares to be allotted pursuant to this item e shall be allotted at a volume weighted average share price below SEK 35.00, i.e. there shall be no pro-rata allotment of the 70,000 Performance shares where the volume weighted average Share price is between the thresholds set out in item d above and in this item e.

Allotment under the CEO's incentive programme 2011 is conditional on the participant remaining employed as the CEO of the Swedish Orphan Biovitrum Group for a three-year period, from 15 August 2011 up to and including 15 August 2014, disregarding certain exceptions determined by the Board, and that the participant, on the allotment date, has not left his/her position following termination of employment either by Sobi or by the CEO himself/herself. Furthermore, the allotment is conditional on the participant retaining his/her private investment during the entirety of the aforementioned period, i.e. from 15 August 2011 up to and including 15 August 2014. If all conditions for allotment under the CEO's incentive programme 2011 are fulfilled, the shares are allotted free of charge following the conclusion of the Measurement period, after approval is granted by the Board of Directors at the Board meeting immediately following this date.

Expensing for long-term incentive programme for CEO Geoffrey McDonough is calculated with the following parameters:

- Number of Performance shares in Pro-rata allotment: 400,000
- Number of Performance Shares in Threshold allotment 1: 30,000
- Number of Performance Shares in Threshold allotment 2: 70,000
- Vesting period 36 months
- Fair value per Performance share in Pro-rata allotment: SEK 5.47
- Fair value per Performance share in Threshold allotment 1: SEK 7.01
- Fair value per Performance share in Threshold allotment 2: SEK 5.32

Share programme 2012

The 2012 Annual General Meeting resolved to approve a performance-based, long-term share programme ("Executive Programme"). The programme 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 programme 2011 ("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 programme (the "Performance period"). For any allotment of common shares ("Performance shares") to be possible under Share programme 2012, the total shareholder return for the Sobi common share must amount to at least 25% during the Performance period.

The value of the Matching shares has been calculated on the allotment date based on the volume weighted price of the Sobi common share on that date under the assumption that no dividends are expected to be paid during the Measurement period. The value of the Performance shares has been calculated, using the Monte Carlo simulation, on the allotment date, taking market conditions into account but under the assumption that no dividends are expected to be paid out during the Measurement period. Important input data in the model were volume-weighted average share price of SEK 21.99 on the allotment date, volatility of 38.0% and a risk free interest rate of 0.92%.

A long-term, performance-based share programme ("All Employee Programme") was adopted at the Annual General Meeting on 26 April 2012. The All Employee Programme covers permanent employees in Swedish Orphan Biovitrum AB (publ) and may involve a total maximum allocation of 24,800 shares in Swedish Orphan Biovitrum AB. The programme is designed so that participants receive 100 shares free of charge if the performance criteria are met and if the individual stays with the company for three years.

Share programme 2012

	Number of Performance shares	Number of Matching shares	Value	Purchase price	Benefit
Other senior management, 10	402,863	98,835	5,807,206	–	5,807,206
Sum	402,863	98,835	5,807,206	–	5,807,206

>> Note 14, cont.

Expensing of Share programme 2010, 2011 and 2012 are calculated with the following parameters:

	Start date	End date	Number of Matching shares	Number of Performance shares	Vesting period (month)	Fair value of Matching share	Fair value Performance share	Anticipated turnover among the relevant employees	Maximum allotment of shares
Share programme 2010	2010-12-12	2013-12-12	67,311	316,502	36	39.71	20.05	5%	383,813
Share programme 2011	2011-12-15	2014-12-15	89,845	494,148	36	13.93	6.63	5%	583,993
Share programme 2012, Leadership programme	2012-05-21	2015-05-14	166,476	504,324	36	21.99	9.02	5%	670,800
Share programme 2012, Personell programme	2012-06-25	2015-05-14	–	–	36	–	12.24	5%	24,800

Volatility is measured as the standard deviation for expected return on the share price and is based on a statistical analysis of daily share prices for the Sobi common share over the last three years. The valuation model also reflects corresponding historical volatility for the share prices of comparable companies during the same period and a correlation between all share prices.

Gender distribution of Board and management

The data in the table included representatives. The data refers to the ratio at closing.

GROUP	2012	2011
Board		
Men	5	4
Women	2	2
	7	6
CEO and other senior executives		
Men	6	9
Women	6	4
	12	13

Note 15

Remuneration and reimbursement

GROUP	2012	2011
PwC		
Auditing assignments ¹	3,491	3,050
of which auditing in addition to audit assignment	1,441	850
Tax assignments	2,643	2,430
Other assignments	1,400	1,600
	7,535	7,080
Other auditor		
Auditing assignments	–	–
PARENT COMPANY	2012	2011
PwC		
Auditing assignments ¹	2,981	2,540
of which auditing in addition to audit assignment	1,441	850
Tax assignments	2,590	1,952
Other assignments	1,350	1,600
	6,921	6,092

¹ "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	2012	2011
Raw materials and consumables	–606,760	–678,958
Other external costs	–687,405	–691,814
Personnel costs	–534,203	–556,125
Depreciation and write-downs	–454,298	–453,079
Other operating expenses	–40,970	–50,533
	–2,323,636	–2,430,505
PARENT COMPANY	2012	2011
Raw materials and consumables	–536,981	–414,008
Other external costs	–663,630	–555,212
Personnel costs	–400,436	–401,162
Depreciation and write-downs	–85,668	–272,673
Other operating expenses	–35,375	–26,742
	–1,722,090	–1,669,801

Note 17

Financial income

GROUP	2012	2011
Interest income, miscellaneous	2,329	2,856
Result from short-term investments	3,880	45
Exchange rate gains/losses on short term receivables	548	2,594
Revaluation of financial asset	–	5,000
Other	557	9
	7,314	10,504
PARENT COMPANY	2012	2011
Interest income, group companies	35,300	–
Interest income, miscellaneous	1,800	2,287
Result from short-term investments	–	42
Exchange rate gains/losses on short term receivables	548	3,748
Revaluation of financial claims	–	5,000
	37,648	11,077

Note 18

Financial expenses

GROUP	2012	2011
Interest expenses, bank loan	–34,365	–48,458
Interest expenses, miscellaneous	–7,882	–7,831
Exchange rate difference liabilities	–11,307	–445
Financing expenses	–4,246	–2,842
Re-evaluation of short-term investments	–	–3,051
Other	–	–105
	–57,800	–62,733
PARENT COMPANY	2012	2011
Interest expenses, bank loan	–34,365	–48,458
Interest expenses, miscellaneous	–2,154	–10,530
Exchange rate difference liabilities	–11,307	–
Financing expenses	–4,246	–2,842
Re-evaluation of short-term investments	–	–3,051
Other	–	–105
	–52,072	–64,987

Note 19

Exchange rate differences affecting operating profit/loss

GROUP	2012	2011
Exchange rate differences affecting operating profit/loss	–18,598	–3,521
	–18,598	–3,521
PARENT COMPANY	2012	2011
Exchange rate differences affecting operating profit/loss	–14,415	–2,245
	–14,415	–2,245

Note 20

Income tax

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

GROUP	2012	2011
Tax expense / income for the year	-7,608	-5,953
Adjustment of taxes related to previous years	-11,343	-
Total tax reported for the Group	-18,951	-5,953
<i>Deferred tax relating to:</i>		
Pensions	-2,324	1,787
Change in tax allocation reserve and excess depreciation	21,537	-77,000
Internal profit in inventories	25,183	3,019
Depreciation of immaterial assets	6,586	41,011
Write down of receivables	-	2,079
Capitalisation of tax loss carry forwards	-28,815	29,011
Revaluation of deferred tax	-	394,828
Other	993	-10
Total deferred tax reported for the Group	23,160	394,725
Total tax reported for the Group	4,209	388,772
PARENT COMPANY	2012	2011
Tax expense / income for the year	-135,773	77,406
Adjustment of taxes related to previous years	-11,343	-
Total tax reported for the Parent company	-147,116	77,406

Reconciliation of actual tax

GROUP	2012	2011
Pre-tax profit	-105,092	-370,845
Tax on the basis of prevailing tax rate for Parent company	27,639	97,532
Effect of foreign tax rates	-2,955	-1,171
Non reported taxable income	-2,362	-
Other non-deductible expenses	-44,376	-7,080
Non-taxable income	5,180	40,498
Interest on tax allocation reserve	-535	-957
Adjustment of tax previous years	-11,444	73
Revaluation of deferred tax	-	124,104
Non valued tax asset	-44,501	-
Effect of changed tax rate	-77,563	-
Revaluation of deferred tax	-	135,773
Reported actual tax	4,209	388,772
PARENT COMPANY	2012	2011
Pre-tax profit	178,702	468,822
Tax on the basis of prevailing tax rate for Parent company	-46,999	-123,300
Non reported taxable income	-2,362	-
Other non-deductible expenses	-43 716 ¹	-1,107
Adjustment of tax previous years	-11,343	-
Non-deductible write-down shares in subsidiaries	-	-141
Non-taxable income	1,805	307
Decrease (+) / Increase (-) in loss carry-forward without corresponding capitalisation of deferred tax	-	124,242
Non valued tax asset	-44 501	-
Revaluation of deferred tax	-	77,406
Reported actual tax	-147,116	77,406

¹ For the most part non-deductible transaction costs related to internal transfers.

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 & licenses	Product rights	Software and other	IT-software in progress	Total
1 January – 31 December 2011							
Net book value – Opening balance	1,600,959	299,206	509,681	2,803,923	6,544	3,981	5,224,294
Additions	4,348	–	1,302	–	4,241	4,594	14,485
Reclassification of acquisition value	–	–	–	–	14,461	–	14,461
Write-downs	–	–126,932 ¹	–	–	–12,600	–	–139,532
Depreciation	–	–	–34,028	–190,713	–3,890	–	–228,631
Net book value – Closing balance	1,605,307	172,274	476,955	2,613,210	10,274	7,057	4,885,077
At 31 December 2011							
Acquisition value	1,639,625	408,352	648,653	3,014,758	56,582	7,057	5,775,027
Accumulated depreciation and amortisation	–34,318	–236,078	–171,698	–401,548	–46,308	–	–889,950
Net book value	1,605,307	172,274	476,955	2,613,210	10,274	7,057	4,885,077
1 January – 31 December 2012							
Net book value – Opening balance	1,605,307	172,274	476,955	2,613,210	10,274	7,057	4,885,077
Commissioning of existing facilities	–	–	–	–	–	8,210	8,210
Additions	–	–	60,834 ²	–	803	–	61,637
Write-downs	–	–	–	–150,764 ³	–	–	–150,764
Depreciation	–	–	–56,142	–211,272	–3,380	–	–270,794
Net book value – Closing balance	1,605,307	172,274	481,647	2,251,174	7,697	15,267	4,533,366
At 31 December 2012							
Acquisition value	1,639,625	408,352	709,487	3,014,758	57,385	15,267	5,844,874
Accumulated depreciation and amortisation	–34,318	–236,078	–227,840	–763,584	–49,688	–	–1,311,508
Net book value	1,605,307	172,274	481,647	2,251,174	7,697	15,267	4,533,366

¹ Investment in certain residual rights in the research programme Leptin, which were sold to Astra Zeneca in 2009. The investment has been written down to zero during 2011.

² Acquisitions in 2012 refer to Arexis (SEK 43 M), Milestone Iron Suchrose (SEK 11 M), O4CP (SEK 2.7 M) and Aloxi (SEK 4.2 M).

³ Write-downs in 2012 refers to the impairment of the product right Multiferon. This, together with the write-down of tangible fixed assets, comprises the total write-down of Multiferon amounting to SEK 162 M. The management deemed it prudent that this assets does not have any value.

>> Note 21, cont.

PARENT COMPANY	Research & Development	Trademarks & licenses	Product rights	Software and other	IT-software in progress	Total
1 January – 31 December 2011						
Net book value – Opening balance	126,934 ¹	65,970	633,458	3,095	3,981	833,438
Commissioning of existing facilities	–	–	–	1,518	–1,518	–
Additions	–	–	–	3,852	4,594	8,446
Reclassification of acquisition value	–	–	–	14,461	–	14,461
Write-downs	–126,934 ¹	–	–	–10,000	–	–136,934
Depreciation	–	–1,010	–48,671	–3,858	–	–53,539
Net book value – Closing balance	0	64,960	584,787	9,068	7,057	665,872
At 31 December 2011						
Acquisition value	126,934	148,846	730,058	51,823	7,057	1,064,718
Accumulated depreciation and amortisation	–126,934	–83,886	–145,271	–42,755	–	–398,846
Net book value	0	64,960	584,787	9,068	7,057	665,872
1 January – 31 December 2012						
Net book value – Opening balance	–	64,960	584,787	9,068	7,057	665,872
Commissioning of existing facilities	–	–	–	–	8,210	8,210
Additions	–	19,472 ²	–	803	–	20,275
Reclassification of acquisition value	–	–	–	–1,424	–	–1,424
Write-downs	–	–	–	–	–	–
Depreciation	–	–2,055	–48,891	–3,444	–	–54,390
Net book value – Closing balance	0	82,377	535,896	5,003	15,267	638,543
At 31 December 2012						
Acquisition value	126,934	168,318	730,058	51,202	15,267	1,091,779
Accumulated depreciation and amortisation	–126,934	–85,941	–194,162	–46,199	–	–453,236
Net book value	0	82,377	535,896	5,003	15,267	638,543

¹ Investment in certain residual rights in the research programme Leptin, which were sold to Astra Zeneca in 2009. The investment has been written down to zero during 2011.

² Acquisitions in 2012 refer to Milestone Iron Suchrose (SEK 11 M), O4CP (SEK 2.7 M) and Aloxi (SEK 4.2 M).

>> Note 21, cont.

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

Goodwill

Assessment of the value of the Group's goodwill items are based on the Group's value in use where the Group is defined as the only cash-generating unit.

Cash flows are based on financial plans that have been established by management covering a five year period. The financial plans have been established based on past performance, experiences and expectations in the market. The plans includes assumptions about the current product development and future product launches for Kiobrina (2015) and haemophilia projects (2016). The financial plans also include assumptions of the development of price, expenses and sales. Cash flows beyond the five year period have been extrapolated using an estimated growth rate of 0–1%. Sobi's goodwill at 31 December 2012 amounts to SEK 1,605 M (1,605). Completed impairment tests show no impairment loss of goodwill.

The following table shows key assumptions used in the calculation of value:

Parameter	2012	2011
Growth rate beyond the initial five-year period	0–1%	2%
Discount rate	10.0%	10.7%

Assumptions regarding Sobi's weighted average cost of capital (WACC):

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

Market risk premium: 4%

Beta: Sobi's development largely follows the general trend on the market and is therefore calculated as 1.

Interest expense: according to Sobi's borrowing costs

Tax rate: according to tax rates in Sweden

Sobi has conducted a sensitivity analysis regarding the following variables in the impairment testing of goodwill: the discount rate, sales and eternal growth rate. The sensitivity analysis indicates that there are good margins in the calculation.

Product rights/Development projects

Testing for impairment of product rights and development is carried out as needed and is 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. When discounting of future cash flows, the discount rate is used as described above.

For impairment testing of research the key factors are future cash flows from the individual asset, the probability to achieve positive outcomes in clinical studies, assumptions, and the best commercial outcome. Future cash flows are estimated with

respect to project development in the short-and long-term and adjusted for the probability that the project will be commercialised. The earlier in the chain of development that the project is, the higher the risk. As it passes through the defined development phases, the likelihood of reaching the market increases. The assessment of the likelihood for a proposal to implement the current development phase successfully is made on the basis of an assessment of the scientific potential of project to have a positive outcome at the individual phase of the development. The best possible assumptions, so-called best-case assumption, are made on basis of the parameters that affect the potential for the project to result in the development of a drug with the highest commercial potential, and are based on what is reasonable to assume about the project's scientific profile using the information available today. The forecast period is based on the product's estimated life of market.

The assumptions are forecasts of future sales, costs attributable to each product, product life and discount rate. 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. Completed impairment testing of the product rights shows no impairment loss.

Impairments in 2012

Sobi has in 2012 assessed the future potential for Multiferon and estimated that value of tangible and intangible assets have to be written down. The valuation is based on a assessment of both Multiferons future value for the company and estimated net realizable value. Impairment losses totaled SEK 162 M and allocated to tangible assets of SEK 11 M and intangible assets of SEK 151 M.

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 2011						
Net book value – Opening balance	6,147	56,704	170,796	2,514	15,285	251,446
Entry into service of existing facilities	–	149	657	–	–806	–
Additions	–	1,737	2,743	577	139	5,196
Reclassification of acquisition value	–	–	–14,461	–	–	–14,461
Disposals	–484	–	–22	–818	–	–1,324
Depreciation	–336	–17,355	–28,515	–644	–	–46,850
Write-downs	–	–	–38,066 ¹	–	–	–38,066
Net book value – Closing balance	5,327	41,235	93,132	1,629	14,618	155,941
At 31 December 2011						
Acquisition value	5,999	626,253	282,154	2,607	14,618	931,631
Accumulated depreciation and amortisation	–672	–585,018	–189,022	–978	–	–775,690
Net book value	5,327	41,235	93,132	1,629	14,618	155,941
1 January – 31 December 2012						
Net book value – Opening balance	5,327	41,235	93,132	1,629	14,618	155,941
Entry into service of existing facilities	–	–	14,606	–	–14,606	–
Additions	–	2,382	2,979	2,603	1,671	9,635
Reclassification of acquisition value	1,401	–200	–1,401	–	–	–200
Disposals	–	–5,296	–1,683	–	–	–6,979
Depreciation	–1,798	–3,880	–14,875	–682	–	–21,235
Write-downs	–	–	–11,505 ²	–	–	–11,505
Exchange differences	–	–	–72	–	–	–72
Net book value – Closing balance	4,930	34,241	81,181	3,550	1,683	125,585
At 31 December 2012						
Acquisition value	7,400	600,250	286,562	5,210	1,683	901,105
Accumulated depreciation and amortisation	–2,470	–566,009	–205,381	–1,660	–	–775,520
Net book value	4,930	34,241	81,181	3,550	1,683	125,585

¹ Write downs during 2011:

The company has written down assets relating to the premises that no longer will be used due to the restructuring in 2011. The Impairment reflects that fact that the assets are no longer being used, and that the book value of these assets does not correspond to the financial benefit that the company had previously expected.

² Write-downs in 2012 refers to the impairment of the product right Multiferon. This, together with the write-down of intangible fixed assets, comprises the total write-down of Multiferon amounting to SEK 162 M. The management deemed it prudent to write down the full tangible- and intangible asset value of (SEK 162 M).

>> Note 22, cont.

PARENT COMPANY	Land and buildings	Plant and machinery	Equipment, tools, fixtures and fittings	Plant in progress	Total
1 January – 31 December 2011					
Net book value – Opening balance	–	56,226	165,592	15,285	237,103
Entry into service of existing facilities	–	149	657	–806	–
Additions	–	512	2,403	139	3,054
Reclassification of acquisition value	–	–	–14,461	–	–14,461
Depreciation	–	–16,650	–27,486	–	–44,136
Write-downs	–	–	–38,066	–	–38,066
Net book value – Closing balance	–	40,237	88,639	14,618	143,494
At 31 December 2011					
Acquisition value	–	619,997	271,702	14,618	906,317
Accumulated depreciation and amortisation	–	–579,760	–183,063	–	–762,823
Net book value	–	40,237	88,639	14,618	143,494
1 January – 31 December 2012					
Net book value – Opening balance	–	40,237	88,639	14,618	143,494
Entry into service of existing facilities	–	–	14,606	–14,606	–
Additions	6,728	2,382	1,899	1,671	5,954
Fusion of subsidiaries	–	3,242	116	–	10,086
Reclassification of acquisition value	–	–200	–	–	–200
Disposals	–	–6,419	–1,683	–	–8,102
Depreciation	–1,799	–3,880	–25,600	–	–31,279
Write-downs	–	–	–	–	–
Net book value – Closing balance	4,931	35,362	77,977	1,683	119,953
At 31 December 2012					
Acquisition value	6,728	596,113	276,813	1,683	881,186
Accumulated depreciation and amortisation	–1,799	–560,751	–198,836	–	–761,233
Net book value	4,931	35,362	77,977	1,683	119,953

Note 23

Shares in group companies

PARENT COMPANY	2012	2011
Accumulated acquisition values		
Accumulated acquisition values, opening balance	4,343,575	4,741,893
Acquisitions	132	4,365
Fusion of subsidiaries	-293	-
Group contribution to subsidiaries	-	163,559
Additional payment Arexis	43,000	-
Liquidation of subsidiaries	-164	-417,512
Participation in limited partnerships Multiferon	-	-148,730
	4,386,250	4,343,575
Accumulated write-down		
Opening balance	-327,945	-327,945
This years write-down	-	-
	-327,945	-327,945
Net book value end of period	-4,058,305	4,015,630

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 AB, 556329-5624	100	100,0	3,655,588
SOBI Middle East FZ-LLC	1,000	100,0	132
Arexis AB, 556573-5130, Gothenburg, Sweden	1,000	100,0	402,571
Swedish Orphan Biovitrum Inc., USA	1,000	100,0	7
SOI Cz	1	1,0	7
			4,058,305

¹ Refers to the percentage of capital holding, which is equal to the percentage of voting rights.

THE FOLLOWING COMPANIES WERE MERGED DURING THE YEAR	Merger data
Biovitrum Treasury AB, 556616-7317, Stockholm, Sweden	2012-01-10
Nya Paradiset 19 AB, 556603-1943, Stockholm, Sweden	2012-01-10
Fastighetsaktiebolaget Paradiset, 556149-2611, Stockholm, Sweden	2012-01-10
SOBI AB, 556578-2983, Stockholm Sweden	2012-04-30
Swedish Orphan Biovitrum Manufacturing AB, 556732-6623, Stockholm, Sweden	2012-04-30
Swedish Orphan Biovitrum Sverige AB, 556566-2078, Stockholm, Sweden	2012-04-30

THE FOLLOWING COMPANIES WERE LIQUIDATED DURING THE YEAR	Liquidation date
Paradisiet B.V., 34209249, Amsterdam, The Netherlands	2012-06-22

Note 24

Financial fixed assets

GROUP	2012	2011
Accumulated acquisition values		
Opening balance	11,410	10,033
Write-down of loan and shares	-3,000	-
Financial asset	-	5,000
Change in pension commitment	-3,727	-3,436
Other	-302	-187
Accumulated acquisition values	4,381	11,410
Book value at end of period	4,381	11,410
PARENT COMPANY	2012	2011
Accumulated acquisition values		
Opening balance	141,313	684
Acquisition	570	-
Financial asset	-	5,000
Write-down of loan and shares	-3,000	-
Change of deferred tax	-135,773	135,773
Accumulated acquisition values	3,110	141,313
Book value at end of period	3,110	141,313

Note 25

Deferred tax receivables and liabilities

Accounted deferred tax receivables and liabilities

GROUP 2012	Deferred tax receivable	Deferred tax liability	Net
Inventory	34,528	–	34,528
Acquired R&D	–	–30,449	–30,449
Acquired product rights	–	–438,751	–438,751
Pensions	7,292	–	7,292
Tax allocation reserve	–	–113,177	–113,177
Other	5,380	–	5,380
Other intangible assets	216,700	–	216,700
Loss carry-forward	196	–	196
	264,096	–582,377	–318,281
Offsetting	–264,096	264,096	–
Net deferred tax receivable/liability	–	–318,281	–318,281

GROUP 2011	Deferred tax receivable	Deferred tax liability	Net
Inventory	9,345	–	9,345
Acquired R&D	–	–48,965	–48,965
Acquired product rights	–	–613,822	–613,822
Pensions	704	–	704
Tax allocation reserve	–	–134,714	–134,714
Other	–	2,056	2,056
Other intangible assets	394,828	–	394,828
Loss carry-forward	37,884	–	37,884
	442,761	–795,445	–352,684
Offsetting	–442,761	442,761	–
Net deferred tax receivable/liability	0	–352,684	–352,684

For the parent company there are a deferred tax asset on SEK 2,3 M (0) for deferred tax on currency hedging.

Non accounted deferred tax receivables

GROUP	2012-12-31	2011-12-31
Deductable temporary differences	44,501	–
Deficit for tax purpose	–	–
Total	44,501	–

PARENT COMPANY	2012-12-31	2011-12-31
Deductable temporary differences	44,501	–
Deficit for tax purpose	–	–
Total	44,501	–

The closing balance of 2011 for tax purposes pertain to one Swedish subsidiary. According to tax legislation, this deficit can be carried forward indefinitely. The deficits are activated because the group still thinks that it is likely that the remaining deficit will be offset against future taxable profits. The value of deferred tax 2012 has been calculated using a tax rate of 22.0% (26.3).

As a result of a decision announced by the administrative court on 3 March 2011, Swedish Orphan Biovitrum AB will be charged an additional amount of SEK 232.2 M as revenue in the tax assessment year 2005, in connection with the sale of the property Paradiset 14. The company has appealed the decision. The disputed amount has decreased the company's loss carry forwards. Therefore, no deferred tax asset linked to this amount has been recognized. Refer to note 37.

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

GROUP 2012	Amount 1 January	Reported in income statement	Recorded in other comprehensive income	Amount 31 December
Inventory	9,345	25,183	–	34,528
Acquired R&D	–40,092	9,643	–	–30,449
Acquired product rights	–613,822	175,071	–	–438,751
Pensions	704	–2,324	8,912	7,292
Tax allocation reserves/excess depreciation	–134,714	21,537	–	–113,177
Other	2,056	993	2,331	5,380
Other intangible assets	394,828	–178,128	–	216,700
Utilisation of loss carry-forward	29,011	–28,815	–	196
	–352,684	23,160	11,243	–318,281

GROUP 2011	Amount 1 January	Reported in income statement	Recorded in other comprehensive income	Amount 31 December
Inventory	6,326	3,019	–	9,345
Acquired R&D ¹	–49,171	9,079	–	–40,092
Acquired product rights	–654,627	40,805	–	–613,822
Pensions	–1,083	1,787	–	704
Tax allocation reserves/excess depreciation	–57,714	–77,000	–	–134,714
Other	–13	2,069	–	2,056
Other intangible assets	–	394,828	–	394,828
Utilisation of loss carry-forward ¹	8,873	20,138	–	29,011
	–747,409	394,725	–	–352,684

¹ For 2011, the figures were 8,873 SEK thousand wrong between line acquired R&D and utilization of loss carry-forward. That has been corrected in above figures.

Note 26

Inventories

GROUP	2012	2011
Raw materials and consumables	14,768	11,465
Work-in-progress	412,549	585,921
Finished products and goods for resale	273,051	296,433
	700,368	893,819

The expenditure for the inventories that was carried as an expense is included in cost of goods sold and amounts to SEK 369,905 thousand (531,212). Provision for obsolescence amounts to SEK 32,515 thousand (53,668).

PARENT COMPANY	2012	2011
Raw materials and consumables	14,768	9,889
Work-in-progress	412,549	553,416
Finished products and goods for resale	190,625	153,540
	617,942	716,845

The expenditure for the inventories that was carried as an expense is included in cost of goods sold and amounts to SEK 276,826 thousand (282,569). Provision for obsolescence amounts to SEK 32,515 thousand (45,025).

Provision for obsolescence is lower in 2012 than 2011, mainly relating to reserves for partner products, Multiferon and validation batches for Tech Transfer Kineret.

Note 27

Accounts receivable and other receivables

GROUP	2012	2011
Accounts receivable	348,380	329,510
Deduction: Provision for decrease in receivable	-5,136	-19,879
Accounts receivable – net	343,244	309,631
Tax receivables	21,375	545
Other receivables	19,105	49,340
Total other receivables	40,480	49,885
Total accounts receivable and other receivables	383,724	359,516

PARENT COMPANY	2012	2011
Accounts receivable	189,433	72,122
Deduction: Provision for decrease in receivable	-5,068	-3,440
Accounts receivable – net	184,365	68,682
Tax receivables	19,065	16,840
Other receivables	12,291	41,320
Total other receivables	31,356	58,160
Total accounts receivable and other receivables	215,721	126,842

No established credit losses are charged against profit for the year.

As of 31 December 2012 accounts receivable amounting to SEK 188 M (135.6) were past due and no write-down was deemed necessary. Provisions for doubtful receivables amounted to SEK 5.1 M (19.9) as of 31 December 2012.

Accounts receivable past due

GROUP	2012	2011
Past due 1–30 days	81,280	40,046
Past due 31–90 days	21,322	19,762
Past due 91–120 days	5,755	6,951
Past due > 121 days	79,351	68,855
	187,708	135,614
PARENT COMPANY	2012	2011
Past due 1–30 days	24,999	18,543
Past due 31–90 days	7,268	2,529
Past due 91–120 days	1,343	-28
Past due > 121 days	44,875	5,697
	78,485	26,741

Amounts, per currency, for accounts receivables and other receivables

GROUP	2012	2011
SEK	72,140	86,067
NOK	13,463	10,254
DKK	19,703	15,297
USD	54,084	58,554
EUR	187,434	161,281
GBP	19,400	15,871
CZK	6,852	-
CHF	-	282
PLN	2,853	-
AUD	4,773	5,701
Other currencies	3,022	6,209
	383,724	359,516
PARENT COMPANY	2012	2011
SEK	67,077	72,799
NOK	13,184	-
DKK	19,675	-
USD	16,759	36,583
EUR	82,536	14,329
GBP	180	149
CZK	5,752	-
PLN	2,853	-
AUD	4,773	429
Other currencies	2,932	2,553
	215,721	126,842

Note 28

Prepaid expenses and accrued revenues

GROUP	2012	2011
Accrued royalty revenues	23,017	23,012
Accrued co-promotion revenues	–	26,007
Prepaid leasing fees	252	293
Prepaid rents	14,911	20,330
Prepaid insurance expenses	2,945	15,654
Prepaid service and maintenance expenses	–	2,954
Prepaid IT Software & Licenses	–	5,014
Prepaid expenses, tech transfer Kineret	34,324	67,438
Other items	38,602	14,025
	114,051	174,727

PARENT COMPANY	2012	2011
Accrued royalty revenues	23,017	23,012
Accrued co-promotion revenues	–	26,007
Prepaid leasing fees	136	–
Prepaid rents	14,216	18,906
Prepaid insurance expenses	1,894	13,839
Prepaid service and maintenance expenses	–	2,954
Prepaid IT Software & Licenses	–	5,014
Prepaid expenses, tech transfer Kineret	34,324	67,438
Other items	34,943	11,975
	108,530	169,145

Note 29

Short-term investments and liquid funds

Specification of security

GROUP	2012		2011	
	Fair value	Book value	Fair value	Book value
Cash and Bank	456,951	456,951	219,043	219,043
	456,951	456,951	219,043	219,043

PARENT COMPANY	2012		2011	
	Fair value	Book value	Fair value	Book value
Cash and Bank	276,462	276,462	175,025	175,025
	276,462	276,462	175,025	175,025

Note 30

Financial assets per category (Group)

	Loans and receivables	Asset at fair value through the profit and loss	Total
31 December 2012			
Assets as per balance sheet			
Accounts receivable	348,380	–5,136	343,244
Liquid funds	456,951	–	456,951
Total	805,331	–5,136	800,195
31 December 2011			
Assets as per balance sheet			
Accounts receivable	329,510	–19,879	309,631
Liquid funds	219,043	–	219,043
Total	548,553	–19,879	528,674

Derivat	2012	2011
Currency hedge	–11,088	–
Interest swap	11	–
	–11,077	–

Note 31

Employee benefits (pension commitments)

The pension commitments are calculated annually on the balance sheet date, based on actuarial calculations. Following the acquisition of Swedish Orphan in 2010, a defined benefit pension plan for the subsidiary in Norway is also reported.

The figures below do not include a special payroll tax of 24.26% of reported assets in accordance with UFR4 (Swedish Financial Accounting Standards Council's Emerging Issues Task Force). For the Norwegian Pension Fund 14.1% in payroll taxes in reported liabilities will be included.

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 Alecia. According to statement UFR3 issued by the Swedish Financial Accounting Standards Council's Emerging Issues Task Force, these are defined benefit plans covering multiple employers.

For the 2012 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 Alecia is therefore reported as a defined contribution plan.

The cost for the year of pension insurance through Alecia amounted to SEK 18,126 thousand (15,839). Alecia's surplus is distributable among the policy holders and/or the insured parties. At the end of 2012 Alecia's surplus in the form of the collective consolidation level amounted to 130.0% (113.0). The collective consolidation level consists of the market value of Alecia's assets as a percentage of insurance commitments calculated according to Alecia's actuarial calculation assumptions, which do not correspond to IAS 19.

Change in benefit obligation during the year:

	2012	2011
Benefit obligation at start of year	140,311	135,558
Service cost	13,268	16,612
Interest cost	4,904	4,781
Actuarial gains (-) / losses (+)	-931	939
Benefits paid	-1,568	-1,535
Settlement	-12,343	-16,048
This year's translation difference	470	4
Benefit obligation at end of year	144,111	140,311

Change in fair value of plan assets during the year:

	2012	2011
Fair value of plan assets at start of year	110,265	104,340
Return on assets	3,845	3,733
Actuarial gain (+) / loss (-)	-1,692	1,534
Contributions	14,268	16,344
Settlement	-12,116	-14,153
Remunerations one-time items	-1,568	-1,535
This year's translation difference	-124	3
Fair value of plan assets at end of year	112,878	110,265

The amounts recognised in the income statement regarding defined benefits are as follows:

	2012	2011
Service cost	13,268	16,612
Interest cost	4,904	4,781
Expected return on plan assets	-3,845	-3,733
Amortisation on actuarial gains/losses	-	1,961
Administration cost	112	91
Collective agreement pension	-117	2,180
Total, included in employee benefits	14,322	21,893

>> Note 31, cont.

Actuarial assumptions on the balance sheet date

SWEDISH PENSION PLAN	2012	2011
Discount rate	3.00%	3.40%
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	3.00%	3.30%
NORWEIGAN PENSION PLAN	2012	2011
Discount rate	3.90%	3.30%
Future salary increases	3.50%	4.00%
Future pension increases	3.25%	3.75%
Expected increase of basic amount	3.25%	3.75%
Expected return on plan assets	3.90%	4.80%

The amounts recognised in the balance sheet are as follows:

	2012	2011
Fair value of plan assets	112,878	110,265
Fair value pension commitment	-144,111	-140,311
Net asset value	-31,233	-30,046
Unrecognised actuarial gains (-) / losses (+)	-	27,754
Net asset value	-31,233	-2,292

The amounts are recognised in the balance sheet as follows:

	2012	2011
Financial fixed assets	-	2,999
Provisions	-31,233	-5,291
Net asset value	-31,233	-2,292

Specification of changes in net assets reported in the balance sheet

	2012	2011
Net asset/liability at beginning of year according adopted balance sheet	-2,292	3,257
Effect of change in accounting principle	-27,800	-
Net pension expense	-14,322	-21,893
Employer compensation	14,267	16,344
Withdrawal from plan assets (-)	-1,568	-1,535
Pensions paid	1,568	1,535
Translation difference	-325	-
Change in actuarial gain on obligations	931	-
Change in actuarial loss on plan assets	-1,692	-
Net asset value	-31,233	-2,292

The actual return on plan assets was SEK 2,631 thousand (5,310).

Allocation of asset type

	2012	%	2011	%
Shares	39,009	35	46,451	42
Bonds	46,842	41	51,178	46
Other	27,027	24	12,636	11
Total	112,878	100	110,265	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 15,322 thousand (12,425) for the financial year 2013.

AS PER 31 DECEMBER	2012	2011	2010	2009	2008
Present value of defined benefit obligation	-144,111	-140,311	-135,558	-107,725	-106,541
Fair value of plan assets	112,878	110,265	104,340	94,781	97,432
Surplus / (Deficit)	-31,233	-30,046	-31,218	-12,944	-9,109
Experience adjustments on plan liabilities, gain (-) / loss (+)	10,267	1,353	1,704	11,170	1,030
Change in assumptions of plan liabilities, gain (-) / loss (+)	-9,649	-415	12,935	-2,312	10,080
Experience adjustments on plan assets, gain (+) / loss (-)	-1,692	1,546	668	-2,173	-2,116

Note 32

Other liabilities, long-term

GROUP	2012	2011
Bond (in SEK)	600,000	–
Liabilities to credit institutions (in SEK)	–	700,000
Other	22,115	–
	622,115	700,000

PARENT COMPANY	2012	2011
Bond (in SEK)	600,000	–
Liabilities to credit institutions (in SEK)	–	700,000
Other	19,750	–
	619,750	700,000

The company has a unused loan facility amounting to a total of SEK 135 M in the form of a variable credit.

During the year, the company repaid the outstanding liability to the bank, which was replaced by a bond loan of SEK 600 M.

Security for the credit consists of a floating charge amounting to SEK 200 M. When the loan was issued, it incurred variable interest equivalent to Stibor 3 months + 500 points, which was changed to a fixed interest of 6.9% by means of an interest swap contract.

Note 33

Provisions

	GROUP		PARENT COMPANY	
	2012	2011	2012	2011
Opening balance	6,719	196,817	–	179,407
Costs incurred	–	–44,525	–	–30,677
Reversed and unused provision	–	–148,730	–	–148,730
Provision this year	24,514	3,157	–	–
Closing balance	31,233	6,719	–	0

Provisions for the year were affected by the voluntary introduction of IAS 19, as of 1 January 2012.

Refer also to the Group statement of changes in equity.

	GROUP		PARENT COMPANY	
	2012	2011	2012	2011
Long-term	31,233	6,719	–	–
Short-term	–	–	–	–
Total provisions	31,233	6,719	–	–

Note 34

Accrued expenses and deferred revenues

GROUP	2012	2011
Provision for vacation pay and bonus incl social security contributions	66,178	71,715
Accrued social security contributions	21,467	20,470
Accrued expenses	207,842	232,024
Prepaid revenues	–	9,557
	295,487	333,766

PARENT COMPANY	2012	2011
Provision for vacation pay and bonus incl social security contributions	51,837	51,410
Accrued social security contributions	19,006	18,070
Accrued expenses	173,459	204,372
	244,302	273,852

Note 35

Pledged assets

GROUP	2012	2011
Shares in subsidiaries	–	3,677,445
PARENT COMPANY	2012	2011
Contingent liabilities	200,000	320,000
Shares in subsidiaries	–	3,655,588
	200,000	3,975,588

Sobi's operating credit agreement includes pledged assets in the form of a floating charge of SEK 200 M.

	Book value 2012	Book value 2011
PARENT COMPANY		
Shares in Swedish Orphan Biovitrum International AB	–	3,655,588

Note 36

Contingent liabilities

In connection with certain acquisitions and licensing agreements, Sobi agreed to pay additional payments (often called milestone payments) linked to certain pre-determined objectives. Listed below are the most significant agreements.

Arexis

On 29 March 2012, Sobi entered into a supplementary agreement regarding the acquisition of the pharmaceutical company Arexis in 2005, implying that all future milestone payments referring to Kiobrina are removed. According to the agreement, Sobi has a commitment to pay SEK 77 M. Upon signing the agreement, Sobi paid SEK 36 M, and will pay SEK 20 M during 2013 and SEK 21 M during 2014. See further in note 37 regarding the requirement of Arexis sellers.

Amgen

The acquisitions of the products Kineret, Kepivance and Stemgen resulted in commitments for milestone payments.

A milestone payment to Amgen at USD 55 M was paid during the first quarter 2013. The payment was dependent on sales volumes for Kineret, which were achieved during the fourth quarter 2012.

O4CP

In January 2012, Sobi signed a global licensing agreement with the French company Only for Children Pharmaceuticals (O4CP) regarding bumetanide reformulated for treatment of diuresis

and seizures in neonates. The new drug is currently in clinical phase II under the EU financed NEMO project. The first market authorisation of the product is expected in 2014. O4CP will be responsible for obtaining market authorisations and for the development and manufacture of drug product. Sobi will be accountable for the commercialisation of the product on a global basis. The agreement included an up front payment by Sobi in the amount of EUR 300 000 and potential future milestones of a value up to approximately EUR 1.7 M. O4CP will also receive royalties on future commercial sales.

Biogen Idec

The agreement between Sobi and Biogen Idec regarding development and commercialisation of long-lasting recombinant factor VIII and factor IX haemophilia programmes was restructured in February 2010. In the beginning of 2012, Sobi and Biogen Idec agreed to disclose further details on their agreement regarding development and commercialization of long-lasting recombinant factor VIII and factor IX haemophilia programs, which was restructured in February 2010. Under the new agreement, Biogen Idec assumed full development responsibilities and costs, as well as manufacturing rights. In addition, the cross-royalty rates were reduced and commercial rights for certain territories were changed.

Subject to the exercise of an option right, Sobi will have commercial rights in Europe, Russia, Turkey and certain countries in the Middle East (the Sobi territory). Biogen Idec has commercialisation rights in North America (the Biogen Idec territory) and all other regions excluding the Sobi territory (the Biogen Direct territory and the Biogen Distribution territory).

ROYALTY AND NET REVENUE SHARE RATES	Method	Rate prior to first commercial sale in Sobi's territory	Rates should Sobi exercise its opt-in right ³	
			Base rate following first commercial sale in Sobi's territory	Rate during reimbursement period
Sobi rate to Biogen Idec on net sales in the Sobi territory	Royalty	N/A	10 to 12%	Base rate plus 5%
Biogen Idec rate to Sobi on net sales in the Biogen North American territory	Royalty	2%	10 to 12%	Base rate less 5%
Biogen Idec rate to Sobi on net sales in the Biogen Direct territory	Royalty	2%	15 to 17%	Base rate less 5%
Biogen Idec rate to Sobi on net revenue ¹ in the Biogen Distributor territory ²	Net revenue share	10%	50%	Base rate less 15%

¹ Net revenue represents Biogen Idec's pre-tax receipts from third-party distributors, less expenses incurred by Biogen Idec in the conduct of commercialisation activities supporting the distributor activities.

² The Biogen Distributor Territory represents Biogen territories where sales are derived utilising a third-party distributor.

³ A credit will be issued to Sobi against its reimbursement of the Opt-in Consideration in an amount equal to the difference in the royalties paid by Biogen Idec to Sobi on sales in the Biogen territory for certain periods prior to the first commercial sale in the Sobi territory versus the rate that otherwise would have been payable on such sales.

>> Note 36, cont.

Under the terms of the option right and following Biogen Idec's submission of a marketing authorisation application to the European Medicines Agency (EMA) for each programme, Sobi may opt to take over final regulatory approval, pre-launch and commercialisation activities in the Sobi territory by making a payment into escrow of USD 10.0 M per programme.

Upon EMA regulatory approval of each programme, Sobi will be liable to reimburse Biogen Idec 50% of the sum of all shared manufacturing and development expenses incurred by Biogen Idec from 1 October 2009 through the date on which Sobi is registered as the marketing authorisation holder, as well as 100% of certain development expenses incurred exclusively for the benefit of the Sobi territory.

To effect Sobi's reimbursement to Biogen Idec for each programme, the cross-royalty structure for direct sales in each company's respective territories will be adjusted until the consideration is paid in full. The mechanism for reimbursement is outlined in the table previous page.

In the event that Sobi exercises its option right, amounts under the amended agreement will become payable as follows:

If the reimbursement of the opt-in consideration has not been achieved within six years of the first commercial sale of the respective programmes, Biogen Idec has the right to require Sobi to pay any remaining balances within 90 days of the six year anniversary date of the first commercial sale.

Should Sobi not exercise its option right with respect to one or both programmes or should Sobi terminate the agreement with respect to one or both programmes, Biogen Idec will obtain full worldwide development and commercialisation rights for such affected programme and will be obligated to pay royalties to Sobi subject to separate terms defined under the restructured collaboration agreement. In addition, if EMA approval for any programme is not granted within 18 months of the applicable EMA filing date, Sobi shall have the right to require that the escrow payment be refunded and revoke its option right for such programme.

Other

In addition, there are a few minor milestone payments linked to cooperative research agreements and distribution agreements.

Note 37

Tax and legal disputes

Sobi has an ongoing dispute with the Tax Agency regarding the sale of the property Paradiset 14. The Swedish property Paradiset 14 was transferred in 2004 to a substantially owned foreign-limited, Nya Paradiset KB, whereupon the unit Nya Paradiset KB was sold to an outside party to market price. The property was transferred to Nya Paradiset KB, supported by the rules for so-called undervalue transfers for a fee equivalent to the tax value of the property. The Tax Agency has in a letter to the County Court April 17, 2008 – under the Act against tax evasion - requested that the rules relating to undervalue transfers is not applicable. This means, according to the Tax Agency, that Swedish Orphan Biovitrum as a result caused by the transfer of property to Nya Paradiset KB be taxed on market value of the property.

On 3 March 2011 the Administrative Court ruled in favor of the Tax Agency's request, explaining that, based on the above transfer and subsequent sale, Sobi will be charged an amount of SEK 232.2 M as revenue in the 2005 tax year. The company appealed to the Administrative Court of Appeal. A stay of proceedings was issued in the case while awaiting the Supreme Administrative Court's (SAC) verdict on another, separate tax avoidance issue, known as the Cyprus case. The Tax Agency also appealed the Administrative Court's ruling, claiming that Biovitrum should be charged an amount of SEK 263.2 M as revenue, thereby implying a profit (after deducting the property's fiscal residual value) of SEK 232.2 M. In the Cyprus case, a Swedish company transferred a property at a price below market value to, in all material aspects, a foreign-owned partnership. The Supreme Administrative Court deemed, in its ruling of 30 May 2012, that the transfer, considering the circumstances of the case, should be taxed as though the property had been transferred at market value. The Administrative Court of Appeal has subsequently assumed responsibility for the processing of Sobi's appeal. Sobi's opinion in the case is that the Tax Evasion Act is not applicable, meaning that the Administrative Court of Appeal should quash the Administrative Court's ruling and reject the Tax Agency's claim that the Tax Evasion Act is applicable. The disputed amount has decreased the company's loss carry forwards. Therefore, no deferred tax asset linked to this amount has been recognized.

On 29 March 2012, Sobi amended its share purchase agree-

ment regarding the acquisition in 2005 of the pharmaceutical company Arexis AB. As stated in Sobi's annual and quarterly reports, the sellers of Arexis initiated arbitration as well as an expert determination procedure in 2011 regarding certain claims related to the share purchase agreement. Both proceedings have been withdrawn as a consequence of the amended share purchase agreement. According to the amended agreement, Sobi has no remaining development or milestone obligations toward the sellers. Under the amended agreement, Sobi will pay the sellers a total of SEK 77 M. Sobi has paid SEK 36 M in connection with the signing of the agreement and will pay SEK 20 M in 2013 and SEK 21 M in 2014.

Note 38

Transactions with related parties

A company related to the chairman of the Board, Orficare, 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 2.9 M (4.1) in 2012.

In January 2013, Bo Jesper Hansen signed an employment contract with the company. The new contract comes into force on 15 January 2013, in conjunction with the expiry of Bo Jesper Hansen's previous three-year employment contract with the company. The new contract expires on 1 May 2014.

Note 39

Significant events after balance sheet date

Distribution agreement signed with Valeant/PharmaSwiss

Sobi entered into an exclusive distribution agreement with Valeant/PharmaSwiss for the products Megace®, Monopril®, Cefzil® and Duricef® for the treatment of indications within oncology, cardio-vascular and anti-infective therapy areas. Under the terms of the agreement, Sobi will have exclusive distribution rights in Ireland, United Kingdom, France, Italy, Germany, Spain, Finland, Sweden, Denmark, Norway, Austria, Belgium, Liechtenstein, Netherlands, Portugal, and Luxembourg. The portfolio has current revenues of approximately SEK 120 M in the Sobi territory.

Savient Co-promotion

Sobi has entered into an exclusive agreement with Savient for the co-promotion of Kineret (anakinra) in the United States. Kineret is indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active Rheumatoid Arthritis (RA) in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs). Kineret is also indicated in the US for the treatment of children and adults with Neonatal-Onset Multisystem Inflammatory Disease (NOMID). Savient will market and promote Kineret beginning 1 April 2013. Sobi Inc. will remain responsible for all Kineret commercial drug manufacturing, supply, and regulatory activities.

New bond amounting to SEK 200 M

Sobi has issued a further SEK 200 M under the current bond loan, to ensure that Sobi can take advantage from the opportunities presented by the pace and scale of our haemophilia programmes.

Distribution agreement with Exelixis

In February 2013, Sobi entered into a three-year agreement to support the distribution and commercialization of Cometriq™ for metastatic medullary thyroid cancer (MTC) in the European Union (EU) and potentially other countries. No other indication is covered by this agreement, and Exelixis maintains full commercial rights for Cometriq in MTC outside the covered territory and for all other indications on a global basis. On November 29, 2012, Exelixis announced that the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for Cometriq for the proposed indication of treatment of progressive, unresectable, locally advanced, or metastatic MTC.

Return of the rights for Willfact

On 1 January 2013 Sobi returned the rights in Germany for Willfact® to LFB, but will retain the rights for the Nordic markets.

Amgen

A milestone payment to Amgen at USD 55 M was paid during the first quarter 2013. The payment was dependent on sales volumes for Kineret, which were achieved during the fourth quarter 2012.

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 26 April 2013, for approval.

Stockholm, 26 March 2013

Bo Jesper Hansen
Chairman

Matthew Gantz

Adine Grate Axén

Hans GCP Schikan

Helena Saxon

Lennart Johansson

Hans Wigzell

Catarina Larsson
Employee representative

Bo-Gunnar Rosenbrand
Employee representative

Geoffrey McDonough
CEO

Our audit report was submitted on 28 March 2013

PricewaterhouseCoopers 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

Report on the annual accounts and consolidated accounts

We have audited the annual accounts and consolidated accounts of Swedish Orphan Biovitrum AB (publ) for the year 2012. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 40–106.

Responsibilities of the Board of Directors and the Managing Director for the annual accounts and consolidated accounts

The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of these annual accounts and consolidated accounts in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the Managing Director determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

Auditor's responsibility

Our responsibility is to express an opinion on these annual accounts and consolidated accounts based on our audit. We conducted our audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and consolidated accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and consolidated accounts in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control. An audit also includes evaluating the appropriateness of accounting

policies used and the reasonableness of accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the annual accounts and consolidated accounts.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinions

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company as of 31 December 2012 and of its financial performance and its cash flows for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the Group as of 31 December 2012 and of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act. 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 consolidated accounts.

We therefore recommend that the annual meeting of shareholders adopt the income statement of the parent company, the statement of comprehensive income of the Group and balance sheet for the parent company and the Group.

Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the Managing Director of Swedish Orphan Biovitrum AB (publ) for the year 2012.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss, and the Board of Directors and the Managing Director are responsible for administration under the Companies Act.

Auditor's responsibility

Our responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on our audit. We conducted the audit in accordance with generally accepted auditing standards in Sweden.

As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss, we examined whether the proposal is in accordance with the Companies Act.

As a basis for our opinion concerning discharge from liability, in addition to our audit of the annual accounts and consolidated accounts, we examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the Managing Director is liable to the company. We also examined whether any member of the Board of Directors 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 the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Opinions

We recommend to the annual meeting of shareholders that the profit be appropriated 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 28 March 2013
PricewaterhouseCoopers AB

Mikael Winkvist
Authorized Public Accountant

Annual General Meeting 2013

Annual General Meeting 2013

Swedish Orphan Biovitrum AB will hold its Annual General Meeting on Friday, 26 April 2013 in the Wallenberg Auditorium at the Royal Swedish Academy of Engineering Sciences (IVA), Grev Turegatan 16, Stockholm, Sweden.

To participate

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 Friday, 19 April 2013. Shareholders must notify the company of their intention to participate no later than Monday, 22 April 2013 and can do so by the following:

- visiting Sobi's website: www.sobi.com
- by telephone: +46 8 697 34 27
- by mail to Swedish Orphan Biovitrum AB, "Annual General Meeting", SE-112 76 Stockholm, Sweden

The notification shall set forth the:

- name
- personal/corporate identity
- address and telephone number (daytime)
- 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 by Friday, 19 April 2013.

Proxy

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 1 year from the issue thereof or such longer period of time stated in the power of attorney, however not more than 5 years. A registration certificate shall evidence the circumstances prevailing at the day of the Meeting and should not be older than 1 year at the time of the Meeting. The original power of attorney 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 available on the company's website, www.sobi.com, and can also be sent to shareholders if requested.

Financial calendar 2013

Q1 Interim Report, January–March,	
and Annual General Meeting	26 April 2013
Half Year Interim Report, January–June	18 July 2013
Nine Months Interim Report,	
January–September	30 October 2013

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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Disclaimer – translation of financial statements and audit report

This English version of Sobi's annual report and audit report is a translation of the official Swedish annual report and audit report which have been prepared in accordance with Swedish law and applicable Swedish recommendations. For this reason, this English version of the annual report and audit report has not been prepared in accordance with the provisions of the Swedish Companies Act and the Annual Accounts Act. The official Swedish annual report and audit report therefore have precedence in the event of any ambiguity.



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