



ANNUAL REPORT 2013

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*Pioneer in
Rare Diseases*

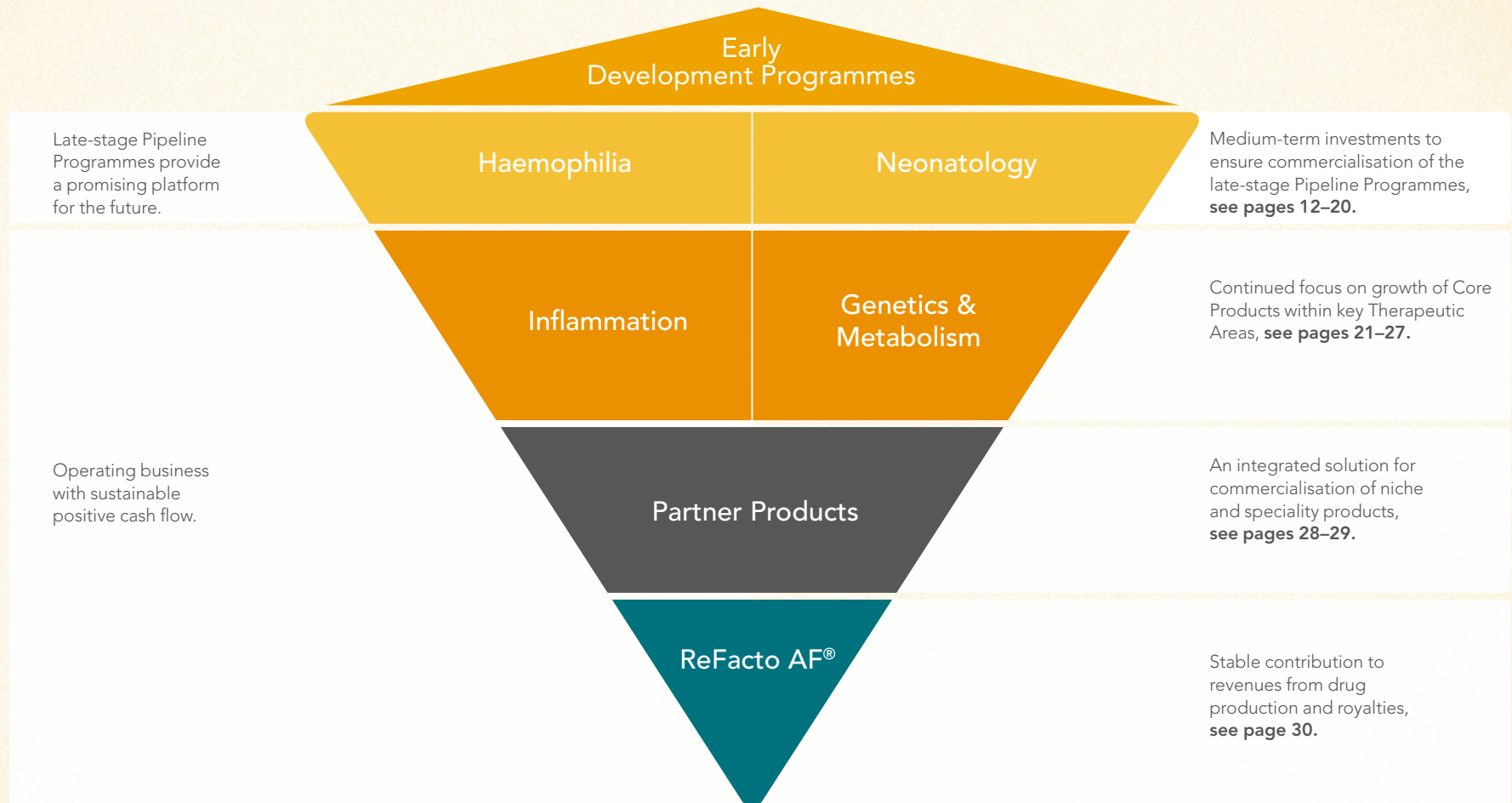
Cover

Kineret has been approved for the treatment of NOMID and, in 2013, of CAPS. The approval of these indications is a realisation of Sobi's commitment to developing effective treatments for children affected by rare diseases.

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Disclaimer In order to utilise 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 & Metabolism with a growing focus on Haemophilia and Neonatology.

Sobi in brief

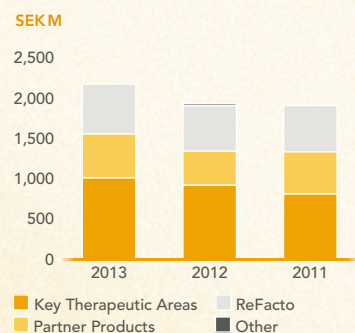
Sobi is an international speciality healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies that improve the lives of patients.

Our key Therapeutic Areas are Inflammation and Genetics & Metabolism, with a growing focus on Haemophilia and Neonatology.

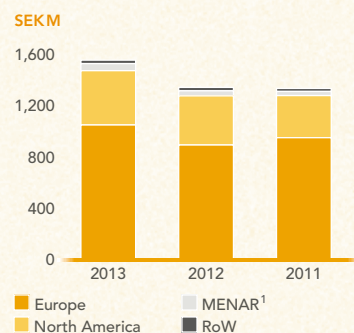
We deliver products to specialist physicians and their patients through our integrated partnership model, which involves constant dialogue with legislators, regulatory authorities, healthcare systems and patients.

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

Revenues by product category

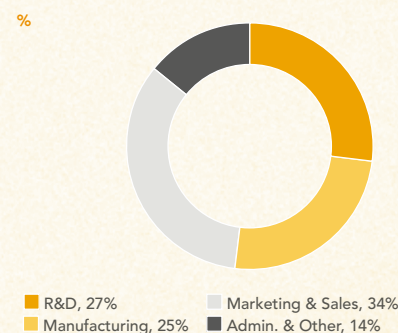


Revenues by region

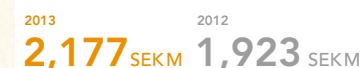


¹ Middle East, North Africa and Russia

Employees by function 2013



Total revenues




Gross margin




EBITA



Pioneer in rare diseases

A close-up photograph of a newborn baby lying down, with a nasal cannula inserted into their nostril. The baby's face is the central focus, showing their eyes, nose, and mouth. A woman's face is visible in the background, looking down at the baby with a gentle expression. Her hands are visible, supporting the baby's head. The lighting is soft and warm, creating a tender atmosphere.

Sobi is passionate about children's health. We are dedicated to developing and delivering products to treat rare diseases and conditions that can help restore vitality and hope to young lives.



"Our commercial progress forms the platform for the launch of our pipeline"

2013 was eventful and positive for Sobi. We made significant progress in many areas towards our goal of being a leading international speciality healthcare company dedicated to rare diseases. The operating business showed strong momentum and our pipeline programmes achieved several key milestones during the year.

Progress in our operating business

Revenues in 2013 increased by 13 per cent compared to the previous year, our gross margin improved by 5 percentage points to 59 per cent, and we strengthened our company financially through stable positive cash flow and improved operating profit.

Our key Therapeutic Areas of Inflammation and Genetics & Metabolism continued their trajectory from 2012, expanding the business in both existing and new markets and growing revenues by 10 per cent. Kineret® was approved in Europe for a new adult and paediatric indication, Cryopyrin-Associated Periodic Syndromes (CAPS), shortly before year end, and we reached an agreement with our distributor for Orfadin® in the US to assume direct responsibility for Orfadin in the US, Canada and Latin America. These developments will continue to support the growth of these businesses.

In addition, we have strengthened our Partner Products portfolio with four significant new partnership agreements:

- Auxilium Pharmaceuticals for the development and commercialisation of Xiapex®, a new generation biologic for the treatment of Dupuytren's contracture, a connective tissue disorder.
- PharmaSwiss for marketing of Megace®, Monopril®, Cefzil® and Duricef® which are approved in the areas of oncology, cardiovascular and anti-inflammatory therapies.
- Exelixis to support the distribution and commercialisation of Cometriq® for the treatment of metastasised thyroid cancer within the EU and potentially also in other countries.

- Hyperion Therapeutics for the sole rights in seven countries in the Middle East for the distribution of a liquid form of Ravicti®, a drug to treat patients with Urea Cycle Disorders (UCD).

Finally, our ReFacto® manufacturing business was stable in 2013 with growth of 9 per cent.

Our commercial progress forms the platform for the launch of our pipeline.

Progress in our Development Programmes

In addition to the launch of Kineret for the treatment of Neonatal Onset Multisystem Inflammatory Disease (NOMID) in the US and the CAPS approval in the EU for children and adults, we also signed an agreement with Amgen giving us the full rights to develop and commercialise Kineret for all therapeutic indications. This supports our long-term goal of exploring the full potential of Kineret and we are now working on firming up our plans in this area.

We are developing a liquid formulation of Orfadin to facilitate the ease and accuracy of administration for Orfadin in paediatric patients. In 2013 we filed registration applications in the EU and plan to do so in the US in 2014. We expect a decision in the EU in 2014 and in 2015 in the US.

Sobi is a founding member of the European Commission funded DevelopAKUre project to develop nitisinone as a potential treatment of the chronic debilitating disease Alkaptonuria (AKU). The programme has progressed during the year with the completion of SONIA 1, an international, randomised dose-finding open-label study. The DevelopAKUre collaboration was chosen from over 200 nominations, to win the RARE Champions of Hope Award for Collaborations in Science¹.

We also acquired additional rights for Kepivance® which allows us to explore a potential new indication based on the results from two phase 3 studies conducted by Amgen. These studies show that Kepivance has the potential to reduce the incidence and duration of severe oral mucositis in patients undergoing treatment for advanced head and neck cancer. This Kepivance programme was presented for the first time at our Capital Market Day events in Stockholm and New York in November 2013.

Before year end, SOBI002 began phase 1 clinical trials. SOBI002 is a novel small biologic molecule that works as a potent and selective inhibitor of complement protein C5, a key protein in human immunological and inflammatory processes and central to a number of important diseases.

In the course of 2013 we completed enrolment of the LAIF trial (Lipase Added to Infant Feeding), our phase 3 study investigating the effect of rhBSSL (recombinant human Bile Salt Stimulated Lipase) on the growth and development of preterm infants born before 32 weeks gestation. In Q1 2014 we learned that rhBSSL did not meet its primary endpoint in this trial – growth velocity measured after four weeks of treatment showed no statistically significant improvement compared to placebo. We expect to evaluate further data from LAIF in the course of 2014, and to assess the financial impact of the topline results in Q2 2014.

Solid foundation for Haemophilia

During 2013 we laid a solid foundation from which to begin commercialisation of our two long-lasting haemophilia drug candidates (rFVIII-Fc and rFIX-Fc), developed together with our partner Biogen Idec. We reinforced our Haemophilia senior medical and commercial teams

by recruiting several highly experienced professionals. Biogen Idec expects to launch both products in the US in 2014, and as of Q1 2014 rFIX-Fc (Alprolix™) had been approved in both Canada and in the United States.

At the end of 2013 we had two ongoing paediatric phase 3 studies with our haemophilia drug candidates in children under the age of 12. Interim results from the studies, which were presented in December at the Annual Meeting of the American Society of Hematology were consistent with pharmacokinetic results in adults and adolescents; prolonged half-life compared to the trial patients' previous treatment regimens.

Pending the outcome of the paediatric studies, we plan to file for marketing authorisation of the products in our territories i.e. Europe, Russia, North Africa and the Middle East.

Priorities in 2014

Looking forward, we will continue to focus on the growth and geographical expansion of our base business, to continuously improve the efficiency of our business model. In addition, we aim to continue our work as a pioneer in rare diseases by advancing our programmes to address the needs of children.

Thanks to our employees, our partners and shareholders for their support and contribution to our successes during the year.



Geoffrey McDonough
President and CEO

¹ The awards are organised by the Global Genes Project, which recognises individuals and collaborations for their contributions to patient advocacy, scientific research and medical care. DevelopAKUre received the 2013 RARE Champions of Hope award at a gala event in September 2013.



Highlights 2013

Pipeline Programmes

- Announced novel clinical trial complement C5 inhibitor programme which entered phase 1 clinical trials.
- Awarded Best Biotech Pipeline at World Orphan Drug Congress.

Haemophilia

- Interim results from two ongoing paediatric phase 3 studies of Sobi's and Biogen Idec's investigational long-lasting recombinant product candidates (rFVIII Fc and rFIX Fc) showed prolonged half-life compared to the patients' previous treatment regimens.
- Leading haematology journal *Blood* published pivotal rFVIII Fc data. Results from the A-LONG study showed that people with severe haemophilia A may achieve effective prevention or reduction of bleeding episodes with one or two prophylactic injections a week.
- Detailed results from the pivotal phase 3 study of rFIX Fc showing that people with severe haemophilia B safely and effectively prevented or reduced bleeding episodes with prophylactic infusions every one to two weeks, were published in *The New England Journal of Medicine*.

Neonatology

- Completed enrolment for Kiobrina LAIF phase 3 study in Europe.

Inflammation

- Received European Commission (EC) and US Food and Drug Administration (FDA) approval to manufacture Kineret drug substance with partner Boehringer Ingelheim.
- Acquired full rights for Kineret and additional clinical data for Kepivance from Amgen.
- Received approval for Kineret for treatment of CAPS in the EU.

Genetics & Metabolism

- Submitted application for Orfadin oral suspension the European Medicines Agency (EMA).
- Announced decision to take direct responsibility for Orfadin in the Americas.

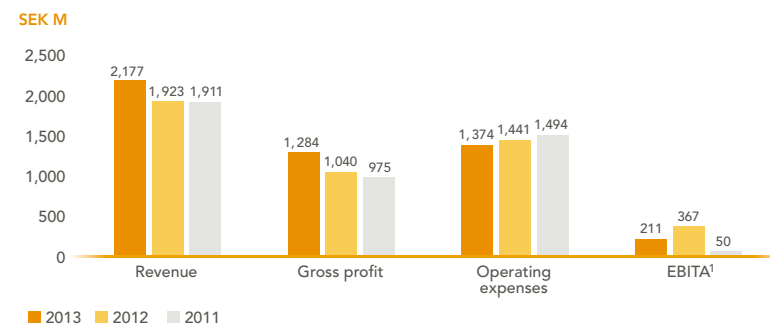
Partner Products

- Gained distribution rights for Megace, Monopril, Cefzil and Duricef from PharmaSwiss.
- Entered partnership with Exelixis to be the sole supplier of Cometriq in Europe for the treatment of Medullary Thyroid Cancer (MTC).
- Auxilium Pharmaceuticals and Sobi entered into a collaboration agreement for Xiapex in 71 European, Asian and African countries.
- Gained rights to distribute Ravicti in the Middle East from Hyperion Therapeutics.

Key figures 2013

- Total revenues increased to SEK 2,176.7 M (1,923.2), an increase of 13%.
- Total product revenues increased to SEK 1,557.7 M (1,344.3), an increase of 16%.
- Gross margin increased to 59% (54).
- EBITA amounted to SEK 211.0 (367.0). 2012 figures include sales of the co-promotion rights to Pfizer of SEK 307.5 M.
- Sobi extended existing bond by additional SEK 200 M in February 2013.
- Sobi reached sales volumes for Kineret that triggered a contractual milestone payment of USD 55 M to Amgen. This was paid in the first quarter 2013.

SEK M	2013	2012	2011
Total revenues	2,176.7	1,923.2	1,910.8
Gross profit	1,284.0	1,040.4	974.6
Gross margin	59%	54%	51%
Operating profit before amortisations (EBITA)	211.0	367.0 ¹	49.5
Operating profit (EBIT)	-66.5	-54.6	-318.6
Profit/loss for the year	-93.0	-100.9	17.9
Earnings per share, SEK	-0.35	-0.38	0.07
Cash flow from operations	185.4	405.5	102.9
Equity per share, SEK	17.6	18.2	18.7
Equity assets ratio	73.2%	76.7%	74.1%



¹ 2012 includes proceeds of SEK 307.5 M from sale of co-promotion rights to Pfizer.

New market dynamics emerging

Sobi is actively engaged in changing the healthcare landscape by contributing to emerging models of pharmaceutical value assessment, pricing, reimbursement and information for patients.

The business model for pharmaceutical companies has historically followed a linear, compartmental approach. The focus was on products for large patient groups, making large sales and marketing infrastructures crucial. Each step in the development of a product was discrete, which led to companies with distinct departments, working in a sequential manner, where one “end” of the process did not necessarily communicate – or need to communicate – with the other. Now there are signs that a new paradigm is emerging.

Over recent years, a variety of factors have come to bear on the pharmaceutical sector. Safety concerns, economic pressures, concerns over prices of new, innovative therapies and a desire for the authorities to understand the actual value of what they are being asked to pay for have all combined to create an environment where the moment of Marketing Authorisation is now just one phase in the development of a new treatment. Instead, the focus will be on evaluation of a product at all stages and by a variety of different stakeholders, at different times during its life cycle.

This will be carried out on more of an ongoing basis than in the past. Stakeholders that have traditionally looked at a product further on in its development will be brought in earlier in the evaluation process. Others will be involved not only at the early stages, but also further on in the development cycle. For example, the job of the regulatory authorities will continue long after Marketing Authorisation as they seek to understand not only the risk profile of a product in day-to-day use after authorisation, but also the actual clinical benefits that a product can bring in a “real world” setting.

Continuous assessment of risk-benefit

These trends in the marketplace are combining to break up the “linear” model of drug development and it is likely to be in the field of orphan medicinal products that such changes manifest first. Initial regulatory authorisa-

tions, with conditional decisions along the way, have long been the hallmark of the orphan sector, where post-authorisation follow-up measures are common. Increasingly early dialogue between regulators, Health Technology Assessment (HTA) bodies and pricing authorities, combined with post-authorisation tools such as those created by the EU's Pharmacovigilance Regulation, mean that the marketing of a new treatment might morph into a more cyclical, rolling process that is associated with conditions and adaptations along the way after a treatment is already in use.

The ability to navigate effectively through a continuous dialogue with external stakeholders will mean that companies must organise themselves in a different way. The new dynamics will require engagement throughout the lifecycle of the products from all parts of the company, as well as constant contact with legislators, regulatory authorities, HTA bodies, payers and patients, in order to understand the needs of each of these critical stakeholders in the pathway from the earliest stages in the development of a potential therapy and continuing throughout its lifecycle.

Sobi's approach

Sobi has considerable experience with this collaborative way of working and is structured to facilitate the communication across functional teams to coordinate different parts of the development process. Sobi's patient-centric structure – bringing Commercial, Medical and Patient Access together in the leadership structure of the company – allows us to explore pioneering solutions supported by working creatively and in constant dialogue with the external environment.

Finding a sustainable model for dialogue of this kind is vital in also finding sustainable solutions for our investors, our employees, the healthcare systems paying for our products and, most importantly, for patients.

A new paradigm on market access



Yann Le Cam
President and CEO
EURORDIS



When EURORDIS was founded almost 15 years ago, we were calling for action based on the principles of social justice and equal rights for all to quality healthcare. This call is more valid than ever!

There are over 30 million patients with rare diseases in Europe affected by one of over 6 000 different diseases. Each of these patients has cumulating vulnerabilities: unmet medical needs, limited scientific knowledge, scattered expertise, psychological and social challenges, as well as the financial and social impact for families at large. Individual countries do not have the expertise available for each of the thousands of different rare diseases. This is why we saw that it would make sense to join forces across all rare diseases and across Europe. Such a large critical mass of patients cannot be ignored anymore. And expertise exists when we take a European level approach. There is a unique, very high added value in acting at the EU level to address the specific issues of rarity.

Today, thanks to the advocacy of EURORDIS in partnership with all relevant stakeholders, there is a comprehensive EU framework of legislations and policies to address the challenges of rare diseases. Not least, is the recently adopted patients' right to healthcare across national borders in the EU.

It is quite clear that a new paradigm is emerging in terms of drug development and its financing. In Europe, rare diseases have spearheaded the ongoing societal debate on the high cost of most innovative treatments, particularly orphan medicines. This is a challenge because of individual national payment systems. Marketing approval is at EU level and coverage decisions at national levels.

EURORDIS is at the forefront in the policy discussions on pricing of orphan medicinal products. We are calling for a broader perspective, focusing on three levels: the cost of R&D; the implementation of the EU legislative framework; the market access.

The costs of R&D for rare disease therapies can decrease significantly while the success rate of development increases with the wider use of adap-

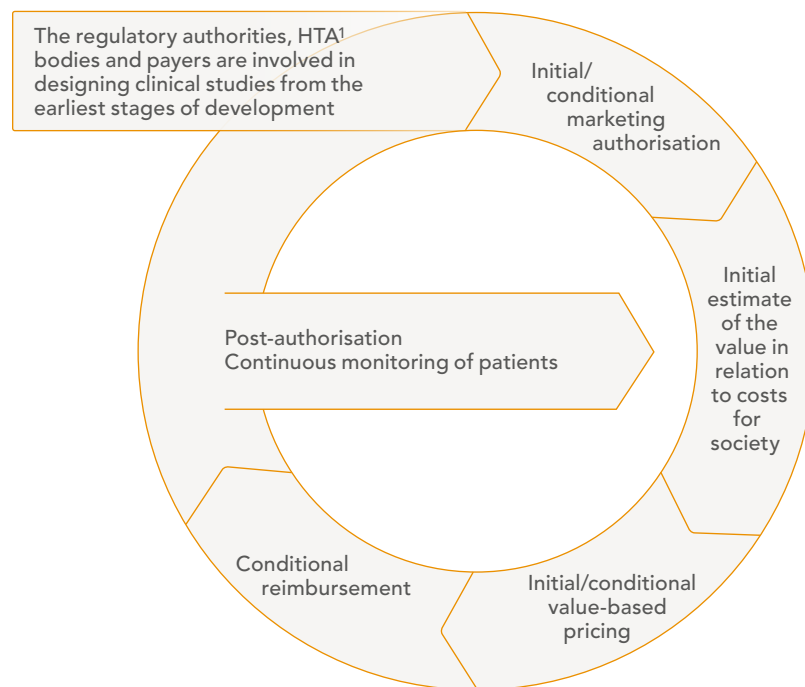
tive design for clinical trials and statistical methods. Patient Progressive Access (also called Adaptive Licencing) would enable market approval at an earlier stage of development; such conditional approval or marketing under exceptional circumstances associated with stringent post-marketing research activities on both benefits and risks, would enable earlier access, higher success rates, lower initial price uptake and a new deal between sponsors-payers.

The conditions of market access could be radically changed through pan-European collaboration in order to create a truly European market: early dialogue between payers and sponsors together with medical experts and patients; common assessment of the (relative) effectiveness through pan-European HTA collaboration; exchange of information on the value of medicines and negotiations of price based on value, volume and post-marketing research; managed entry agreements and joint procurements, etc.

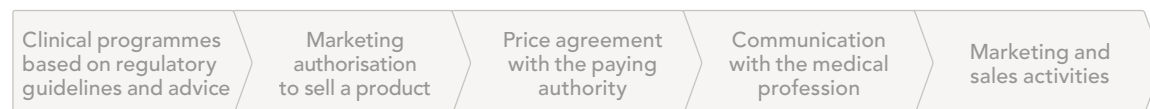
This change in paradigm will require a certain supranational approach, but also more partnerships, starting at the early stages of development, and continuing throughout the entire process to market access and beyond. It also requires patients to be involved, along with legislators, paying agencies, and companies, in a serious and frank dialogue that is not opportunistic. For the companies, such a dialogue will help create value and additionally reduce the risks associated with the development of new drugs.

This dialogue has already started – and Sobi is a highly instrumental key player. More bodies need to engage in these debates and pilots. Ultimately, it is all about making sure that innovative solutions to new drugs actually reach the patients, at as early a stage as possible. I am convinced that this is where we are heading, though perhaps it will take five to ten years to get there.

Yann Le Cam is a co-founder and, since 2002, Chief Executive Officer of the European Organisation for Rare Diseases – EURORDIS, which brings together over 600 member patients' organisations from 58 countries.

NEW
MODEL

Rolling process where authorisation is linked to conditions for adaptations once the treatment is in use

PRIOR
MODEL

Linear model where marketing authorisation is the definitive entry into the market

ORPHAN MEDICINAL PRODUCTS

Sobi's main focus is in the field of speciality pharmaceuticals and orphan medicinal products. Orphan medicinal products are developed to treat rare diseases that are often chronic, seriously debilitating and life-threatening. Orphan medicinal products are produced and sold in much smaller quantities when compared to medicines for more general use.

There are special incentive systems in place to support the development of treatments for rare conditions, which differ from region to region around the world. These can include fee reductions, research grants, the ability to participate in public-private partnerships and often a period of "market exclusivity" for a specific product to treat a specific indication.

The US was early in introducing legislation on orphan drugs in 1983. Similar legislation followed in Japan, Australia and within the EU.

Prior to the creation of these frameworks, there were a handful of treatments available for rare conditions. Since the creation of these incentives, several hundred have been successfully developed and brought to market. Sobi has been involved in the field of orphan medicinal products since the earliest days of the field.

¹ Health Technology Assessment

Long-term sustainable model needed for orphan medicinal products



Dr Ad Schuurman
Dutch Health Care Insurance Board (CVZ)

I have been involved in the issue of orphan medicinal products for 15 years, that is, the entire legislative period in the EU, where the first Orphan Regulation was adopted in 1999. During the first 10 years, industry consisted mostly of small cap companies and I felt great enthusiasm to cooperate with the patients and the companies at the time.

Now, new and bigger players have entered into the field. Nearly 70 orphan medicinal products for about 55 different indications are currently approved for reimbursement from the paying authorities. The definition of orphan has swelled too much. The positive attitude that has prevailed for societal acceptance is changing. The small volumes and high price model/paradigm is beginning to erode confidence. The financial crisis has accelerated this shift in attitude.

I think many share the view that we cannot continue as we are now. But how we shall proceed is the big question. At the same time, it is critical for orphan medicinal products that we find a sustainable model.

At the first evaluation of a drug, we are often not provided with sufficient data and we have to put our foot down and demand a renegotiation. Conditional approval, which includes regular evaluations post market launch, is a possible way forward, but it has not been fully tried out yet. In the Netherlands we have the ambition to do a revaluation every 4 years for such treatments.

At the same time, we do not want to look at the price only. For this reason MEDEV, a collaboration between paying agencies within the EU, has established a unique pilot project to develop a common methodology for a coherent European evaluation. It is a project where Sobi participates and where we try to find ways to act in a more pan-European, collaborative way across borders and between stakeholders.

I hope we can find a model that is both good for the community, patients and businesses. But it is still challenging for many companies, who I believe need to revise their business models. Companies should invest more in long-term relationships with the authorities and rebuild the social contract, by collaborating more about the value and benefits.

Dr. Ad Schuurman is Head of the Business Contact Centre and International Affairs of the Dutch Healthcare Insurance Board, CVZ. Between 2006 and 2012, he was Chairman of MEDEV and has also been a representative to several expert committees within the EU.

Cooperation between all stakeholders is key to the future



Dr Paolo Siviero
Italian Medicines Agency (AIFA)

Right now we are in a very interesting situation in terms of pricing and reimbursement of medicinal products in the EU. The big question is to weigh the price and value, i.e., patient benefit, with volumes. There are many implications to this, with the simultaneous ambition of facilitating a faster market access.

I believe we need to collaborate to estimate the value of the product. Individual countries cannot bear the burden on their own to create a clear picture of what we are paying for and why.

If nothing else, we must accept that there are risks with the new situation and that it brings with it a number of uncertainties that all players must be alert to. Both patients and companies must understand this increasing uncertainty about a drug's long-term existence. We all have to get used to the fact that a given price negotiated is not going to last forever. We must become more adaptable in a new and uncertain environment. Otherwise, it's not sustainable to maintain the high level of prices.

There is an awareness of this in the pharmaceutical industry and especially in a company like Sobi who has a partnership and leadership role in the discussions now underway. I think it may be easier for companies working with orphan drugs to embrace the new signals and be more flexible, because they are accustomed to consider and reconsider a drug in its various stages. It is also in this area that it is easiest to cooperate at EU level, to define the value of the product from the clinical trial level to follow up with the various stakeholders involved, resulting in synergies from the outset.

MEDEV is an informal group of contributors who collaborate on pricing and reimbursement issues. We are national but here we are trying to build something new, to the benefit of all. We are very aware that we are sometimes regarded as one of the opponents, both by industry and patients. We are used to taking difficult decisions, but we are also ready to cooperate. The next few years will be interesting and there is a strong recognition that we need to do something together to face the future.

In 2014 *Dr. Paolo Siviero* became chairman of MEDEV, a collaboration between paying agencies in Europe, consisting of representatives of national health authorities in the EU and Switzerland. He is also the manager of the department of economic strategy and drug policy at the Italian Medicines Agency AIFA, where he held several positions since 2008.

A pioneer in rare diseases

Sobi develops, manufactures and commercialises treatments with a particular focus on four specialised therapeutic areas: Inflammation, Genetics & Metabolism, Haemophilia and Neonatology. Sobi also partners with other manufacturers to bring niche and speciality products to Europe, Russia, and the Middle East.

Vision

We are inspired to pioneer a world in which rare disease patients are diagnosed at birth, receive effective and sustainable therapy, and go on to live full and healthy lives.

Mission

Our mission is to develop and deliver innovative therapies and services to improve the lives of patients.

Strategy

Sobi aims to become a leading international company focusing on specialised pharmaceuticals to treat rare diseases by operating at a scale where we can maintain authentic relationships both internally and externally in order to focus on patients' and society's needs.

Drawing on 35 years of experience in developing biopharmaceutical products (biologics) and 25 years of experience of commercialising those products for patients with rare diseases, Sobi is well-positioned to build value for patients, society and shareholders in a collaborative and sustainable way.

- A near-term focus on growing Sobi's key Therapeutic Areas while maintaining a positive cash flow from operations.
- Investment in the medium-term aimed at ensuring successful commercialisation of late-phase potential products in the development portfolio.
- Generation of long-term growth by growing organically and through acquisitions.
- Fostering an organisation that promotes a pioneering spirit and grows in value rather than in number of people. Securing partnerships with other companies is part of that strategy.
- Supporting constant dialogue with the company's stakeholders during the full life cycle of the projects and products.
- Continued development of the strategically important capacity at Sobi's biological manufacturing facilities.
- Attracting, retaining and developing people who share our goals, vision and mission and giving them the space to develop their full potential.

Business model

Sobi is an integrated biopharmaceutical company with strong roots in rare diseases and biologics. The company's expertise ranges from preclinical development, process development and manufacturing of protein drugs, to market entry and commercialisation.

A key aspect of the business model is creating an integrated and innovation-promoting approach to the entire life cycle of the products, through building on internal expertise and cross-functional collaboration. The business model is intended to ensure that Sobi can continue to be a pioneer in the area of rare diseases. Sobi has structured its operations in such a way to allow for integrated engagement at all stages of the development, authorisation and commercialisation phases. This allows us to take advantage of our extensive in-house expertise at every stage of the process.

We make this a reality at every step

- **How we select development projects** is guided by our innovation model. We define the unmet need for patients, with patients, we ask what is desirable for physicians, we consider what payers will value sustainably over time, and we apply our particular biologics assets and rare disease capabilities.
- **Drug development** – Sobi conducts preclinical research, phase 1 to phase 4 clinical studies by means of a combined in-house and sourcing model. Along the way, clinical trials in various phases take place and drugs that are already on the market are further developed, e.g., re-purposed for new indications or conditions or in new formulations that are better for the patient. This is often done in cooperation with the regulatory authorities, medical personnel, academic institutions and patient organisations, amongst other stakeholders.

- **Development in legislation and regulations** which requires, among other things, remaining updated on emerging requirements for market entry, value assessments and pricing systems. Getting this information early on in the development process is very important in order to assess the potential of a project and allow the most effective use of Sobi's resources – both human and capital allocation. Sobi is keen to involve all the stakeholders in the development process, including the regulatory authorities, those responsible for value assessments and the relevant pricing and reimbursement systems, together with the patients organisations and care providers, in order to identify their needs and get their views on the value and contribution that projects in development can bring in relation to the benefits for patients and society.
- **Manufacturing** – at Sobi, advanced process development goes hand-in-hand with the development of new, biological drugs. It is strategically important for Sobi that both of these functions – clinical design and development and manufacturing – work closely together.
- **Distribution and sales** – Sobi has built up an organisation that covers more than 20 countries in Europe in addition to the US, Canada, the Middle East and Australia. Sobi has expertise in each country on the specific regulations and the authorities concerned, as well as well-established relationships with customers.
- **Speciality partnering services** – Sobi offers expertise not only for our own products but also as a distribution service – our Partner Products business – for other companies. This provides synergy for all of the products in Sobi's portfolio and provides a cost-effective way for companies from outside Europe

to enter the market without having to invest in building their own infrastructure. This can allow market entry for those companies – giving patients access to their treatments and technologies – without having to build in the costs of establishing an own presence across the region.

- **Feedback on outcomes** is a source of information for new drug development because unmet needs can be identified and treatment results can be improved. Publications and revised treatment guidelines can also be used in Sobi's development process.
- **A pioneering spirit** – Sobi is engaged in a variety of "first in class" collaborations with stakeholders, with the objective of seeking new ways to develop and make treatments available to patients. This includes the ground-breaking patient-led DevelopAKUre consortium, a multi-stakeholder collaboration partially funded by the European Commission, which is seeking to develop a treatment for Alkaptonuria (AKU), a disease that is so rare that any other approach would be non-viable. We hope that this public-private partnership will deliver not only a treatment for AKU, but also serve as a model for other such approaches going forward. We are also involved in a pilot project with a group of national payers to establish if dialogue at different stages of the development for treatments for rare diseases will create a better understanding of the value and, hopefully, a smoother, more collaborative and accelerated approach to the pricing, reimbursement and – ultimately – patient availability of the treatments.



R&D – a patient access focused model adapted for rare diseases

Sobi's Research & Development (R&D) expertise ranges from late preclinical development to commercialisation of biologics, including protein drug process optimisation and manufacturing. The R&D work is based on a model where biological research and process scale-up is integrated with a modern Patient- and Customer-Centric Commercialisation model (PC3).

Innovative biologics for rare diseases

Sobi's development programmes reflect the company's focus on innovative biologics for rare diseases. The R&D portfolio contains several projects with the potential to be adapted for other indications. One such example is Kineret where the original indication was Rheumatoid Arthritis (RA), and where the drug has now been approved for the treatment of the rare diseases Cryopyrin-Associated Periodic Syndromes (CAPS) and Neonatal Onset Multisystem Inflammatory Disease (NOMID) in children and adults. In addition, a new liquid formulation of Orfadin has been developed to treat children and is currently under regulatory review in the EU.

Sobi's own platform for R&D enables the use of innovative methods that integrate biological research, process scale-up and full scale development throughout the process of commercialisation. The benefits of the platform are that it can be an interface between new discoveries, it can integrate research and development processes and it can offer benefits of scale that are appropriate for differ-

ent projects with the overall objective of maximising value of our programmes. In this context, Sobi's production facilities are an important knowledge resource. This applies both to the pilot facilities that develop active substances for internal R&D and to quality assurance of external products and technology transfer. The platform can also be integrated with other external partners in various partnership projects.

Patient- and Customer-Centric Commercialisation

Sobi's way of working – Patient- and Customer-Centric Commercialisation, aiming at understanding the "patient journey" and addressing the unmet need in a multidisciplinary fashion – closely integrates headquarters and countries. By being flexible and agile, Sobi can more easily apply knowledge about patient needs and other stakeholders relevant for patient access to the entire R&D process.

AN INDUSTRY FIRST – THE DevelopAKUre CLINICAL PROGRAMME

- DevelopAKUre is a clinical trial programme for the drug nitisinone, the first potential treatment for Alkaptonuria (AKU). It is made up of 13 hospitals, Sobi, consultancies, universities, biotech companies and national AKU patient groups.
- AKU is a genetic disease which damages the bones and cartilage, causes severe pain and leads to health problems such as osteoarthritis, heart disease and kidney infections. It is extremely rare and generally affects only one in every 250,000 people worldwide. AKU prevents the body from breaking down a substance called homogentisic acid (HGA).
- DevelopAKUre is taking place at a select few clinics across Europe. The programme reached several important milestones during 2013.
- Sobi is one of the founding partners of DevelopAKUre.

R&D Pipeline 2013

Indication	Project	Partner	Pre-Clin.	Phase 1	Phase 2	Phase 3	Launch
CAPS	Kineret	Sobi					
Haemophilia A	rFVIII Fc	Biogen Idec					
Haemophilia B	rFIX Fc	Biogen Idec					
Improve growth in preterm infants	Kiobrina	Sobi					
Oral Mucositis in head & neck cancer	Kepivance	Sobi					
Hereditary Tyrosinaemia type 1	Orfadin Liquid	Sobi					
Hereditary Tyrosinaemia type 1	Orfadin 20mg capsule	Sobi					
Alkaptonuria	Nitisinone (Orfadin)	DevelopAKUre					
Complement-mediated disease	SOBI002	Affibody					
Enzyme replacement therapy	SOBI003	Sobi					
IL-1-driven disease	IL-1 Affibody	Affibody					

Pipeline Projects Life Cycle Management (LCM) pipeline

Collaboration essential

The medical need of the patient is always at the centre of the company's R&D programmes and informs all aspects of commercialisation including evidence generation from the start through patient access, and reimbursement throughout the product life cycle. We recognise that novel discoveries can originate anywhere, so we are flexible in both adapting new technologies, and in founding collaborations with other creative innovation partners. We believe the innovation model of the future will see greater leverage for companies who can work together on integrated projects and/or in academic-industry collaboration with shorter development times while making the most of each party's expertise and sharing value.

THE SOBI002 PROGRAMME – COMPLEMENT C5 INHIBITOR

- In November 2013 Sobi announced its intention to bring a novel investigational biopharmaceutical drug candidate, SOBI002, into a phase 1 trial.
- SOBI002 is a small biologic molecule based on the Affibody® platform that works as a potent and selective inhibitor of complement protein C5, a key protein in human immunological and inflammatory processes and central to a number of important diseases.
- The advancement of SOBI002 into a phase 1 clinical trial marks an important milestone for Sobi as it validates the company's partnership-oriented biologics innovation model and could address a wide set of rare disease indications where C5 plays a role.
- The study will evaluate single and repeated doses of SOBI002 administered subcutaneously and intravenously in healthy volunteers.



Åsa Auduly and her son Vidar. Åsa is a registered nurse and senior lecturer at Mid Sweden University in Sundsvall. In 2011 she received her Ph.D. on a dissertation in health sciences about individuals' abilities and possibilities for self-management of chronic illness.

WE CHOSE TO HAVE CHILDREN – DESPITE THE RISK OF HAEMOPHILIA

“My family consists of my husband and our two boys, Vidar 6 years and Kettil 3.5 years. Both boys have a severe form of haemophilia and have received prophylactic treatment since the age of one. Today, they receive four to five injections weekly. Sometimes we change the treatment days, depending on their activities.

I grew up with two brothers who also have haemophilia and I've known I was a carrier since my late teens, so for me haemophilia is intertwined with my own history. Of course I was thinking, especially in adolescence, whether to have children or not. But when my husband and I got married, we had already made up our minds, and in some ways we anticipated we would have a child with haemophilia when we expected Vidar.

Growing up with my brothers, I thought I knew everything about having a child with haemophilia. But my experience was not from a parent's perspective so it felt quite lonely and I had many thoughts in the beginning.

We do not allow the bleeding disorder to be a barrier to a normal life. Of course we have to take into account that our children have special needs; to bring medication on longer outings and perhaps added protection, for example when skating. You need to organise life around the kids, but then it works. And of course the kids should not fight, but no children should fight!

Children also have the right to be involved by knowing how their bodies work. That means you have to explain the bleeding disorder at a level which they can understand. We have tried to play down the injections, for instance to do positive activities simultaneously, such as watching a movie. Our kids can also play cool in front of their friends – “an injection is nothing to be afraid of”.

For us it was right to have children despite the risk of haemophilia. The first time I had no doubts. Before the second child, we had more knowledge of what it really meant, and everything had gone very well with Vidar. I guess all parents feel more confident with baby number two and it was true for us even with the bleeding disorder. And now a third child is on its way this summer! This time it is a girl.”

Åsa Auduly

Stepping forward for people with haemophilia



Sobi's development of two long-lasting coagulation factors together with partner Biogen Idec offers the possibility of a step forward for people with haemophilia.

Therapeutic Area

Sobi and Biogen Idec are developing recombinant human coagulation factors for the treatment of people with haemophilia A and B. These potential therapies are formed by fusing the human coagulation factor with a portion of human immunoglobulin molecule, IgG. The resulting fusion protein uses a natural mechanism for IgG metabolism that delays the elimination of the factor and cycles it back into the bloodstream, enabling it to remain in the body longer after an injection. The recombinant coagulation factors are produced without the addition of human or animal protein, and are believed to be broken down and eliminated by a natural process in the body.

Potential of long-lasting clotting factors

In 2012 clinical phase 3 studies in adults (≥ 12 years) were concluded for both haemophilia programmes. These studies are known as the A-LONG and B-LONG studies and were aimed at evaluating these new agents for people with haemophilia A and haemophilia B, respectively.

The A-LONG and B-LONG studies were open-label, multicentre trials, designed to evaluate safety, pharmacokinetics and efficacy in the prevention and treatment of bleeding in people with severe haemophilia A and B. They included prophylactic and episodic treatment as well as surgery. The results from the phase 3 studies

ABOUT HAEMOPHILIA

Haemophilia A and B are two in a group of rare, congenital diseases where the blood's ability to clot is impaired. The difference between the two is determined by which coagulation factor is deficient in the blood. In haemophilia A it is factor VIII that is missing and in haemophilia B, factor IX. Globally, there are about 170,000 people with haemophilia A and B identified according to the World Federation of Hemophilia Annual Global Survey 2012, around 80 per cent of which have haemophilia A.

Haemophilia is a recessive X-chromosome linked bleeding disorder and therefore, almost exclusively boys are affected. Since women have two X-chromosomes, there is a 30 per cent risk that boys born to mothers who are carriers will be born with haemophilia. However, about half of all those diag-

nosed with haemophilia have no known previous family history of the condition. In those cases it is assumed that a new mutation has occurred spontaneously.

The level of severity of both haemophilia A and B varies between mild, moderate and severe, depending on the level of active clotting factor that the body produces and people with both haemophilia A and B share the need for intravenous injections of coagulation factors. This can be to treat an acute bleeding episode or on a regular basis as prophylactic treatment. Treatment is important to stop or prevent bleeding that could otherwise lead to pain and joint damage or, in some severe cases, be life-threatening.

Current commercially available coagulation factors require regular intravenous injections which, in the case of prophylaxis, may mean 2 to 4 injections a week or

sometimes even more frequently to maintain the levels of clotting factors in the blood, as these are broken down and expelled from the body. This can be very challenging, particularly for small children. Long-lasting coagulation factors will, therefore, fill an important medical need. There is a potential for improvement of prophylactic treatment because less frequent injections may be required.

Research carried out by Sobi among haemophilia healthcare professionals in Europe shows that long-lasting agents are ranked as the most desirable improvement that could be made to existing therapies.

point to a significant reduction in the number of injections needed annually, potentially up to 50–100 fewer injections a year for a patient on prophylactic treatment. The results from the A-LONG study indicate that some patients may be treated with 1-2 doses per week, while B-LONG patients could be treated once every 1-2 weeks.

Market potential

The total current market for haemophilia A and B within Sobi's territories 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 regimens. Both of these trends should favour the profile of the long-lasting factors under development.

Only approximately 30 per cent of the world's population of people with haemophilia receive regular treatment according to the World Federation of Hemophilia Annual Global Survey 2012.

Development in 2013

During the first quarter of 2013 Biogen Idec filed a biologics licence application (BLA) with the US Food and Drug Administration (FDA) for the use of rFVIII-Fc to treat haemophilia A. A BLA was filed a few months earlier for rFIX-Fc for the treatment of haemophilia B.

In the US approval of rFIX-Fc under the name Alprolix™ is expected to take place in first half of 2014, and rFVIII-Fc under the name Eloctate™ is expected to be approved in mid-2014. In November 2013, the leading scientific journal *Blood* – a publication of the American Society of Hematology – published detailed clinical trial data for

Eloctate, and results for Alprolix were published in *The New England Journal of Medicine* in December 2013.

Further analysis of the results of the A-LONG and B-LONG phase 3 studies was carried out during the year and presented at different scientific conferences. This confirmed the potential of both of the drug candidates due to their prolonged half-lives to reduce numbers of injections for patients taking treatment prophylactically, treat acute bleeds with fewer injections and controlling bleeding when used in the surgical setting.

Longer-term, almost all those participating in the A-LONG and B-LONG studies and receiving treatment have continued their treatment after the end of their participation in the trials, in an extension study phase for both haemophilia A (Aspire) and haemophilia B (Byond).

In Europe, studies in children under the age of 12 are required before a marketing authorisation application for

ABOUT THE KIDS A-LONG AND KIDS B-LONG STUDIES AND INTERIM DATA PRESENTED IN DECEMBER 2013.

Kids A-LONG and Kids B-LONG are on-going, multi-centre phase 3 studies of rFVIII-Fc and rFIX-Fc for previously treated children under age 12 with haemophilia A and B, respectively. Kids A-LONG and Kids B-LONG are designed to investigate the safety, efficacy and pharmacokinetics (PK) of rFVIII-Fc and rFIX-Fc.

Kids A-LONG and Kids B-LONG are multi-centre phase 3 studies of rFVIII-Fc and rFIX-Fc for previously treated children under age 12 with haemophilia A and B, respectively. Kids A-LONG and Kids B-LONG are designed to investigate the safety, efficacy and PK of rFVIII-Fc and rFIX-Fc. The Kids A-LONG interim

data showed that the mean half-life of rFVIII-Fc was approximately one and a half times that of the subjects' prior factor VIII therapies. The Kids B-LONG interim data showed that the mean half-life of rFIX-Fc was more than three times longer than the subjects' prior factor IX therapies. For both rFVIII-Fc and rFIX-Fc, prolonged half-lives were seen in each age group analysed – under six and six to under 12 years old.

In 43 children treated with rFVIII-Fc as of February 8, 2013, and 23 children receiving rFIX-Fc as of April 23, 2013, no inhibitors (antibodies that may interfere with the activity of the therapy) were detected. In this

interim analysis, the pattern of treatment-emergent adverse events reported was typical of the populations studied, with no unique safety issues identified.

Final results of the paediatric studies will evaluate the safety and efficacy of rFVIII-Fc and rFIX-Fc, as well as provide further PK information. Investigators plan to report these results at a future medical meeting. The primary endpoint for both studies is the occurrence of inhibitor development over the study period. Secondary outcome measures include the annualised bleeding rate, or projected number of yearly bleeding episodes, and assessments of response to treatment.

the European market can be filed, according to guidelines from the European Medicines Agency (EMA). Two such studies have been ongoing during the year, Kids A-LONG and Kids B-LONG in haemophilia A and B, respectively. At the American Society of Hematology meeting in December 2013, interim results from Kids A-LONG and Kids B-LONG were published, demonstrating that rFVIII Fc and rFIX Fc have consistently prolonged half-lives in children, compared to study participants' prior therapies. The results were consistent with pharmacokinetic results in adults and adolescents from previous studies.

Priorities

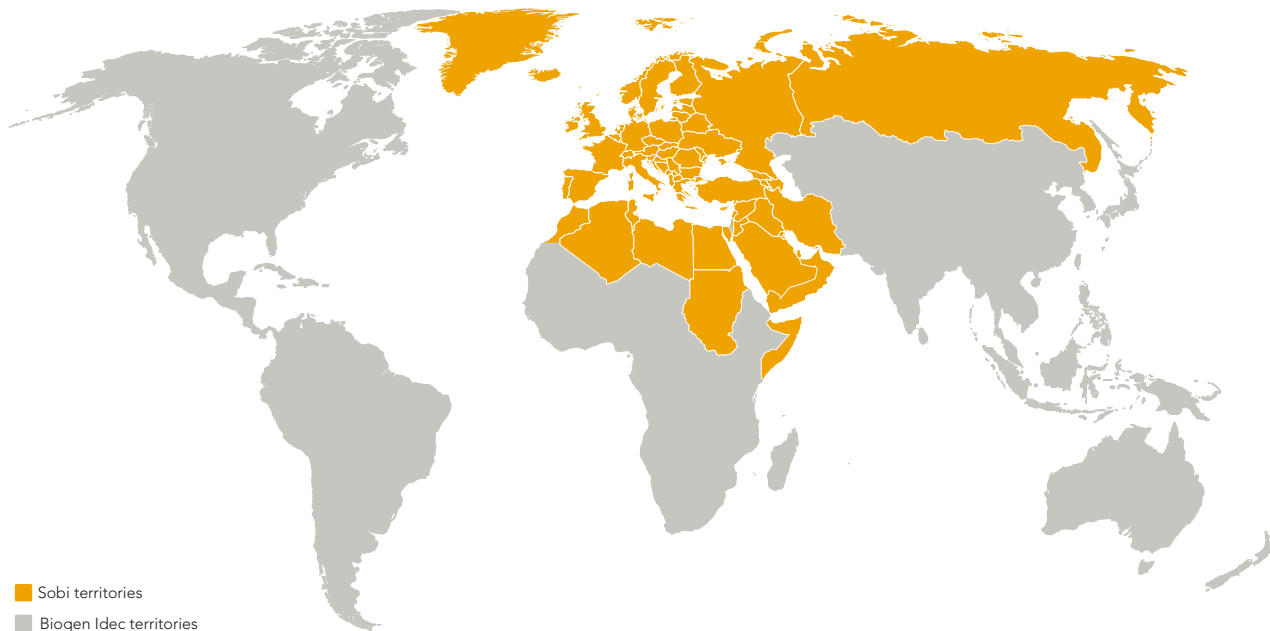
In 2013, Sobi reinforced its Haemophilia senior medical and commercial teams by recruiting several highly expe-

rienced professionals. Sobi is investing to prepare for the commercial launch of the haemophilia products within its territories, pending regulatory approvals. The company expects 2016 to be the first year the products will generate significant revenue within Sobi's territories.

The partnership with Biogen Idec


Sobi's collaboration with Biogen Idec goes back to 2007 when Biogen Idec acquired Syntonix. Biovitrum had established a partnership with Syntonix in 2005 for the development of a drug candidate to treat haemophilia B. Under this partnership Biovitrum had initiated process development work, which was then transferred to Biogen Idec following the Syntonix acquisition.

The terms of the current agreement with Biogen Idec stipulate that Biogen Idec has full responsibility for development activities and costs within the haemophilia programme, as well as for manufacturing. Subject to the exercise of its option right at EMA filing for each product, Sobi will have exclusive commercial rights in Europe, Russia, Turkey and certain countries in the Middle East. Biogen Idec has and will retain commercialisation rights in North America and all other regions excluding those covered by Sobi under the terms of the option agreement. For more detailed information, see Note 36, page 103.



Sobi territories

Albania	Iceland	Romania
Algeria	Iran	Russia
Andorra	Iraq	San Marino
Armenia	Ireland	Saudi Arabia
Austria	Italy	Serbia
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	Macedonia	The Netherlands
Denmark	Malta	Tunisia
Djibouti	Mauritania	Turkey
Egypt	Moldova	UAE
Estonia	Monaco	Ukraine
Finland	Montenegro	United Kingdom
France	Morocco	Vatican City
Georgia	Norway	Yemen
Germany	Oman	
Greece	Poland	
Hungary	Portugal	
	Qatar	



A unique project in the care of preterm infants

Kiobrina represents an exciting new biologic in neonatology. Sobi is committed to innovation in the paediatric and neonatal areas where there remains a high degree of need for pharmaceuticals specifically developed for young patients.

Kiobrina – exploring enzyme therapy to support growth in preterm infants



Kiobrina is a unique development programme to advance the care of preterm infants by supporting growth and development in the initial postnatal period. Babies who demonstrate improved growth during their first few weeks may have a reduced risk of future complications, and improved neurodevelopment¹.

Medical progress

In recent decades the percentage of infants born prematurely has increased throughout much of the world. At the same time, great medical progress has been made to improve survival rates for this vulnerable patient group, particularly in industrialised countries. Thanks to advanced neonatal intensive care it is now possible for infants to survive after being born as early as week 22–24 of gestation², but the rate of morbidity remains high. This makes it more important than ever to find ways to reduce the short- and long-term complications that can result from a premature birth.

Significance of early growth

Every year more than 600,000³ infants are born before week 32 of gestation. About 35 per cent of them do not receive fresh breast milk. The reason for not receiving fresh breast milk can be a result of the mother's medical condition or for example cultural traditions.

BSSL is a natural enzyme in fresh breast milk which is responsible for the majority of fat digestion, leading to the absorption of long chain polyunsaturated fatty acids (LCPUFA). These LCPUFA's support overall growth⁴, and are especially important building blocks for the growing brain and eye⁵. BSSL is not present in formula and is inactivated by heating, which means it is also lacking in pasteurised breast milk.

In recent years more has become known about the risk of complications associated with premature birth. In the

short-term, premature infants can suffer from a variety of complications involving the brain, lungs, gut and eyes.

The long-term complications can include Cerebral Palsy (CP), impairment in hearing and vision, and delays or deficiencies in neurocognitive development. It has become increasingly clear over the past decade that premature growth rate in the Neonatal Intensive Care Unit (NICU) is inversely correlated with neurodevelopment outcomes at 24 months of age – cross-sectional data demonstrates that premature infants with the best neurodevelopment outcomes as toddlers were those with the highest growth rates while in the NICU. Growth velocity and quality of growth are the most important determinants of the length of stay for a preterm infant in a NICU⁶.

Finally, the weekly cost of caring for a patient in a NICU can be significant, and poor neurodevelopment outcomes have both financial and social costs.

Therapy Area

Kiobrina is recombinant human bile salt stimulated lipase (rhBSSL) which has been developed by Sobi as an enzyme therapy to be given in combination with pasteurised breast milk or infant formula to preterm infants who cannot receive fresh mother's breast milk. Data from two phase 2 studies involving 63 patients showed that Kiobrina significantly improved growth after one week of treatment of infants born before week 32 of gestation. The data also showed increased absorption of the fatty acids omega-3 (DHA) and omega-6 (ARA).

¹ Pilling et al. Growth patterns in the growth-retarded premature infant. Best Practice & Research Clinical Endocrinology & Metabolism vol 22, No3, 447-462, 2008.

² Sobi Capital Markets Days. Advances in Neonatal Care Have Led to Dramatic Reductions in Mortality. 42, 2013.

³ Refers to Argentina, Australia, Canada, China, Egypt, EU, Iran, Israel, Korea, Mexico, Russia, Saudi Arabia, Turkey, the US, Venezuela.

⁴ 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.

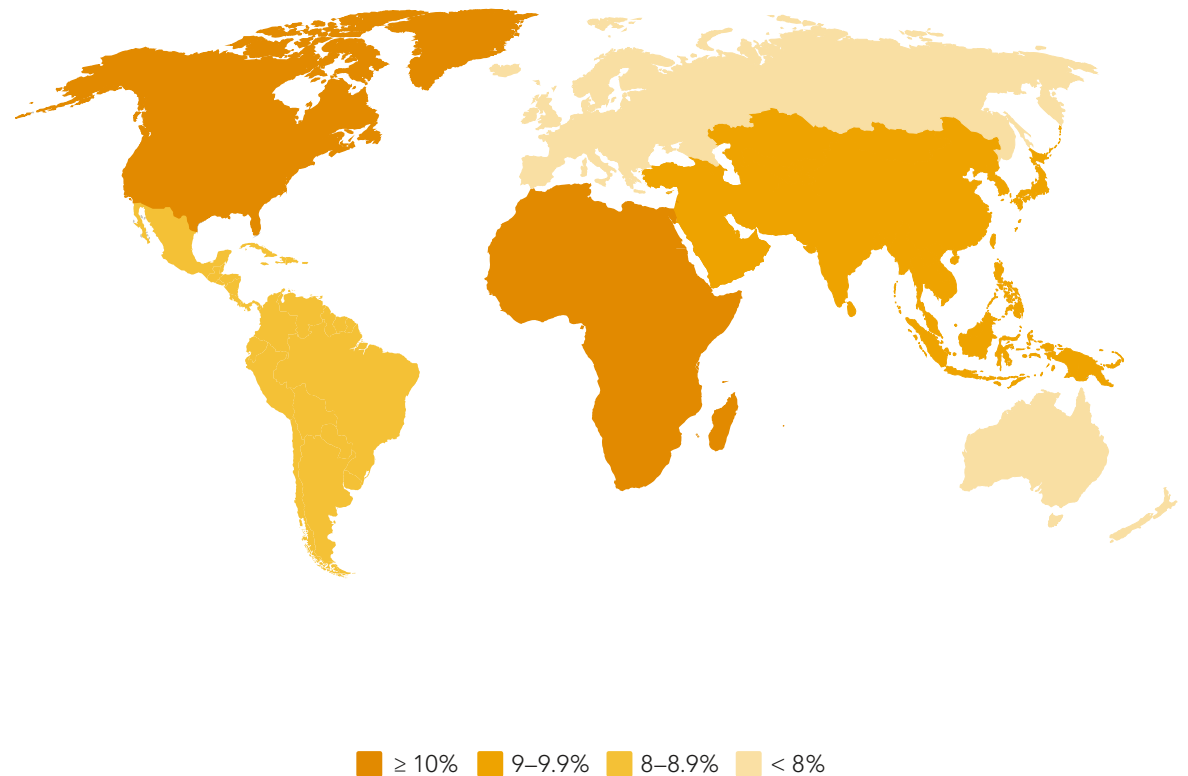
⁵ Innis S.M. Fatty acids and early human development.

⁶ American Academy of Pediatrics Committee on Fetus and Newborn. Hospital Discharge of the High-Risk Neonate. Pediatrics. 2008

Development in 2013

Sobi is conducting a pivotal phase 3 trial of Kiobrina called the LAIF study – Lipase Added to Infant Feeding. LAIF is being conducted in 50 centres across 10 countries in Europe, and in May 2013 completed the enrolment of more than 400 premature babies born before week 32. The study is designed to evaluate the efficacy, safety and tolerability of Kiobrina. The primary endpoint of the study is growth velocity measured after 4 weeks of treatment with Kiobrina, and there are several exploratory secondary endpoints related to outcomes at three months. In addition, LAIF includes an assessment of neurodevelopment at 12 months. Sobi has established an additional 12 month extension study which will repeat the neurodevelopment assessment at 24 months of age in all patients.

Preterm birthrates



Our key Therapeutic Areas



The products within our key Therapeutic Areas are proprietary pharmaceuticals for which Sobi has global or regional rights. Currently, Sobi's Core Products are in two of the company's key Therapeutic Areas: Inflammation (Kineret) and Genetics & Metabolism (Orfadin, Ammonaps®, Ammonul® and Ravicti).

47 per cent of Sobi's revenues

Kineret and Orfadin are Sobi's two largest products in terms of revenue. Both products continue to be developed; Kineret to treat the rare diseases Cryopyrin-Associated Periodic Syndromes (CAPS) and Neonatal Onset Multisystem Inflammatory Disease (NOMID) in children and adults and Orfadin with a new liquid formulation to facilitate the ease and accuracy in administration of the desired Orfadin dose to paediatric patients and to increase convenience for the patients and their caregivers.

In 2013 sales of Kineret increased by 16 per cent for the full year while sales of Orfadin increased by 3 per

cent. Together these products accounted for around 43 per cent of the company's total revenues. Total revenues for the key Therapeutic Areas increased in 2013 by 10 per cent to SEK 1,012.0 M (921.0).

Outlook

Sobi's 2013 revised agreement with Amgen to acquire the full rights for Kineret will allow Sobi to develop the drug for use in new therapy areas.

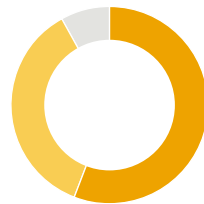
There is growth potential for both current markets and a number of new geographies including the US, Russia, Central and Eastern Europe and the Middle East.

Key Therapeutic Areas

SEK M	2013	2012	2011
Kineret	561.7	484.7	422.0
Orfadin	365.9	356.7	315.7
Other products	84.4	79.6	74.6
Total	1,012.0	921.0	812.3

Revenues by product, 2013

%



■ Kineret, 56% ■ Orfadin, 36% ■ Other products, 8%



Kineret – applying ten years of experience to care for children

Kineret (anakinra) is a biologic that can reduce the activity of IL-1, a key driver of inflammation in several diseases. Kineret continues to grow across all major regions supported by new indications such as NOMID and CAPS. The approval of these indications is a key milestone for Sobi and the company's efforts to make innovative products available for patients with debilitating and often life-threatening diseases.

Therapeutic Area

Kineret is a recombinant protein drug that blocks the biologic activity of the Interleukin-1-receptor (IL-1R), a key mediator of inflammation and a major contributing cause of autoinflammatory diseases in both adults and children.

Kineret was first approved in 2001 to ease the symptoms and slow the progression of structural joint damage in moderate to severe Rheumatoid Arthritis (RA) in adults who have failed at least one Disease-Modifying Antirheumatic Drug (DMARD).

In recent years Sobi has focused on expanding the indication for Kineret to paediatric indications. In 2012 Kineret became the first and only drug approved by the US Food and Drug Administration (FDA) for the Neonatal-Onset Multisystem Inflammatory Disease (NOMID) indication in children and adults. NOMID is the most severe form of Cryopyrin-Associated Periodic Syndromes (CAPS).

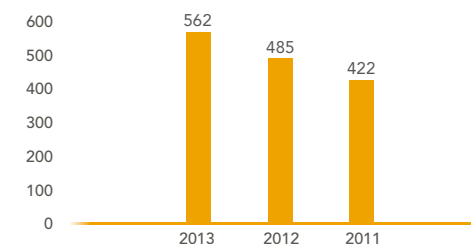
Market potential

Epidemiological forecasts indicate that the number of patients with Rheumatoid Arthritis (RA) in the seven largest markets¹ will increase to 5.2 million in 2019, from around 4.7 million in 2010. Today around 60 per cent of patients are diagnosed and about 30 per cent of them, i.e., some 800,000 patients, are treated with biological therapies. Due to the potential to treat patients with a wide variety of inflammatory diseases, Kineret could be seen as a suitable option for the treatment of up to 25 per cent of all high-risk RA patients where other medications have not been effective. Today, Kineret is used in less than 1 per cent of these RA patients.

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

Revenues, Kineret 2011–2013

SEK M



Total reported sales of Kineret increased by 16% to SEK 561.7 M (484.7).

A CHANCE TO LIVE AND THRIVE

"Our story begins 12 hours after our second son was born. I was recuperating and snuggling with my precious Louis in the wee hours of the night, when I noticed he looked red and purple all over. Doctors from all floors came to see him and take pictures, but no one had any answers. As his mother, I knew something was not right. He had hives coming and going every day and fevers and night time vomiting three to four times a week, leaving him exhausted.

In his first few years he would have good days, but others when he couldn't even walk, his knees hurt him too badly. His little life was filled with more pain than most adults experience in a lifetime.

When he was four, we moved to Minnesota within driving distance of the Mayo Clinic. We scheduled an appointment, and finally a biopsy pointed in the direction of NOMID and we had the genetic test to confirm it. We then went to see a paediatric rheumatologist who had seen this disease before. So, it was when he was five years old that he finally began to receive anakinra through a daily injection.

His life turned around immediately! The very next day his hives disappeared and he never had another vomiting episode. This was incredible for him and our family. At five years, he had also fallen completely off the growth charts by a large margin. After two years and 5 months on anakinra he has moved up to the 25th percentile! That alone would affect his quality of life for the better! He can actually live and thrive and not just barely survive each day! As we are learning to readjust to Louis' new life, he has many challenges to face ahead of him. However, on his medication, it is possible to hope, dream and be excited.

Thank God that at Mayo Clinic they had seen enough to be able to find the answers we needed and solve his case so that he could be finally treated correctly. With the right medicine, children can function and thrive even with this debilitating genetic mutation. But they have to be diagnosed correctly to get the medicine they need to overcome it and stay ahead of it. It doesn't eliminate the challenges in their lives, and there will be many, but it gives them a chance to not just survive, but truly thrive in their lives."

Theresa Martin



Theresa Martin, mother of five sons, three of whom have been diagnosed with NOMID, is married to Peter, who also has NOMID. They say their faith sees them through the tough times.

To read more about the Martins, please visit www.caringbridge.org/visit/louisfm.

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Development in 2013

Revenues from Kineret in 2013 amounted to SEK 561.7 M (484.7), an increase of 16 per cent. The revenue growth derives from increases in both volume and prices.

During 2013, the European Commission (EC) and FDA gave approval for Sobi to move manufacturing of the active ingredient in Kineret from the US biotech company Amgen in the US to Boehringer Ingelheim's facility in Vienna, Austria. This approval also allows the continued distribution of Kineret in the US and ensures efficient, long-term supply for Kineret.

In November 2013 the European Commission approved Kineret for the treatment of rare disease

CAPS in children aged 8 months and older and adult patients. This decision followed a positive recommendation issued a few months earlier by the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA).

Priorities

2014 will see the launch of the CAPS indication across many of the main EU markets. Sobi will provide Kineret for home treatment in a prefilled syringe with a graduated label to allow precise and flexible dosing in children and adults.

Following the successful launch of Kineret in NOMID in the US, Sobi plans to maximise operations in this key market, and intends to increase its scope and presence there throughout the year.

Sobi intends to refocus commercial efforts around the original indication of RA, and to launch an effort to help healthcare providers identify patients who would most benefit from Kineret treatment in this indication.

INFLAMMATORY DISEASES

Diseases caused by chronic inflammation may result in loss of function in an organ, a specific tissue or throughout large parts of the body. Inflammatory diseases range from very rare autoinflammatory conditions such as Cryopyrin-Associated Periodic Syndromes (CAPS) to rheumatoid conditions such as Rheumatoid Arthritis (RA). RA is an autoimmune inflammatory disease caused by deficiencies in the immune system that leads to chronic and debilitating pain. The disease affects around 1 per cent of the population in the EU and US. It is more common in women than in men by about two-to-three fold. RA usually occurs between the ages of 40 and 60.

CAPS constitutes a group of rare autoinflammatory diseases with an incidence estimated to be 1:1,000,000 worldwide. CAPS is characterised by

uncontrolled overproduction of Interleukin-1 (IL-1) which induces a number of inflammatory responses such as fevers, rash, joint pain, headaches, conjunctivitis and many other symptoms. In its most severe form, Neonatal-Onset Multisystem Inflammatory Disease (NOMID), the disease is also associated with chronic aseptic meningitis, hearing loss, craniofacial abnormalities, bone lesions and increased mortality.

In Europe NOMID is also called chronic infantile neurologic cutaneous and arthritis syndrome (CINCA).

Awareness among researchers and healthcare professionals of the mechanisms behind inflammation and the effects of IL-1 is growing. IL-1 has been shown to be a major contributor in both localised and systemic inflammation in the body. Recently more common disorders such as gout, diabetes, dry eye disease

and atherosclerosis have also been associated with IL-1-related chronic inflammation¹. Current drugs aimed at blocking IL-1 may result in the patient's condition normalising and the progression of joint damage being delayed, but there is still no cure for these diseases. Control of inflammation by blocking IL-1 can prevent irreversible organ damage and preserve organ function.

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

Reference: Sibley CH, Plass N, Snow J, et al. Sustained response and prevention of damage progression in patients with neonatal-onset multisystem inflammatory disease treated with anakinra: a cohort study to determine three- and five-year outcomes. *Arthritis Rheum.* 2012;64(7):2375-2386.

Orfadin – a life-saving treatment



Orfadin (nitisinone) is well-established in all major markets and continues to demonstrate growth in existing and new countries. A new liquid dosage form is in development to facilitate dosing for children.

Orfadin is a pharmaceutical for Hereditary Tyrosinaemia type 1 (HT-1), a rare genetic disorder that causes liver failure, kidney dysfunction and neurological problems. Left untreated, patients have a very limited life expectancy.

Therapeutic Area

Orfadin was commercialised by Sobi after it was developed for clinical use by two Swedish scientists in the early 1990s. The launch of the drug signalled the beginning of Sobi's commitment to developing innovative therapies for children with life-threatening diseases. To date, Orfadin has saved the lives of hundreds of children around the globe. Before Orfadin became available, patients were severely disabled and 70 per cent of them did not survive beyond the first four years of life.

This therapy area also includes Ammonaps which is used for the Urea Cycle Disorders (UCD) indication. UCD is a hereditary enzyme deficiency that prevents the body from removing ammonia from the blood stream which normally takes place in the so-called urea cycle. Sobi

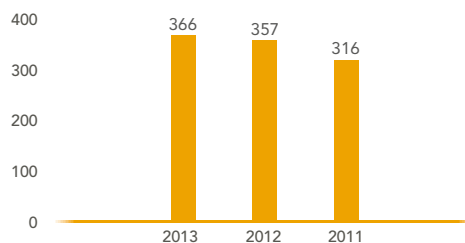
also distributes Ammonul for named patient use in Europe and the Middle East for the acute treatment of hyperammonaemia and, in the Middle East, Ravicti for the chronic treatment of UCD.

Market potential

Worldwide, HT-1 affects about one newborn in 100,000, although there are geographical variations. Several countries have started to include HT-1 in their newborn screening programmes. The US has included HT-1 in newborn screening programmes in 48 states, and earlier diagnosis of patients and treatment initiation is also gaining ground in Europe where newborn screening for HT-1 is making progress. The incidence of UCD is estimated at one newborn per 35,000.

Revenues, Orfadin 2011–2013

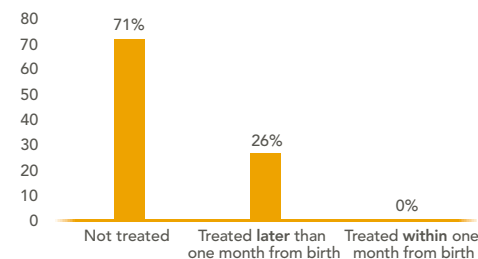
SEK M



Total reported sales of Orfadin increased by 3% to SEK 365.9 M (356.7).

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

Development in 2013

In 2013 there was growth in all major markets, although the growth was offset by higher discounts in the US as a result of the Affordable Care Act. Sales of Orfadin amounted to SEK 365.7 M (356.7), an increase of 3 per cent. Sales for this therapy area as a whole amounted to SEK 450.3 M (436.3).

In August 2013 Sobi filed an application with the European Medicines Agency (EMA) for a liquid formulation of Orfadin. This new dosage form has been developed to facilitate the ease and accuracy in administration of the desired Orfadin dose to paediatric patients and to increase convenience for the patients and their caregivers. Approval of the liquid formulation in Europe will extend Orfadin's market exclusivity.

Building real-life evidence of the benefits of therapies, such as Orfadin, and sharing this knowledge is critical to the optimal care for patients with rare diseases. Sobi participates on a regular basis in activities with this purpose.

In 2013 an article was published for the first time containing detailed treatment recommendations for care of patients with HT-1. A group of international

HT-1 experts was behind the article which was published in the *Orphanet Journal of Rare Diseases*¹. The recommendations are expected to be significant for all care providers who, in many cases, are only treating a few patients with HT-1.

In 2013 Sobi hosted a symposium during the International Congress of Inborn Errors of Metabolism in Barcelona. At the symposium, which attracted an audience of more than 300 people, a number of experts presented the various aspects of what is required for optimal care of HT-1 patients. Sobi also organised a symposium for the first time in North Africa on the importance of early diagnosis of HT-1. The symposium was held in connection with the North African congress of paediatricians.

During the year Sobi initiated a project focusing on the importance of patient adherence to their treatments. The project is based on the knowledge that many patients with chronic diseases do not follow the recommendations with respect to their medicines and research in HT-1 showing barriers to adherence to treatment and diet. Among other things, Sobi hosted a symposium in London entitled "Internal metabolic disease – the teenage years" to increase awareness about aspects such as

the problem of being a teenager with a chronic disease and how best to motivate teenagers to follow directions regarding the medicines they need.

Sobi has obtained the sole rights for the distribution of Ravicti for named patient use in the Middle East under an agreement with Hyperion Therapeutics. Ravicti is the new generation of drug for the treatment of patients with UCD and is approved by the US Food and Drug Administration (FDA) for the treatment of adults and children aged two and above.

Priorities

Sobi is continuing to further evaluate laboratory tests to facilitate optimal dosing and care of HT-1 patients. Another priority is facilitating patient medication, e.g., by developing liquid formulations, setting up home deliveries, and by training care personnel in general about chronic diseases to help patients comply with their treatment regimens.

¹ de Laet et al. Recommendations for the management of tyrosinaemia type 1. *Orphanet Journal of Rare Diseases* 2013, 8:8.

ABOUT HEREDITARY METABOLIC DISEASES

In people with Hereditary Tyrosinaemia type 1 the body cannot fully break down the amino acid tyrosine. Toxic substances are formed and accumulate in the body, which can cause liver failure, kidney dysfunction, neurological problems and death. In the most common form of the disease, symptoms arise within the first six months of life. In the past, without available

treatment, only 29 per cent of these children survived their first four years of life.

Orfadin blocks the breakdown of tyrosine and thereby prevents the toxic substances from forming. In addition to treatment with Orfadin, the patient needs to be on a special diet to limit tyrosine intake. The diet involves low amounts of tyrosine and phenylalanine.

Urea Cycle Disorder (UCD) is a group of serious conditions where patients suffer from deficiencies in the enzymes required to turn ammonia into urea. Patients therefore present with elevated levels of ammonia in the blood. If the condition is left untreated, it can cause neurological damage, coma and even death.

GRACE DOES ALL THE THINGS A NORMAL CHILD WOULD DO

"I had a normal pregnancy, and a normal birth. Our newborn Grace was perfect and weighed 8lb 4oz. When Grace was 3 weeks old the bottom of her back and bum cheeks turned purple and red like a big bruise. Our GP sent us straight to the hospital where we finally were told that Grace had a problem with her liver and we were transferred to a special children's liver unit in St. James's Hospital in Leeds. After two days, they gave us the diagnosis. We had never heard of Tyrosinaemia before.

This affected our family on a massive scale. Grace was our first child, and this perfect gorgeous little bundle was ill, with a very rare liver problem. At that time Grace was one of only 301 children in the world that were known to have the disease! So we thought life would never be the same. We felt very alone and that there was nowhere to turn to. There were lots of uncertainties about the future and nitrosinone was a very new drug back then.

But we all pulled together, and with the help of our friends and family we learned to cope. Everything we do in our daily lives is for Grace. However, we have not wrapped her in cotton wool and she has done and does do all the things a normal child would! She went to nursery at 6 months, she goes to a normal mainstream school where she is doing very well, she has a horse, she is captain of the school football team, netball team, running team.

We do get asked about the disease all the time, and people are shocked because Grace is a picture of health, and she has this infectious personality and lovable sunshine outlook so people can't believe it, but that's what makes her extra special.

Grace's GP is amazing and he saved her life! Grace has a special place in his heart, and she loves to be able to talk to him. Her consultant is also amazing, and over the years he put my mind at rest on many occasions as I have always had lots of questions!

I believe quality of life is making the best of what you can. Treat your children as you would have done if they didn't have the rare disease. Live life to the maximum, love them unconditionally, give them all the life experiences you can and enjoy every minute. This is their journey not yours. Be there to support, and laugh a lot!"

Sarah Taylor



Grace is now 11 and lives with her mum Sarah, dad, and brother Harry age 3, who hasn't got Tyrosinaemia, in Lancashire. She enjoys horse riding, plays netball, likes street dance and is looking forward to starting secondary school in September.



Partner Products – commercial partner for niche medicines

Sobi Partner Products is a division within Sobi that offers small and mid-sized pharmaceutical and biotech companies an integrated solution for the commercialisation of their products throughout Europe, the Middle East and North Africa. Partner Products specialises in cost-effectively managing niche products in a number of therapy areas. Sobi Partner Products entered into several significant new partnerships in 2013.

A full commercial partner

Sobi has more than 25 years of experience in marketing niche and speciality products in collaboration with and on behalf of various partners. Sobi's extensive experience provides a competitive advantage and facilitates entry into the market for small and mid-sized pharmaceutical companies with speciality products. They otherwise might find it hard to navigate the regulatory system and to find the path to specialist physicians, nurses, health-care payers and other customers. Companies also have better access to key partners in healthcare systems where Sobi has built a broad network.

Sobi Partner Products aims to be a full commercial partner throughout the lifecycle of the product, i.e., from the planning stages to management of mature products. The services include implementation of strategies for regulatory approval, pricing and reimbursement, as well as preparing for the launch of supplementary and/or subsequent marketing initiatives, tender management and logistics. Irrespective of the size of the company, in the end it is about helping to ensure that important medical needs are met in various therapy areas so that all patients receive optimal treatment.

Niche products

Partner Products can present a broad offering to partners throughout Europe, the Middle East and North Africa. Currently the business has partners in a wide range of therapeutic areas including haematology,

oncology, emergency medical treatment and antidotes, infectious diseases and other areas of speciality care.

Sobi Partner Products is always open to working with new partners where there is an unmet medical need and a mutual interest.

Development in 2013

Total sales of Partner Products for the full year were SEK 545.7 M (423.3), including co-promotion revenues for ReFacto AF®/BeneFIX®. 2012 included revenues from discontinued products of SEK 12.0 M.

Sobi entered into a 10-year partnership agreement during the year with Auxilium Pharmaceuticals for the development and commercialisation of Xiapex in 71 Eurasian and African countries. Xiapex is a novel biological drug for the treatment of Dupuytren's contracture, which has been approved by the regulatory authorities in the US, the EU and Canada for the treatment of adults. Preparation is under way to file an application with the European Medicines Agency (EMA) for the treatment of Peyronie's disease. Dupuytren's contracture is a hereditary disease of the connective tissue where collagen is stored in the connective tissue in the palm of the hand which can cause the fingers to lock in a curled position. Peyronie's disease affects the patient's penis in a similar way. This partnership agreement gives Sobi exclusive rights to market the drug for both of these indications.

Under a distribution agreement between Sobi and PharmaSwiss, Sobi has the rights to market Megace, Monopril, Cefzil and Duricef, which are approved in the areas of oncology, cardiovascular and anti-infective therapies. The rights apply in 15 countries within the EU.

Under a three-year agreement, Exelixis has chosen to partner with Sobi to support the distribution and commercialisation of Cometriq within the EU. Cometriq has been developed to treat metastatic Medullary Thyroid Cancer (MTC). An application is currently under consideration by EMA for the approval of the drug as treatment for MTC.

Some of our partners



Partner Products

SEK M	2013	2012	2011
Current portfolio	545.7	411.3	373.6
Co-promotion	0	12.0	105.0
Discontinued products	0	0.0	45.0
Total	545.7	423.3	523.6

Therapeutic Areas

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

Products by Therapeutic Area (selected)

Haematology	Oncology	Emergency medicines and antidotes	Infectious diseases and speciality care
Defibrotide	Aloxi	Cyanokit	Betapred
Erwinase	Cometriq	Fomepizole	Buronil
Ferriprox	Kepivance	Ruconest	Mezavant
Willfact	Megace	ViperaTAb	Xiapex
	Multiferon		
	Removab		
	Yondelis		



Long-term manufacturing partnership with Pfizer

Sobi has been manufacturing the haemophilia drug ReFacto AF®/Xyntha® for the global market on behalf of Pfizer under a long-standing partnership. Sobi's biologics production facilities also fill an important function in the company's own development work.

Partners since 1998

ReFacto AF/Xyntha is a recombinant protein drug for the treatment of haemophilia A. Factor VIII injections and proper healthcare allow most people 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 selected global markets.

Sobi manufactures the drug substance for ReFacto AF/Xyntha for Pfizer, which sells the product globally. The partnership with Pfizer began in 1998. As the global supplier, Sobi receives manufacturing revenues as well as royalties on Pfizer's sales of ReFacto. The supply agreement is in effect until 2020 with an option to extend. The royalty agreement is in place until 2016. The active ingredient is produced in Sobi's Good Manufacturing Practice (GMP) biologics facility in Stockholm, Sweden.

Development in 2013

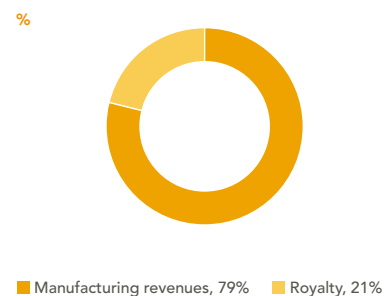
Total ReFacto revenues for 2013 (manufacturing and royalty) amounted to SEK 619.0 M (565.8). Total manufacturing revenues for 2013 increased by 13 per cent to SEK 491.9 M (436.0). Total royalty revenues for the full year decreased by 2 per cent to SEK 127.1 M (129.8). Revenue for 2013 includes delivery of validation batches of SEK 65.8 M.

Efforts to increase production capacity and efficiency at the Stockholm facility continued in 2013 as part of a long-term capacity expansion plan.

Revenues

SEK M	2013	2012	2011
Manufacturing revenues	491.9	436.0	451.7
Royalty revenues	127.1	129.8	123.3
Total	619.0	565.8	575.0

Revenues by category, 2013



Summary – Sobi's Product portfolio

	PRODUCT/PROGRAMME	THERAPY AREA
Key Therapeutic Areas		
Proprietary products or products where Sobi has global or regional rights.	Kineret®	Inflammation
	Ammonaps®	Genetic and metabolic diseases
	Ammonul®	
	Orfadin®	
	Ravicti®	
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.	Defibrotide®	Haematology
	Erwinase®	
	Ferriprox®	
	Willfact®	
	Aloxi®	Oncology
	Cometriq®	
	Kepivance®	
	Megace®	
	Multiferon®	
	Removab®	
	Yondelis®	
	Cyanokit®	Emergency medicines
	Fomepizole	
	Ruconest™	
	ViperaTAb™	
	Betapred	Other
	Buronil®	
	Mezavant®	
	Xiapex®	
	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 3	Haemophilia
	rFIX Fc (haemophilia B) in phase 3	
	Kiobrina® (improve growth in premature infants) in phase 3	Neonatology
	SOBI002 (complement C5 inhibitor)	Genetic and metabolic diseases

Key Therapeutic Areas,
share of total revenues, 2013

47%

Partner Products, share of total
revenues, 2013

25%

ReFacto Manufacturing and royalties,
share of total revenues, 2013

28%

Focused, integrated approach to sustainability

Sobi reports on its sustainability efforts within the framework of the Global Reporting Initiative (GRI) and applies the fourth-generation guidelines (G4) in accordance with the “Core” option. Central to G4 reporting is to focus sustainability communication on aspects essential for the company and its stakeholders. Sobi carried out a materiality analysis in 2013 to identify these aspects.

Sobi’s materiality analysis

The point of departure for Sobi’s materiality analysis consisted of the framework of the GRI stakeholder dialogue for the industry, combined with a company-specific analysis of the issues addressed by media and by other companies in the industry. Representatives for a number of strategic functions within Sobi evaluated where Sobi has an actual impact via its products, services and relationships, and also identified where in the operation such impact arises. The process culminated in a number of relevant topics that reflect Sobi’s financial, environmental and social impact and/or that affect evaluations and decisions among important stakeholder groups.

A broader group of internal and external stakeholders was provided with the opportunity to prioritise the relevant identified aspects and topics via a survey and targeted interviews. The surveyed stakeholder groups included representatives from the research community, investors, customers, government agencies, healthcare, suppliers, unions, employees, patient organisations, non-governmental organisation (NGOs) and the media. All groups except for the last three contributed their views.

The result was a map of the areas crucial to Sobi’s external stakeholders and those strategically important for Sobi as a company. The highest priority issues for Sobi to address and communicate about were identified by weighing the views of stakeholders, the company’s strategy and risk profile, and their actual impact.

The three most important aspects – both for external and internal stakeholders – were patient health and safety, access to health and medicine, and engagement with patient organisations. Other important aspects were clinical trials ethics and safety, employee recruitment and retention as well as regulatory, and legal challenges and anti-corruption. The survey serves as support for setting priorities in the company’s business strategy, communications and stakeholder dialogue.

Patient health and safety

Sobi’s products are evaluated by international and national regulatory authorities in accordance with strict, established and harmonised standards before they are granted marketing authorisation. Sobi continually investigates, analyses, and balances benefits and risks for patients of both marketed products and drugs under development. Protecting patient safety is Sobi’s most important task.

Sobi always adheres to the Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – in its clinical programmes. Sobi’s employees ensure compliance with both internal and external rules in all clinical trials in which Sobi is a sponsor, and potential side effects of pharmaceuticals are identified in collaboration with physicians and patients. Sobi has market authorisation for a number of medications in different markets, which includes the obligation to collect, process and report adverse events and other safety information to drug regulatory authorities in accordance with international laws and regulations.

Sobi has an efficient system and network for collection, analysis and communication of adverse events and other safety information related to the medications that the company markets and develops. Sobi’s drug safety division is mandated to continuously capture, evaluate and communicate signals to ensure the benefit of the company’s pharmaceuticals – with the safety and best interests of the patients in mind. All employees have a responsibility to report any suspected product complaints and any side effects of Sobi’s products about which they may become aware. Employees therefore complete an annual training course for this purpose. The reporting requirements are regulated by a Standard Operating Procedure (SOP) that Sobi’s employees undertake to follow.

Sobi regularly updates this SOP to reflect changes in legislation and best practices. In Sweden, Sobi is part of

the pharmaceutical insurance scheme, which covers those suffering from any adverse effects that may have arisen from drug treatment or participation in clinical trials in Sweden.

Access to health and pharmaceuticals

At Sobi we believe that an integrated approach to delivering therapies is essential to ensuring that patients will benefit in practice from the innovative therapies 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 healthcare 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 (PC3).

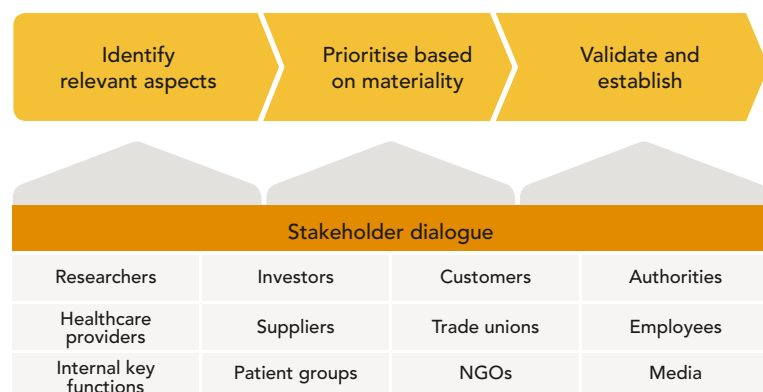
One long-term objective for Sobi is to make its pharmaceuticals accessible worldwide, which is a challenge, especially in developing countries. Sobi is committed to playing an active role in the dialogue with stakeholders, governments and healthcare systems across the globe, to ensure that patients get timely and sustainable access to required therapies. We are also committed to provid-

ing bridging solutions for patients while these dialogues are active and on-going, provided commitments to building sustainable, long-term solutions are in process.

Engagement with patient organisations

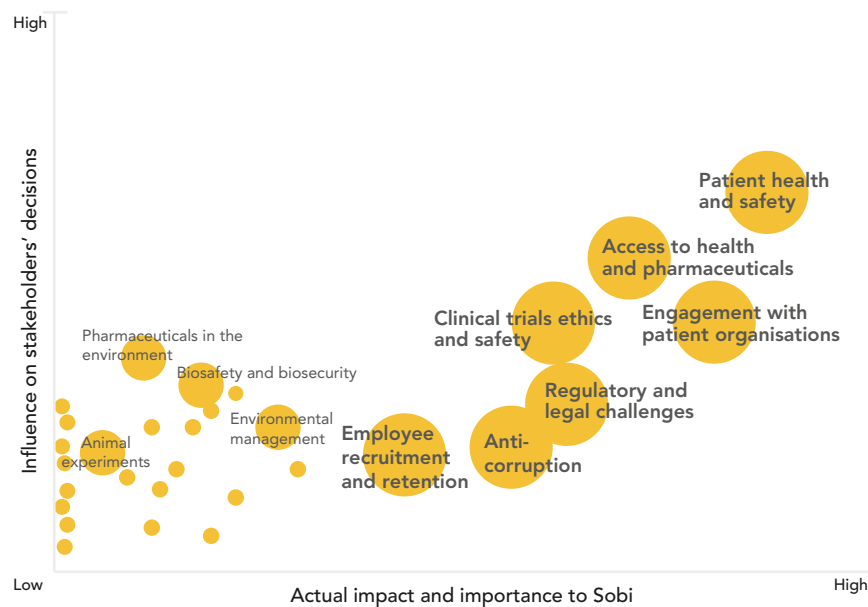
Learning that a child has a serious or life-threatening rare disease can be overwhelming for both the child and the child's family. Treatment and supportive care are often complicated and, because such diseases are rare, knowledge about them is often inadequate, even among healthcare professionals.

Process of materiality analysis



Materiality analysis

Outcome



The materiality analysis is a tool to understand issues most material and relevant for a company. The vertical axis shows how stakeholders assess the importance of aspects relevant to Sobi and the pharmaceutical industry. The horizontal axis is Sobi's own assessment, in relation to business strategy and operations.

Sobi prioritises education and information materials for healthcare professionals, patients and families. Sobi supports a number of patient organisations and engages in active dialogue with them to understand their needs and to build mutual understanding of how the specific rare disease manifests and is treated. A complete list of the patient organisations that Sobi supports can be found on www.sobi.com.

Knowledge also frequently differs among geographical areas, even after treatment becomes available. Meanwhile, medical knowledge about rare diseases is increasing. Sobi works to facilitate the transfer of knowledge in healthcare and has collaborated with expert medical groups to develop several comprehensive training programmes for healthcare providers who treat patients with rare diseases. Several of these programmes are now certified by public healthcare providers.

To stay abreast of global changes and to contribute to the development of stable conditions for pharmaceutical

and healthcare systems, Sobi is a member of several representative industry bodies on both national and international level. Another important aspect of Sobi's business model is to help create and support a society that promotes research, development and investment in the knowledge economy and scientific sector. Sobi also belongs to several industry organisations that work to promote understanding, cooperation and collaboration across borders. A list of the organisations to which Sobi belongs can be found on www.sobi.com.

Regulatory and legal challenges

Sobi is active in a highly regulated environment, where the company has to comply with laws and regulations in both research and marketing. A general trend towards greater awareness of liability issues and legal risks is increasing demands for transparency. Companies are expected to report more information on legal proceedings and in the pharmaceutical industry transparency requirements relating

to clinical results are stricter. Sobi welcomes this transition and continuously works to maintain both its own standards and the standards of its business partners in this regard.

A new regulatory environment has also developed surrounding market conditions and pricing for pharmaceuticals. Applications for marketing authorisation are made today in a step-by-step process, often resulting in conditional approval which must be followed up and evaluated. Medicines are priced according to new and more complex models. These trends create challenges for the entire pharmaceutical industry, but for Sobi the changed conditions have created clear opportunities. Sobi's approach is well-suited to navigation in and compliance with the new legal environment.

Clinical trials ethics and safety

All clinical studies that Sobi sponsors are carried out and reported in accordance with applicable law and international standards of Good Clinical Practice. Before a clinical

SUPPLY CHAIN

Sobi purchases materials, goods and services from more than 1,000 different suppliers. Creating good relationships with these suppliers is a way to promote sustainability and responsibility within the business. Sobi strives to apply consistent rules for all suppliers based on Sobi's Code of Conduct and Ethics.

Purchasing at Sobi primarily falls into two main categories: those governed by international and national

regulatory agency requirements and standards, and those of a general nature for all businesses, regardless of industry. Purchases in the first category are made after careful evaluation according to Sobi's own governing documents and procedures, followed by continuous assessment. In the second category, Sobi procures the best terms and conditions from Sobi's suppliers, balancing price with quality, while

taking current industry standards of responsibility into account. Sobi's suppliers are primarily based in Europe and the US.

Sobi's value chain and patient access to healthcare and pharmaceuticals are integrated to a growing extent with a focus on health and safety.

trial is initiated it undergoes an internal approval process, as well as review and approval by regulatory authorities and independent ethics committees.

Sobi strives to maintain the highest ethical, technical and scientific standards in all clinical research. The company ensures that clinical researchers and centres involved in studies sponsored by Sobi are qualified in terms of education and experience and that they have the necessary resources to conduct the study. The majority of Sobi's clinical trials are carried out by Contract Research Organisations, in cooperation with physicians and patients.

Sobi's outsourcing process is regulated in internal job and process descriptions, SOPs. Ultimate responsibility for strategy, quality and integrity, including implementation and maintenance of quality control systems, as well as reporting of a study, always rests with Sobi in its capacity as sponsor. Sobi publishes information about all clinical trials in which the company is a sponsor on www.clinicaltrials.gov. In 2013 there were no cases of violations of legislation or standards aimed at protecting the health and safety of people included in clinical studies.

Employee recruitment and retention

Sobi's business model combines advanced research with commercial activity. Sobi is a knowledge-intensive company with high expectations of individual employees, which is necessary to build an innovative corporate culture with a high achievement level and to create value for our stakeholders. The goal is to attract, develop and retain skilled employees within Sobi's area of operation and to create an environment in which people can thrive and feel committed to the company's mission to improve patients' quality of life.

Good terms of employment are crucial for recruiting and retaining 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 strives to create a culture based on individual responsibility. In order for employees to understand how their own work contributes to the company's mission, Sobi has a strong corporate culture with common goals and transparent communication. Continuous professional development for all employees is crucial for developing the product portfolio and strengthening production processes, a prerequisite for successfully launching and selling the products.

The company has a well-defined performance management process, whereby managers and employees jointly set individual goals for the coming year in line with the company's overall goals. The individual goals are then followed up at specified times during the year. Employee performance is then evaluated in relation to the goals, but how the goals are achieved is also important.

In 2013, 40 per cent of the total number of employees were men and 60 per cent were women. In the Executive Leadership Team and the Board of Directors the corresponding figures were 67/33 per cent and 71/29 per cent (excluding employee representatives). Respectively, all employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

Anti-corruption

In 2013 Sobi launched its Code of Conduct & Ethics to all its employees. It contains a section specifically addressing the areas of anti-corruption and anti-bribery. Further, during 2013 Sobi also performed a global risk analysis in all areas, including all its subsidiaries. The analysis contained detailed questions related to anti-corruption and anti-bribery. The result confirmed the importance of knowledge about the exposed parts of the world. Within the area of healthcare compliance, specific guidelines have been issued and training sessions have been performed in order to provide an ethical business standard for transparent promotional

READ MORE ON OUR WEBSITE

In addition to the key areas described above, Sobi actively works with several other relevant aspects, especially, i.e.:

- Environmental Management
- Animal Experiments

There are also areas that are important for the pharmaceutical industry in general, but which are of limited relevance to Sobi's operations, i.e.:

- Biosafety and Biosecurity
- Pharmaceuticals in the environment

Information on the above areas is available on www.sobi.com/About-Sobi/Corporate-responsibility

and non-promotional activities and interactions with Health Care Professionals, Providers, Payers and Patient Organisations. During first half of 2014 a global Anti-Corruption Policy will be launched throughout Sobi and training will be provided to all employees in order to prevent corruption in all Sobi's activities.

Global Reporting Initiative Index 2013

INDICATOR OVERVIEW

ASPECT/TOPIC	APPLIED INDICATORS
Customer health and safety	PR1; PR2
Access to health and medicine	EC8
Engagement with patient groups	PR5
Regulatory and legal challenges	SO4; SO5; SO8; PR2; PR4; PR9
Clinical trial ethics and safety	PR1; PR2
Employee recruitment and retention	LA1; LA6; LA11; LA12

About this report

Sobi reports on an annual basis on its sustainability work, as a part of the Annual Report. Sobi is applying level 'Core' in accordance with the Global Reporting Initiative's (GRI) most recent guidelines for sustainability reporting, referred to as G4. The indicators presented below are all selected on the basis of a so called materiality analysis which is further described on pages 33–34 in this report. The indicator overview to the left lists the GRI indicators applied to reflect the aspects and topics assessed to be most material for Sobi. All cross references below relates to pages in Sobi's Annual Report 2013 or on www.sobi.com.

● = Fully reported ● = Partly reported

STANDARD DISCLOSURE	CROSS-REFERENCE	REPORTED	COMMENT
Strategy and analysis			
G4-1 CEO statement	2–3, 33, www.sobi.com	●	
G4-2 Description of key impacts, risks and opportunities	33–35, 48–50	●	
Organisational profile			
G4-3 Name of the organisation	72	●	
G4-4 Primary brands, products and services	31	●	
G4-5 Location of organisation's headquarters	72		
G4-6 Countries where the organisation operates	83	●	
G4-7 Nature of ownership and legal form	51–52, 72	●	

STANDARD DISCLOSURE	CROSS-REFERENCE	REPORTED	COMMENT
G4-8 Markets served	Inside cover, 43	●	
G4-9 Scale of the organisation	46, 62, 83	●	
G4-10 Total workforce by employment type, contract, region and gender	83	●	
G4-11 Percentage of employees covered by collective bargaining agreements		●	All employees in the Swedish operations (representing approximately 80 per cent of Sobi's employees) are covered by collective bargaining agreements.
G4-12 Describe the organisations' supply chain	34	●	
G4-13 Significant changes during the report period	2–4, 13	●	
G4-14 Explanation of how the precautionary principle is applied	32–35	●	Risk management is integrated with all strategic and operational work. There is a specific procedure for handling of hazardous chemicals which describes how to identify, assess and handle risks including the application of the precautionary principle.
G4-15 Endorsement of external codes, principles or initiatives	32	●	In clinical programmes and trials, Sobi adheres to the ethical principles of the Declaration of Helsinki, developed by the World Medical Association (WMA). Sobi also adheres to the ethical rules of LIF (trade organisation for the research-based pharmaceutical industry in Sweden).
G4-16 Memberships in associations	www.sobi.com	●	A list of membership in associations is available on www.sobi.com
Identified material aspects and boundaries			
G4-17 Operational structure of the organisation	60	●	
G4-18 Process for defining report content	32	●	
G4-19 Material aspects identified in the process for defining report content	32–35	●	
G4-20 Aspect boundaries within organisation		●	Employee indicators cover the Swedish operations (representing approximately 80 per cent of Sobi's employees). Other indicators cover all of Sobi's operations.

STANDARD DISCLOSURE	CROSS-REFERENCE	REPORTED	COMMENT
G4-21 Aspect boundaries outside organisation	32–35	●	
G4-22 Explanation of the effect of any re-statements of information provided in earlier reports		●	There have been no re-statements of information since previous reports.
G4-23 Significant changes from previous reporting periods regarding scope, boundaries, etc.		●	There has been no changes regarding scope, boundaries etc., since previous reports.
Stakeholder engagement			
G4-24 List of stakeholder groups	32	●	
G4-25 Basis for identification and selection of stakeholders with whom to engage	32	●	
G4-26 Approaches to stakeholder engagement	32–35	●	
G4-27 Key topics and concerns raised by stakeholders	32–35	●	
Report profile			
G4-28 Reporting period		●	Calendar year 2013
G4-29 Date of most recent previous report		●	April 2013
G4-30 Reporting cycle		●	Annual
G4-31 Contact point for questions regarding the report		●	Oskar Bosson, Head of Communications oskar.bosson@sobi.com
G4-32 Table identifying the location of the Standard Disclosures in the report	36–38	●	
G4-33 Policy and current practice with regard to seeking external assurance for the report		●	This report has not been subject to external assurance.
Governance			
G4-34 Governance structure of the organisation	53	●	

STANDARD DISCLOSURE	CROSS-REFERENCE	REPORTED	COMMENT
Ethics and integrity			
G4-56 Values, principles and norms of behaviour such as codes of conduct and codes of ethics	35, 50, www.sobi.com	●	Sobi's Code of Conduct and Ethics is available on www.sobi.com.

INDICATORS FOR MATERIAL ASPECTS	CROSS-REFERENCE	REPORTED	COMMENT
ECONOMIC			
Indirect economic impacts			
Management approach	33, www.sobi.com	●	Sobi's Charter on Patient Access Bridging Programmes is available on www.sobi.com
G4-EC8 Significant indirect economic impacts	33	●	
SOCIAL			
LABOUR PRACTICES AND DECENT WORK			
Employment			
Management approach	35	●	
G4-LA1 Rate of employee turnover by age group, gender and region			
Occupational health and safety			
Management approach	35, 46	●	
G4-LA6 Rates of injury, occupational diseases, lost days, work related fatalities, by region and by gender	35		During 2013 there were fourteen incidents resulting in minor injuries, none of which led to lost time in terms of sick-leave.

INDICATORS FOR MATERIAL ASPECTS	CROSS-REFERENCE	REPORTED	COMMENT
Training and education			
Management approach	35	●	
G4-LA11 Employees receiving regular performance and career development reviews, by region and by gender	35	●	
Diversity and equal opportunity			
Management approach	35, 46	●	
G4-LA12 Composition of governance bodies and employees according to diversity indicators	35, 88	●	
SOCIETY			
Anti-corruption			
Management approach	34–35, www.sobi.com	●	
G4-SO4 Communication and training on anti-corruption policies and procedures		●	All questions relating to anti-corruption and anti-bribery are discussed in Sobi's Code of Conduct & Ethics. In Sweden Sobi is a member of LIF, the research based pharmaceutical industry organisation and follows their "The Ethical Rules for the Pharmaceutical Industry". These guidelines specifically includes provisions on anti-corruption. The Sobi European organisation follows the European Federation of Pharmaceutical Industry and Associations (EFPIA) rules and standards. The rules are consistent with the WHO code of ethics for marketing of pharmaceuticals. The Sobi US organisation follows the Office of Inspector General, U.S. Department of Health & Human Services (OIG) and the Pharmaceutical Research and Manufacturers of America (PhRMA) rules and guidelines.

INDICATORS FOR MATERIAL ASPECTS	CROSS-REFERENCE	REPORTED	COMMENT
G4-SO5 Confirmed incidents of corruption and actions taken	34–35	●	During 2013 no case of corruption involving Sobi or Sobi's employees have been brought to the attention of the company management.
Compliance			
Management approach	34–35, www.sobi.com	●	
G4-SO8 Significant fines and non-monetary sanctions for non compliance with laws and regulations		●	During 2013 Sobi has not identified any non-compliance with laws and regulations, which possibly could have led to fines or non-monetary sanctions.
PRODUCT RESPONSIBILITY			
Customer health and safety			
Management approach	32–35, www.sobi.com	●	
G4-PR1 Percentage of significant product and service categories for which health and safety impacts are assessed for improvement	32–35	●	
G4-PR2 Incidents of non-compliance with regulations concerning health and safety impacts of products		●	During 2013 Sobi has not identified any non-compliance with laws, regulations or voluntary codes concerning the health and safety impacts of its products.
Products and services labeling			
Management approach	32–35, www.sobi.com	●	
G4-PR4 Incidents of non-compliance with regulations and voluntary codes concerning product and service information and labeling		●	During 2013 Sobi has not identified any non-compliance with laws, regulations or voluntary codes concerning product and service information and labeling.

INDICATORS FOR MATERIAL ASPECTS	CROSS-REFERENCE	REPORTED	COMMENT
G4-PR5 Results of surveys measuring customer satisfaction		●	Sobi's objective is to identify where value can be added for patients and their physicians. By creating and maintaining a dialogue with this community, and also with governments and payers, Sobi seeks to ensure that treatments are delivered in a sustainable way. At Sobi this is referred to as a Patient and Customer Centric approach to Commercialisation (PC3). Sobi complies with the ethical rules of LIF (trade organisation for the research-based pharmaceutical industry in Sweden) that does not allow regular customer surveys to be conducted for prescribed pharmaceuticals.
Marketing communications			
Management approach	32–35, www.sobi.com	●	
G4-PR7 Incidents of non-compliance with regulations concerning marketing communications		●	During 2013 Sobi has not identified any non-compliance with laws, regulations or voluntary codes concerning the marketing of its products.
Compliance			
Management approach	32–35, www.sobi.com	●	
G4-PR9 Significant fines for non-compliance with laws and regulations concerning the provision and use of products and services		●	During 2013 Sobi has not identified any non-compliance with laws, regulations or voluntary codes concerning the provision and use of its products.

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Operations

Highlights 2013

- Total revenues increased to SEK 2,176.7 M (1,923.2), an increase of 13 per cent.
- Revenues from key Therapeutic Areas increased by 10 per cent.
- Gross margin increased to 59 per cent (54), driven by efficiency gains in production of ReFacto AF®, and completion of technology transfer for Kineret®.
- During 2012 other operating revenues and expenses, were 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 before amortisation of intangible assets (EBITA), was SEK 211.0 M (367.0).
- Profit for the period amounted to SEK –93.0 M (–100.9), corresponding to earnings per share of SEK –0.35 (–0.38).
- Cash flow from operations amounted to SEK 185.4 M (405.5).
- Issued additional SEK 200 M under the current bond loan.
- Reached sales volumes for Kineret that triggered a contractual milestone payment of USD 55 M to Amgen. This was paid in the first quarter 2013.
- Phase 3 data confirm long-lasting characteristics of rFIXFc and rFVIII Fc across multiple haemophilia populations
- Completed enrolment in Europe for phase 3 registrational study for Kiobrina®.
- Launched phase 1 complement C5 inhibitor programme.
- Submitted application for Orfadin® oral suspension to European Medicines Agency (EMA).
- European Commission approved Kineret for the treatment of CAPS.
- Signed four new partnership agreements with Auxilium Pharmaceuticals, Exelixis, Hyperion Therapeutics and PharmaSwiss.

Key figures

SEK M	2013	2012
Total revenues	2,176.7	1 923.2
Gross profit	1,284.0	1 040.4
Gross margin	59%	54%
Operating profit before amortisations (EBITA)	211.0	367.0
Operating profit before non-recurring items (EBIT)	–66.5	–54.6
Profit/loss	–93.0	–100.9
Earnings/loss per share, SEK	–0.35	–0.38

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

Sobi's operations

Sobi is an international speciality healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. Sobi's key Therapeutic Areas are Inflammation and Genetics & Metabolism, with three late-stage biological development projects within Haemophilia and Neonatology. We also market a portfolio of speciality and rare disease products for partner companies.

In 2013 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 include proprietary products and products sold through distribution and licensing agreements. Product sales primarily in Europe and North America.

Revenues

Total revenues in 2013 increased to SEK 2,176.7 M (1,923.2). 2013 included revenues from sales of validation batches to Pfizer about SEK 65.8M. Sales of the products in key Therapeutic Areas increased by 10 per cent, the Partner Product portfolio by 29 per cent, growth in ReFacto AF manufacturing and royalties showed an increase of 9 per cent.

SEK M	2013	2012
Key Therapeutic Areas	1,012.0	921.0
Partner products	545.7	423.3
ReFacto	619.0	565.8
Other revenues	–	13.1
Total revenues	2,176.7	1,923.2

Gross margin

The gross margin, increased to 59 per cent (54) 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 Boehringer Ingelheim.

Expenses

Operating expenses decreased by 5 per cent to SEK 1,374.1 M (1,440.9). The decrease was the result of write-down of Multiferon® 2012, which was offset by higher costs for the phase 3 programmes.

Sales and administrative expenses increased to SEK 898.2 M (961.1). 2012 includes a write-down (intangible- and tangible assets) of Multiferon of SEK 162.3 M. Research and development expenses increased by 14 per cent to SEK 455.7 M (401.6); phase 3 programmes for haemophilia and Kiobrina accounted for the increase.

Non-recurring items were SEK 0 M (–37.1) for the full year. 2012 included 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 3.4 M (304.9). 2012 included 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 before amortisations (EBITA) amounted to SEK 211.0 M (367.0). 2012 includes sales of co-promotion rights to Pfizer of SEK 307.5 M. Amortisation of intangible assets amounted to SEK 277.6 M (421.6). 2012 includes write-down of Multiferon of SEK 150.8 M. Operating profit (EBIT) amounted to SEK –66.5 M (–54.6).

Net financial items

Net financial items for the full year 2013 amounted to SEK –56.9 M (–50.5). Financial income of SEK 14.3 M (7.3) is primarily as a result of gains related to currency fluctuations and interest income from cash balances. Financial expenses of SEK 71.2 M (57.8) are mostly due to interest related expenses.

Taxes

The tax expense for the year was SEK –16.0 (–18.9) and deferred tax amounted to SEK 46.5 M (23.2).

Other comprehensive income and expenses

Net other comprehensive income and expenses amounted to SEK 4.2 M (5.7) and consist of cash flow hedge relating to the bond and the reassessment of the pension obligation.

Cash flow and investments

Cash flow from operations amounted to SEK 185.4 M (405.6). Net non-cash items amounted to SEK 258.4 M (468.6) and were mainly attributable to amortisation and write-downs of product rights and licences, offset by reversal of deferred taxes.

Cash flow from investing activities amounted to SEK –404.6 M (–67.3) and was mostly attributable to investments in intangible assets.

A decrease in working capital had a positive impact on cash flow of SEK 19.9 M (37.7 M). Inventories increased, mainly for ReFacto AF as well as stock build up for new products, including Xiapex®, was built up. Although accounts receivable increased reflecting growth in sales in the final months. This was offset by a increase in current liabilities, mainly accounts payable, which had a positive impact on working capital.

Financial position

Cash and cash equivalents as of 31 December 2013 amounted to SEK 445.1 M (457.0).

The total bond loan was increased by SEK 200 M on 28 February 2013. Total bond amounts to SEK 800 M, with maturity in 2017. The bond loan has a floating interest of 3 months Stibor + 500 bps, which was swapped to a fixed rate of 6.6 per cent. The loan is listed on NASDAQ OMX Stockholm.

Net debt as of 31 December 2013 amounted to SEK 352.5 M, compared to SEK 134.6 M per 31 December 2012.

Equity

Consolidated shareholders' equity as of 31 December 2013 amounted to SEK 4,769.2 M, compared to SEK 4,837.9 M as of 31 December 2012.

The Parent company

Revenues for the Parent company in 2013 amounted to SEK 1,841.9 M (1,640.5). Operating profit was SEK –17.9 M (265.4). Net profit was SEK –7.6 M (31.6). In 2012, the driver was the proceeds from the sale of the Nordic co-promotion rights of SEK 307.5 M to Pfizer.

Cash and cash equivalents and short-term investments as of 31 December 2013 amounted to SEK 373.5 M (276.5). Shareholders' equity as of 31 December 2013 amounted to SEK 5,621.6 M (5,607.4), the variance being driven by the profit for the year as well as costs associated with the company's share programmes.

Key figures – 5 years

SEK M	2013	2012	2011	2010	Proforma 2009 ²	2009
Total revenues	2,176.7	1,923.2	1,910.8	1,906.7	2,065.6	1,297.0
Adjusted profit/loss for the period	–93.0	–63.8	98.3	–16.7	–	32.4
Cost of goods and services sold	–892.7	–882.8	–936.3	–685.7	–664.3	–375.7
Research and development expenses	–455.7	–401.6	–555.7	–558.8	–603.1	–569.4
Operating profit/loss	–66.5	–54.6	–318.6	–10.3	72	16.2
Financial items – net	–56.9	–50.5	–52.2	–82.2	–	16.3
Profit/loss for the period	–93.0	–100.9	17.9	–104.5	–	32.4
Earnings/loss per share ¹ , SEK	–0.35	–0.38	0.07	–0.47	–	0.29
Earnings/loss per share after full dilution ¹ , SEK	–0.35	–0.38	0.07	–0.47	–	0.29
Number of shares, in thousands	270,390	265,227	265,227	212,181	–	50,396
Equity ratio	73.2%	76.7%	74.1%	61.4%	–	48.2%

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

² Proforma figures due to the acquisition of Swedish Orphan.

Sales by business area and geographical region

Key Therapeutic Areas

The products within key Therapeutic Areas portfolio, Inflammation and Genetics & Metabolism, (Kineret, Orfadin, Ammonaps®, Ammonul® and Ravicti®) showed a 10 per cent increase to SEK 1012.0 M (921.0).

Total sales of Kineret increased by 16 per cent to SEK 561.7 M (484.7) as a result of both volume and price increases, the latter driven mainly by US.

Total sales of Orfadin increased by 3 per cent to SEK 365.9 M (356.7). The business showed consistent volume increase in most geographies, offset by higher rebates in the US due to the Affordable Care Act.

Partner Products

Total sales of Partner Products amounted to SEK 545.7 M (423.3). The four new partnership agreements with Auxilium Pharmaceuticals, Exelixis, Hyperion Therapeutics, and Pharma-Swiss signed in 2013 have contributed to the sales growth. Total sales for Partner Products in 2012 included co-promotion revenues of SEK 12.0 M. Total revenues for Partner Products increased by 29 per cent. The key growth drivers in the portfolio were mainly Yondelis® and the new products Xiapex, Cometriq® and the PharmaSwiss portfolio.

Total sales of Kepivance® increased by 6 per cent to SEK 87.1 M (82.3). Total sales of Yondelis increased by 32 per cent to SEK 73.3 M (55.4).

ReFacto AF

Total ReFacto AF manufacturing and royalty revenues amounted to SEK 619.0 M (565.8). Total manufacturing revenues increased by 13 per cent to SEK 491.9 M (436.0). Revenue for 2013 includes delivery of validation batches of SEK 65.8 M. Planned validation batch deliveries were completed in the fourth quarter 2013.

Total royalties decreased by 2 per cent to SEK 127.1 M (129.8). In February 2012, Sobi and Pfizer extended their supply agreement for ReFacto AF/XYNTHA until 31 December 2020, with an option to further renew.

Sales by key product

SEK M	2013	2012
Inflammation: Kineret	561.7	484.7
Genetics & Metabolism: Orfadin	365.9	356.7
Genetics & Metabolism: Other	84.4	79.6
Key Therapeutic Areas	1,012.0	921.0
Current portfolio	545.70	411.3
Co-promotion revenues	0.0	12.0
Partner Products	545.7	423.3
Manufacturing revenues	491.9	436.0
Royalty revenues	127.1	129.8
ReFacto	619.0	565.8
Other revenues	0.0	13.1
Total revenues	2,176.7	1,923.2

Product sales by region

(Excluding ReFacto manufacturing and royalty revenues)

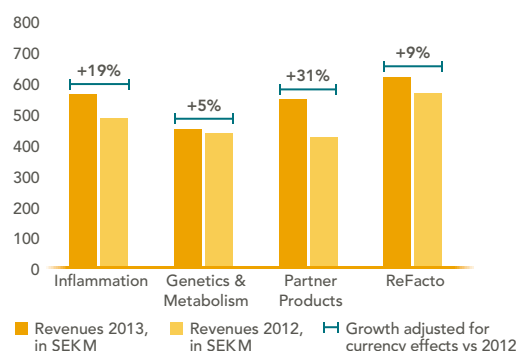
SEK M	2013	2012	Change
Europe	1,052.3	896.0	17%
MENAR ¹	55.1	38.5	43%
North America	423.1	383.1	10%
RoW	27.1	26.8	1%
Sum	1,557.7	1,344.3	16%

¹ Middle East, North Africa and Russia

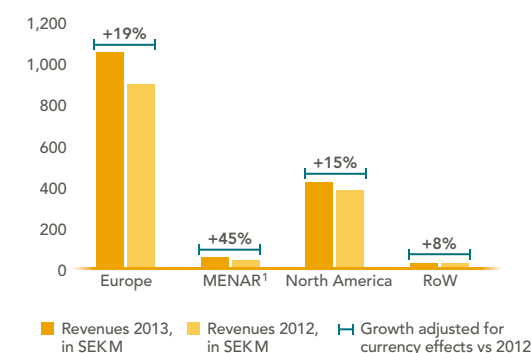
Products per business line

Key Therapeutic Areas	Partner Products	ReFacto
Inflammation	Kepivance	Manufacturing
Kineret	Yondelis	Royalty
Genetics & Metabolism	Xiapex	
Orfadin	Megestrol	
Ammonaps	Ferriprox	
Ammonul	Aloxi	
Ravicti	Cometriq	
	Betapred	
	Defibrotide	
	Fosinopril	
	Other	

Revenues by product category



Revenues by region



¹ Middle East, North Africa and Russia

Development

Sobi's development projects include three phase 3 programmes: rFIXFc and rFVIII Fc within Haemophilia and Kiobrina within Neonatology, and one phase 1 programme, SOBI002, a novel complement C5 inhibitor. There are also preclinical and lifecycle management projects.

Phase 3 data confirm long-lasting characteristics of rFIXFc and rFVIII Fc across multiple haemophilia populations

At the Annual Meeting of the American Society of Hematology (ASH) in December 2013 Sobi and partner Biogen Idec presented results from phase 3 studies of their investigational long-lasting recombinant factor VIII and IX Fc fusion protein candidates for haemophilia A and B, rFVIII Fc and rFIXFc, including an interim paediatric analysis of paediatric pharmacokinetics (PK) data for the companies' on-going Kids A-LONG and Kids B-LONG. The interim data demonstrated that rFVIII Fc and rFIXFc have consistently prolonged half-lives (a measure of the time a therapy circulates in the bloodstream) in children, compared to study participants' prior therapies.

Kids A-LONG and Kids B-LONG are multi-centre phase 3 studies of rFVIII Fc and rFIXFc for previously treated children under age 12 with haemophilia A and B, respectively. Kids A-LONG and Kids B-LONG are designed to investigate the safety, efficacy and PK of rFVIII Fc and rFIXFc. The Kids A-LONG interim data showed that the mean half-life of rFVIII Fc was approximately one and a half times that of the subjects' prior factor VIII therapies. The Kids B-LONG interim data showed that the mean half-life of rFIXFc was more than three times longer than the subjects' prior factor IX therapies. For both rFVIII Fc and rFIXFc, prolonged half-lives were seen in each age group analysed – under six and six to under 12 years old.

In 43 children treated with rFVIII Fc as of February 8, 2013, and 23 children receiving rFIXFc as of April 23, 2013, no inhibitors (antibodies that may interfere with the activity of the therapy) were detected. In this interim analysis, the pattern of treatment-emergent adverse events reported was typical of the populations studied, with no unique safety issues identified.

Final results of the paediatric studies will evaluate the safety and efficacy of rFVIII Fc and rFIXFc, as well as provide further PK information. The primary endpoint for both studies is the occurrence of inhibitor development over the study period. Secondary outcome measures include the annualised bleeding rate (ABR), or projected number of yearly bleeding episodes, and assessments of response to treatment.

No. of patients required in European studies	rFVIII Fc	rFIXFc
Previously treated patients >=12 years	50	20
Previously treated patients 6 – <12 years	25	10
Previously treated patients <6 years	25	10

Ref. European Medicines Agency (EMA)

Completed enrolment in Europe 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 therapy to improve growth in preterm infants who receive pasteurised breast milk or infant formula. The on-going phase 3 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 was enrolled in the study in the first half of 2013. The trial enrolled patients in approximately 50 centres across 10 European countries.

Kiobrina, phase 3 study

Placebo-controlled, double blind study
4 weeks treatment
More than 400 patients, born before pregnancy week 32
10 countries, 50 sites

Kiobrina, phase 3 observational study

24 months
All patients from the registration study will be followed until 24 months

Launched phase 1 complement C5 inhibitor programme

In November 2013, Sobi announced its intention to bring a novel investigational biopharmaceutical drug candidate, SOBI002, into a phase 1 trial. SOBI002 is a small biologic molecule based on the Affibody platform that works as a potent and selective inhibitor of complement component C5, a key protein in human immunological and inflammatory processes and central to a number of important diseases. The study will evaluate single and repeated doses of SOBI002 administered subcutaneously and intravenously in healthy volunteers.

Shared information regarding phase 3 data for Kepivance

In November 2013, Sobi shared data from two phase 3 clinical trials acquired from Amgen concerning Kepivance. The trials demonstrate the potential for Kepivance to reduce the incidence and duration of severe oral mucositis, a complication of chemotherapy and radiotherapy regimens for Head and Neck cancers. The company is in discussions with the US Food and Drug Administration (FDA) regarding the potential for a supplemental Biologics License Application (sBLA) filing to support a label expansion for Kepivance.

Submitted application for Orfadin oral suspension to EMA

In August 2013, the company announced that its application for Orfadin oral suspension had been validated by the European Medicines Agency (EMA). The new dosage form has been developed to facilitate the ease and accuracy in administration of the desired Orfadin dose to paediatric patients and to increase convenience for the patients and their caregivers. The oral suspension is included in a Paediatric Investigation Plan (PIP) agreed with EMA in March 2012.

European Commission approved Kineret for the treatment of CAPS

Sobi's Marketing Authorisation application for Kineret for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), in the EU, filed in November 2012, was approved by the European Commission (EC) in November 2013. Kineret is now approved for use in children aged 8 months and older, weighing 10 kg or more, who suffer from CAPS. In December 2012, Kineret became the first and only FDA-approved therapy for Neonatal-Onset Multisystem Inflammatory Disease (NOMID)/Chronic Infantile Neurologic Cutaneous and Arthritis syndrome. Sobi will provide Kineret for home treatment in a prefilled syringe with a graduated label to allow precise and flexible dosing in children and adults.

Other information

New and amended partnership agreements during the year Distribution agreement signed with PharmaSwiss

Sobi entered into an exclusive distribution agreement with 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 Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom. 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 in the US. Savient started to market and promote Kineret as of 1 April 2013. Sobi remains responsible for all Kineret commercial drug manufacturing, supply and regulatory activities. For more information, see note 39.

Distribution agreement with Exelixis

In February 2013, Sobi entered into a three-year agreement to support the distribution and commercialisation of Cometriq for metastatic Medullary Thyroid Cancer (MTC) in the 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.

Collaboration agreement with Auxilium

Auxilium Pharmaceuticals and Sobi entered into a long-term collaboration for the development, supply and commercialisation of Xiapex, a novel, first-in-class biologic for the treatment of Dupuytren's contracture. In addition, work is on-going to file for approval of Xiapex for the treatment of Peyronie's disease in the EU. Auxilium remains primarily responsible for the global development of Xiapex in Dupuytren's contracture and Peyronie's disease and will be responsible for drug manufacturing and supply. Sobi is responsible for clinical development and regulatory activities and associated costs corresponding to any additional trials required in its licensed territories. Under the terms of the collaboration agreement, Sobi has exclusive distribution rights in 71 European, Asian and African countries.

Distribution agreement with Hyperion

Hyperion Therapeutics, has granted Sobi the exclusive rights to distribute Ravicti Oral Liquid on a named patient basis for the chronic treatment of Urea Cycle Disorders (UCD) in the Middle East. Under the agreement, Sobi has the rights to provide Ravicti in Saudi Arabia, Oman, United Arab Emirates, Jordan, Kuwait, Qatar and Bahrain.

Taking direct responsibility for Orfadin in the US, Canada and Latin America

Sobi has decided to take direct responsibility for Orfadin in the US, Canada, and Latin America by terminating the current distributorship agreement with their partner Rare Disease Therapeutics, Inc. (RDT). The distributorship will transfer to Sobi on 1 April 2014 for the US and Canada, and on 1 January 2015 for Latin America.

Acquired full rights for Kineret and additional clinical data for Kepivance from Amgen

Sobi acquired the full rights to develop and commercialise Kineret from American biotechnology company Amgen for all therapeutic indications. The revised agreement builds on the previous agreement that gave Sobi rights for Kineret within the field of Rheumatoid Arthritis (RA) and four orphan drug indications, including CAPS.

Sobi also acquired the right to additional data for Kepivance allowing the company to explore a potential new therapeutic indication based on two completed phase 3 trials performed by Amgen. The two randomised double blind placebo-controlled trials, involving more than 400 patients, demonstrate the potential for Kepivance to reduce the incidence of severe oral mucositis in patients undergoing treatment for advanced head and neck cancer.

Under the terms of the amended agreement, Sobi and Amgen have restructured the financial terms of their original deal to accommodate the acquisition of additional rights and data.

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.

Extended bond amounting to SEK 200 M

28 February 2013, Sobi 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.

Subsidiaries in Belgium

A new subsidiary in Belgium, BVBA Swedish Orphan Biovitrum, was established in the second half of the year.

Strengthened leadership team

The senior leadership team was strengthened with the appointment of Mats-Olof Wallin as Chief Financial Officer and Dennis Pedersen as Senior Vice President Human Resources.

Legal issues

Arexis

On 29 March 2012, Sobi amended its share purchase agreement regarding the acquisition in 2005 of the pharmaceutical company Arexis AB. 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, SEK 20 M during the first quarter 2013 and will pay SEK 21 M in 2014. For more information see note 37.

Paradiset 14

Sobi has elected not to pursue the dispute with the Swedish Tax Agency regarding the real estate Paradiset 14. The company has already reduced its tax loss carry forward by SEK 232.2 M for the tax year 2005. The company now expects to make a final payment of SEK 0.8 M in 2014. This payment has been accrued in 2013. For further background, see note 37.

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 to use industrial-scale biological reactions to produce organic substances. Compliance with the terms of the permit is reported annually in an environmental report prepared for the local supervisory authorities. In Solna the company has facilities that are subject to a reporting obligation for the professional production, through chemical or biological reactions, of organic or inorganic substances in trial, pilot or laboratory scale or other non-industrial scale production. The stipulations for this permit mainly relate to emissions to water and include a requirement to adjust the pH of process water. In 2013 there were no transgressions of the stipulations to report at any of the facilities.

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 2013 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.

Employees

The average number of employees in 2013 was 546 (514), of which 394 (385) were in Sweden. Salaries and other remuneration amounted to SEK 407.5 M (353.4), of which SEK 278.4 M (243.1) 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 2013, 42 per cent were men and 58 per cent 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 are based on ergonomics, chemicals, biosafety, electrical safety and fire safety. There were no workplace accidents to report to the Swedish Work Environment Authority in 2013. In 2014, permission from the Swedish Work Environment Authority will be sought for handling of hydrazine.

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 employee'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 excessive risktaking. The variable salary may not amount to more than 50 per cent of the annual gross salary (including pension) for the CEO and not more than 20–50 per cent 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 and will be presented at the AGM for approval. The remuneration is based on position, performance and the company, respectively, and the employee's fulfillment of objectives determined in advance. The outcome is dependent on the fulfillment of certain predetermined performance requirements. The aim of having long-term incentive programmes is to create a long-term commitment to Sobi, to offer the participants the possibility of taking 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 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 per cent 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 such action.

Guidelines and remuneration 2013

Guidelines and other terms of employment approved by the Annual General Meeting in 2013 can be found in note 14.

Share and option programmes

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

Significant events after the reporting period

Sobi moves to Large Cap Index on NASDAQ OMX Stockholm

On 2 January 2014 Sobi was transferred to the Large Cap category on the NASDAQ OMX Stockholm stock exchange.

Termination of co-promotion activities for Kineret with Savient Pharmaceuticals, Inc.

The US Bankruptcy Court for the District of Delaware has approved the acquisition of Savient Pharmaceuticals, Inc by Crealta Pharmaceuticals LLC. The Court rejected the agreement between Savient and Sobi for co-promotion of Kineret in the US as per January 31, 2014. The agreement will therefore be terminated as per the same date and Sobi will assume all promotion activities previously performed by Savient.

Health Canada approves Alprolix™

Sobi's partner Biogen Idec announced that Health Canada approved Alprolix (Coagulation Factor IX (Recombinant), Fc fusion protein), rFIXFc, for the control and prevention of bleeding episodes and routine prophylaxis in adults, and children aged 12 and older, with haemophilia B. Alprolix is the first approved long-acting haemophilia B therapy and is indicated to prevent or reduce the frequency of bleeding episodes with prophylactic injections scheduled once weekly or once every 10–14 days.

Kiobrina pivotal phase 3 study did not meet primary endpoint

Topline data from the company's pivotal phase 3 study of its enzyme therapy Kiobrina (rhBSSL - recombinant human Bile Salt Stimulated Lipase) showed that rhBSSL did not meet its primary endpoint, growth velocity measured after four weeks of treatment, with no statistically significant improvement in growth velocity in preterm infants treated with rhBSSL compared to placebo. The financial and operational effects of the results are still being investigated.

US FDA approves Alprolix™

Sobi's partner Biogen Idec announced that the US Food and Drug Administration (FDA) approved Alprolix (Coagulation Factor IX (Recombinant), Fc fusion protein), the first recombinant, DNA derived haemophilia B therapy with prolonged circulation in the body. Alprolix is indicated for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with haemophilia B.

Outlook for 2014

- Total revenues for the full year 2014 are expected to be in the range of SEK 2,300 to 2,500 M.
- Gross margin is expected to be in the range of 58–60 per cent.
- Operating costs are expected to increase as the company continues to prepare for the planned launch of the three phase 3 pipeline programmes.

Proposed appropriation of profit

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

SEK	
Share premium reserve	4,123,895,863
Retained earnings	556,735,493
Profit/loss for the year	–7,648,558
Total	4,672,982,798

The Board of Directors and the Chief Executive Officer propose that the funds at their disposal, SEK 4,672,982,798, be carried forward.

Risk Management



The overall risk management structure consists of eight inter-related components, that cover the entire company regardless of geographical location, activity or functional area:

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

Risk management is a component of sound corporate governance. All business activities involve risks and controlled risk taking is a necessary part of the healthcare industry. Our risk management process involves ensuring that risks and uncertainties are proactively identified at an early stage, assessed and managed. Creating awareness of risks enables them to be limited and controlled while business opportunities can be pursued to create value.

The Sobi Risk Management & Compliance Committee (RMCC) is responsible on behalf of management for developing, main-

taining and monitoring an integrated and effective process to constantly assess and report risks of significance for our business. Identified risks may have a significant effect on our financial position, operational goals and results, and our reputation.

The RMCC, which meets regularly throughout the year, consists of the senior executives responsible for the most important functions and ad hoc members called in on an agenda-driven basis.

The Chairman of the Committee is Sobi's General Counsel and Compliance Officer and Sobi's Risk Manager is the Secretary of the RMCC. Reports are presented on a quarterly basis to

the company's Executive Leadership Team and Audit Committee, and a review of the work of the committee is presented four times a year to the Board of Directors.

The risk management processes follow the established Committee of Sponsoring Organizations of the Treadway Commission – Enterprise Risk Management Integrated Framework (COSO – ERM), which forms the foundation for Sobi's Risk Management Policy.

In 2013 Sobi's Global Policy Risk Management was revised and implemented throughout the organisation including all market companies. The Risk Management Policy involves

proactively managing risk and ensuring that risks are consistently identified, assessed and controlled to ensure the continued growth of our business. In 2013 we also launched a process for continuity planning.

Sobi also has a Crisis Management Policy and a Crisis Management Team in place, tasked with developing effective management and preventative measures in the event of a crisis. The Crisis Management Team arranges crisis response exercises on a regular basis to ensure good preparedness. This is an important part of the company's effort to optimally manage any potential crisis.

Objective and definitions

Sobi works to ensure that risk management is effectively integrated to operations on a day-to-day basis. Risk management is intended to provide the basis for sound decision-making on which risks are appropriate to take in the course of doing business and how to manage them with a full understanding of the consequences. Line managers and project managers are responsible for risk management within their departments, areas of responsibility and projects. This makes it possible to identify and assess events that may affect the company's ability to achieve its objectives.

Risk assessment allows the line managers, project managers and company management to determine early on to what extent potential events may impact the achievement of the company's objectives and strategies. Sobi assesses events from two perspectives – likelihood and impact – and normally use a combination of qualitative and quantitative methods to evaluate both elements. Based on this assessment, our risk responses are assigned to the following categories: Avoidance, Reduction, Sharing or Acceptance.

Key risk areas

Sobi develops and markets innovative pharmaceuticals to improve the treatment of serious diseases. Sobi accepts the risk associated with developing new drugs that meet the patients' needs with respect to safety and efficacy. Research and development of new drugs and the regulations regarding research and development, manufacturing, testing, and marketing and sales of pharmaceutical products are complex and may change over time. Below is a summary of the main risks and uncertainties that may affect the company's operations. The risk areas are not ranked in any particular order, but are categorised and described.

Development risks

Developing new drugs to bring to the market

Sobi currently has a number of projects in clinical development and several projects in preclinical development. Developing 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 through the development process. However, the risks remain substantial even up to and including phase 3 clinical development, while the costs progressively increase as the project moves into the later clinical phases.

Before the company can get approval to launch any of its candidate drugs it must demonstrate that they are of high quality, safe and provide the expected effect through sufficient, well-controlled preclinical studies and clinical trials. The number of preclinical 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 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 candidate drugs are not sufficiently effective or they may prove to have undesirable or unintended side effects, toxicities or other undesirable properties. This may disrupt, affect, delay or stop clinical development and prevent or limit the commercial application of the candidate drug.

Difficulties obtaining and maintaining approval for new products from registration authorities

Before the launch of any of Sobi's biopharmaceutical products is initiated, Sobi 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 product.

Even if Sobi'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 preclinical 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 FDA in the US, the EMA in Europe or other regulatory authorities may require additional information, which may delay or limit new approvals.

If any products in Sobi's product portfolio receives marketing authorisation, this does not guarantee that the products will be

assigned the expected price and reimbursement status within the national or regional healthcare systems, nor receive 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 products 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 to maintain a balanced product portfolio is to enter into partnership agreements, e.g., joint development and/or authorisations and launch with other pharmaceutical and biotech companies. Partnerships might also be with academic institutions. 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.

Inadequate intellectual property protection 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.

Conversely, the technologies that Sobi uses in its research or that are included in products or candidate drugs that the company is working to develop and potentially commercialise, may unintentionally infringe patents or patent applications owned or controlled by other companies. If such situations should arise, Sobi will work with the other party or parties to try to reach agreements in order to allow the work to continue.

Manufacturing of biopharmaceuticals and quality risks

Sobi manufactures native and recombinant protein biopharmaceutical products and is dependent on the company's advanced production facilities in Stockholm and Umeå, Sweden, meeting all quality standards, being maintained and readily available. Sobi also collaborates in 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. Sobi must, therefore, 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 the loss of the entire manufacturing investment.

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 production and research & development involve the controlled use of biological materials and chemicals.

Sales and market risks

Competition risk

The market for speciality pharmaceuticals is characterised by significant competition and rapid technology development. Sobi's competitors include international pharmaceutical, biotech and speciality 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 Sobi's 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 a similar product or entirely new concepts which prove to be of greater value for the patients. Sobi therefore initiates collaborations with external research teams 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 the best possible protection against competition, Sobi focuses on strong protection of intellectual property.

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 means that Sobi and the healthcare industry in general operate under strong price pressure. In most markets where Sobi is active, governments exercise 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 being covered by, and permitting entitlement to, reimbursement 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 imports and distribution. The use of pharmaceuticals may also be affected by new guidelines, recommendations and studies published by authorities and other bodies.

Product counterfeiting

The supply of traditional prescription pharmaceuticals is facing an increasing challenge in the form of illegally produced pharmaceutical products and by access to counterfeit products in certain distribution channels. This phenomenon has been observed in an increasing number of geographical markets and via the internet. These 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 costs are incurred in SEK, while a significant proportion of 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 generated, 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 January 2013 the CEO signed the Sobi Code of Conduct & Ethics, "the Code," which has since been implemented throughout the organisation and signed by all of the employees. The purpose of the Code is to help all employees play a part in Sobi's sustainable development. Compliance with laws and relevant regulations when we do business on behalf of Sobi is a fundamental responsibility for every employee.

Issues relating to social responsibility and sustainable business practices are crucial for the world and also play an increasingly important role in a company's competitiveness and profitability and are therefore important for their stakeholders and shareholders as well.

To respect human rights, promote fair employment practices and ensure good working conditions, environmental responsibility and good business ethics, the Code, which is applied globally in production, delivery, sales and support for all of Sobi's products and services, is a key document. In addition to the Code, Sobi has developed numerous policies to ensure uniform working methods and to reduce the risk of noncompliance.

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 2013 was 110 million shares for a total value of SEK 5,459 M (2,356).

The share price rose in 2013 by 82 per cent, from SEK 36.6 at the beginning of the year to SEK 66.75 at the end of the year. The highest price paid was SEK 70.25 (3 December 2013) and the lowest was SEK 37.2 (2 January 2013). The last price paid in 2013 was SEK 66.75. Sobi's shares are included in the OMX Stockholm Pharmaceuticals & Biotechnology PI Index, which rose by 33.6 per cent during the same period.

The market capitalisation at the end of the year was SEK 18,1 billion.

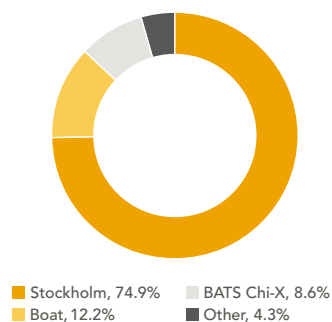
Share capital

The share capital at the end of the year amounted to SEK 148,363,001 distributed at 270,389,770 shares, with a quota value of approximately SEK 0.55. As per December 2013 all 270,389,770 shares are ordinary shares. During 2013 all C class shares have been converted into ordinary shares.

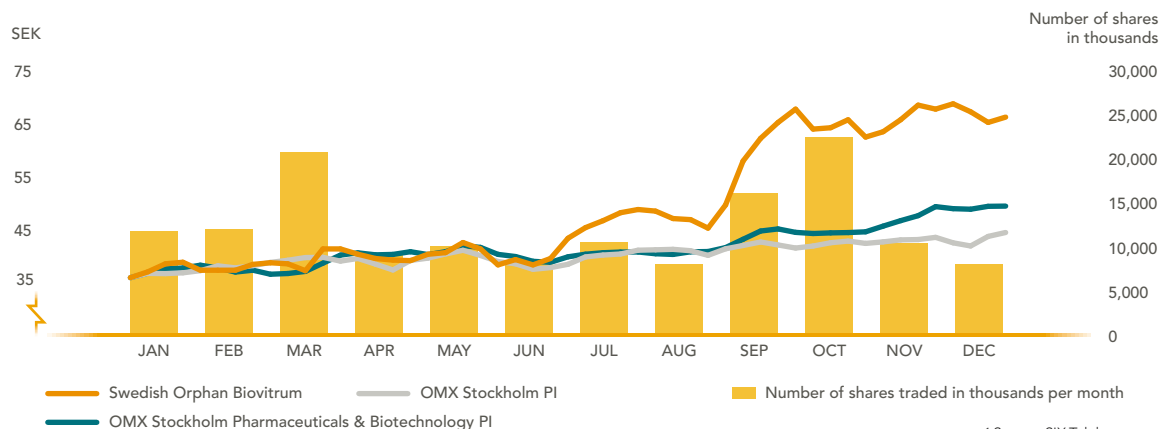
Development of share capital and number of shares

	No. of shares	Share capital SEK
December 2012	269,634,858	147,947,800
September 2013, New share issue of C class shares	754,912	415,201
December 2013	270,389,770	148,363,001

Trading places



Sobi share price and trading volume during 2013¹

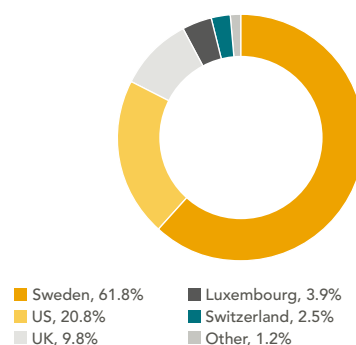


¹ Source: SIX Telekurs

Shareholders

At the end of the year Sobi had a total of 10,153 shareholders (8,006). Investor AB was the largest owner with 39.8 per cent of the capital and 39.8 per cent of the votes. The 15 largest shareholders accounted for a total of 75.5 per cent of the capital and 75.5 per cent of the votes. Approximately 59 per cent of the shares were owned by Swedish legal entities, such as institutions and funds.

Shareholders by country



Largest shareholders as of 30 December 2013¹

Shareholder	Number of shares	Share capital, %	Share votes, %
Investor AB	107,594,165	39.79	39.79
Goldman Sachs & Co, W9	12,913,295	4.78	4.78
State Street Bank & Trust Omnibus	12,784,039	4.73	4.73
SSB Client Omnibus AC OM07 (15 PCT)	10,482,031	3.88	3.88
Bo Jesper Hansen	8,893,846	3.30	3.30
Handelsbanken Fonder AB RE JPMEL	7,582,696	2.80	2.80
SIX SIS AG, W8IMY	6,435,573	2.38	2.38
Swedbank Robur Fonder	6,355,431	2.35	2.35
Livförsäkringsaktiebolaget Skandia	6,307,331	2.33	2.33
JPM Chase NA	6,206,565	2.30	2.30
Skandia Fonder	4,182,519	1.55	1.55
JPM Chase NA	3,389,323	1.25	1.25
Catella Fondförvaltning	3,180,615	1.18	1.18
Tredje AP-Fonden	3,163,277	1.17	1.17
Total	199,470,706	73.79	73.79
Other	66,230,116	24.48	24.48
Swedish Orphan Biovitrum AB	4,688,948	1.73	1.73
Total	270,389,770	100.0	100.0

¹ Information on ownership based on information from Euroclear Sweden, which implies that that the nominee shareholders' holdings may be included in the table and that the actual owners are, as a consequence, not indicated.

Analyst coverage

Carnegie	Kristofer Liljeberg
Danske Bank	Mattias Häggblom
Deutsche Bank	Richard Parkes
Swedbank	Johan Unnéus
Jefferies	Eun K. Yang
Nordea	Erik Hultgård
Goldman Sachs	Eleanor Fung
Pareto Securities	Yilmaz Mahshid

Short facts Sobi share

Listing	NASDAQ OMX Stockholm
Number of shares	270,389,770
Market capitalisation	SEK 18.05 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
- CEO instructions
- 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 six months of the end of the financial year in order to decide on adopting the income statement and balance sheet and on the appropriation of profits or losses.

② Nomination Committee

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

③ Board of Directors/Chairman of the Board

The Board's responsibility for the Group's organisation and administration involves ensuring the satisfactory control of accounting procedures, fund management and general financial circumstances. The Board also decides on overall goals, strategies, the financial structure, policies, appointment of the Chief Executive Officer (CEO), executive compensation, acquisitions, disposals and major investments. The Board approves and adopts the annual reports and interim reports, and is responsible for proposing a dividend, if any, at the AGM. The Board's work is based on its working procedures, CEO instructions and the principles for the division of duties between the CEO, the Chairman of the Board, Board members and the various committees established by the Board. The Board's working procedures and the CEO instructions are revised and updated once a year.

The Chairman of the Board leads the Board's work, monitors the company's progress and ensures that important issues are addressed as needed and that all important decisions are preceded by an active and constructive discussion. The Chairman is employed by the company as an 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 issues relating to the company's internal control. 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 accounting principles and adjustments to accounting documents that affect financial reporting, consulting with management and the auditors regarding compliance with laws and regulations relating to financial matters and an annual review of auditors' fees.

⑤ Compensation & Benefits Committee

It is the responsibility of the Compensation & Benefits Committee to propose guidelines and principles for the company's remuneration programmes. This includes oversight of and proposals for remuneration for senior executives and for long-term incentive programmes, pension plans and other issues relating to remuneration for 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 on 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 is composed of individuals with a broad range of skills as well as in-depth and extensive experience in R&D and in producing and selling pharmaceuticals. In addition, Executive Leadership Team members possess the requisite skills in finance and business, law, human resources and communications. The company's operative management is based on the decision-making procedure established by the Board, as reflected in the organisational and governance model based 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 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 prepares 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 statutes, the company applies the Swedish Corporate Governance Code without deviating from it.

This corporate governance report is for the 2013 financial year. The report constitutes a part of the formal Annual Report and has been reviewed by the company's auditors.

Shareholders, share capital, the share and voting rights

At the end of 2013 Sobi has a total of 10,153 (8,006) shareholders. Investor AB was the largest shareholder, holding 39.8 per cent (39.9) of the share capital and 39.8 per cent (40.5) of the voting rights. The 15 (15) largest shareholders accounted for 75.5 per cent (75.2) of the share capital and 75.5 per cent (76.6) of the votes. 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 generated by 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 general 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) is to 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 2013

At the Annual General Meeting (AGM) on 26 April 2013, directors Bo Jesper Hansen, who was also re-elected as Chairman, Adine Grate Axén, Matthew Gantz, Lennart Johansson, Helena Saxon, Hans GCP Schikan and Hans Wigzell were re-elected to serve until the 2014 AGM.

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

The AGM also voted in favour of a long-term incentive programme and the hedging measures associated with it. The AGM also resolved to approve the Board's proposal on the transfer of treasury shares. The minutes of the 2013 AGM are available at www.sobi.com.

Annual General Meeting 2014

The AGM will be held on Thursday 8 May 2014 in the Wallenberg Auditorium at the Royal Swedish Academy of Engineering Sciences (IVA). See the last page of the Annual Report.

Nomination Committee

According to the instructions and statutes adopted by the AGM on 26 April 2013, the Nomination Committee is to consist of four members, three of whom are to represent the company's three largest shareholders as of the final banking day in August 2013, based on statistics from Euroclear Sweden AB. As stipulated in the same resolution, the fourth person is to be the Chairman of the Board. The composition of the Nomination Committee is to be announced at least six months before the AGM.

The Nomination Committee for the 2014 AGM consists of: 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 of Directors

Composition of the Board

During the 2013 fiscal year the Board consisted of seven directors elected at the AGM on 26 April 2013, as well as two employee representatives and two deputies appointed by the trade unions. Three members, including the employee representatives, were women. For further details on the Board, see pages 58–59.

Sobi is a speciality pharmaceutical company with a focus on marketing, developing and producing pharmaceutical products to treat rare diseases. The portfolio contains products that are marketed and that are 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 expertise.

Chairman of the Board

The duties of the Chairman of the Board, apart from leading the Board in its work, include monitoring the progress 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 is to consult with the CEO regarding strategic matters, participate in important external relationships and represent the company with regard to ownership issues. The Chairman is also responsible for ensuring that the work of the Board is regularly evaluated and that new directors receive adequate instruction. The Chairman of the Board is employed by the company as executive chairman. As such, his duties include representing the company in dealings 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 of 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 this report was published.

Number of meetings

The Board meets at least five times a year, usually in conjunction with the publication of the interim and annual financial statements and the AGM. Additional meetings or teleconferences are convened 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 eight meetings for 2014.

The Board's work in 2013

The Board held 21 meetings in 2013, whereof 9 ordinary card meetings and 12 extra board meetings. Out of the 12 extra board meetings, 5 meetings where decisions taken per capsulam. The statutory board meeting was held 26 April 2013. Sobi's General Counsel served as secretary at the meetings. Other Sobi employees presented reports. The number of extra Board meetings where required in order to address the issue of the bond loan, suggestions for potential partnerships and several matters regarding commercial agreements.

Important board decisions in 2013

- Extended of the bond loan
- Proposals on potential partnerships
- Evaluation and amendment of commercial agreements
- Development of the project portfolio
- Recruitment of key personnel

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 nine times during the year. The table below shows the attendance of each director at the meetings. The company's elected auditors attended six of the meetings. Topics discussed at the meetings included the auditors' planning of the audit, their observations and scrutiny of the company, auditors' fees and the company's interim reports. The large number of meetings during the year was mainly due to personnel and organisational changes within the finance department and the renegotiation of the company's credit facilities. For information on remuneration for 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. Sobi's head of human resources serves as secretary to the Committee, but is not a member.

The Compensation & Benefits Committee met eight times during the year. The table below shows the attendance and status (independent/dependent) of each director. At the 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 allocations for the long-term incentive programme. The proposals for guidelines for CEO and senior management remuneration will be presented at the AGM in May 2014 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 in relation to senior management: Hans Wigzell (Chairman) and Hans GCP Schikan. The third member, Bo Jesper Hansen, is not independent in relation to management. The Committee's work in 2013 included advising on acquisitions and licensing of new research projects. The Committee convened twice in 2013, with all three members present at one meeting and two members present at the other.

Board remuneration

The AGM held on 26 April 2013 resolved that for the period up to the next AGM, remuneration for the Board of SEK 2,190,000¹ will be paid, of which SEK 300,000 will 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 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 & Benefits Committee, a fee of SEK 50,000 will be paid 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 of SEK 50,000 will be paid 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 SEK 10,000 is to be paid to the members of the Board who reside in Europe but outside the Nordic region, and a fee of SEK 20,000 is to be paid to the members of the Board who reside outside Europe.

For more information on remuneration for the Board, see note 14.

¹ The board remuneration paid out was SEK 2,151,700 due to the fact that the Chairman of the Board did not receive any compensation for his work on the committees.

	Independence	Attendance ⁴		
		Board	Audit Committee	Comp. & Ben. Committee
Bo Jesper Hansen	1	20/21	–	8/8
Hans Wigzell	●	17/21	–	–
Lennart Johansson	2	20/21	9/9	–
Helena Saxon	2	20/21	9/9	8/8
Adine Grate Axén	●	19/21	7/9	–
Hans Schikan	●	19/21	–	7/8
Matthew Gantz	●	19/21	–	–
Catarina Larsson	3	21/21	–	–
Bo-Gunnar Rosenbrand	3	21/21	–	–

¹ Director to be regarded as dependent in relation to both the company and its management.

² Director to be regarded as dependent in relation to larger shareholders.

³ Employee representative.

⁴ The figures in the table show the total number of attendance/meetings. The Board held 21 meetings in 2013, whereof 9 ordinary card meetings and 12 extra board meetings. Out of the 12 extra board meetings, 5 meetings where decisions taken per capsulam.

Changes to the Board

The Board was re-elected in its entirety at the AGM in April.

Executive Leadership Team

Each year, the Board determines the division of duties 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 meets at least every other month.

In 2013, the Executive Leadership Team met once a month and at year-end 2013, it consisted of 12 members.

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

Remuneration for senior management

In order to attract and retain talented and motivated employees Sobi has established long-term incentive programmes. All employees receive a fixed salary and a variable salary component. The variable component, which is in accordance with a system adopted by the Board, is based on both overall company goals and individual goals. The variable salary component may not exceed 10–50 per cent of the 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. In 2013, efforts to streamline and develop the processes in the accounting department have continued.

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

1. Control Environment
2. Risk Assessment
3. Control Activities
4. Information and Communication
5. Monitoring

1. Control Environment

The control environment constitutes the basis of the company's internal control. The control environment mainly comprises the culture on which the Board and management base their work and communication. It is the foundation for all internal governance and control components, bringing order and structure in the form of manuals, processes and policies.

The basis for internal control of financial reporting consists of a clear organisational structure, decision-making processes, authority and responsibilities that are documented, and communicated in governing documents.

The guidelines for Sobi's business activities can be found on the Company's website and include the following:

- 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 policies, 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 as well as results with the requirements of shareholders and other interested parties for stable, long-term value growth and control. One prerequisite for effective risk assessment is that set targets are communicated. Risk assessment involves identifying and analysing relevant events and risks that could have a negative impact on Sobi's ability to achieve its established goals, and as such is the basis for risk management.

Structured risk assessment or risk management make it possible to a) identify and mitigate risks that affect internal control with respect to financial reporting and b) identify and manage the specific risks associated with changes. 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 and the relevant controllers carry out risk analysis regarding financial reporting to identify and assess risks in the various accounting and reporting processes. Work in 2013 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

Control activities involve the manuals, processes and policies that ensure that directives and decisions are implemented. 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 Team and Board.

Information on manufacturing can be found in the general risk section.

4. Information and communication

Sobi has information and communication channels aimed at ensuring efficient and accurate information services relating to financial reporting. Effective communication is important for all of the company's employees. 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, COO, CFO, General Counsel, VP External Affairs & Chief Patient Access Officer and Head of Communications.

Financial information is regularly presented in the form of:

- Interim reports and full-year reports.
- 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. Monitoring

The Board and the Audit Committee decide on the arrangements for monitoring, following up and evaluating 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 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 and risk management 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, Orphazyme ApS, Karolinska Development AB, and Ablynx NV.

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

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 and Core 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

7 Hans Wigzell

Born 1938.

Board member since 2005.
M.D, D.Sc., Professor of Immunology.

Other appointments: Chairman of Rhenman & Partners Asset Management AB. Board member of Karolinska Development, RaySearch Laboratories AB (publ), Valneva SE (publ), Sarepta Therapeutics, Inc. (publ) and AB Wigzellproduktion. 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

2 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

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 and Mölnlycke Health Care.

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

Shares: 15,500

8 Catarina Larsson

Born 1952.

Employee Representative.
Laboratory engineer.
Board member since 2001.

Representative of Federation of Salaried Employees in Industry and Services.

Shares: 1,461

3 Adine Grate Axén

Born 1961.

Board member since 2010.
M.Sc. from Stockholm School of Economics, Harvard AMP.

Other appointments: Board member of BSKyB Ltd, Sampo OY, 3 Scandi, Swedavia AB and Madrague AB. Chairman of Nasdaq OMX Stockholm's Listing Committee and Chairman of the Board of Alhanko & Johnson AB. Vice Chairman of Sjunde AP-fonden.

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

Shares: 32,000

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 Organon and Genzyme.

Shares: 0

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: 3,922¹

Mikael Winkvist

Auktoriserad Revisor
PricewaterhouseCoopers AB

¹ Includes shareholding of next of kin and/or legal entities.

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: 239,564

5 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

9 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

2 Alan Raffensperger

Born 1960.

Senior Vice President, 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: 50,549

6 Dennis Pedersen

Born 1970.

Senior Vice President Human Resources.

Employed since 2013.

Dennis has an educational background as officer, with speciality in leadership development, analytical studies and tactics, Royal Danish Officers Academy.

Previous positions: Dennis has a long experience of transformation of local HR models to more integrated international operating models, gained from various leading HR positions in several international companies including Genzyme, Ferring Pharmaceuticals and A.P. Møller-Mærsk. He joined Sobi from Takeda, where he held the position as Director Human Resources, Northern Europe.

Shares: 0

10 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: 13,184

3 Mats-Olof Wallin

Born 1951.

Senior Vice President, Chief Financial Officer.

Employed since 2013.

B.Sc. at the University of Uppsala.

Previous positions: Mats-Olof has more than 30 years of experience in the pharmaceutical industry, gained from various executive positions within companies such as Pharmacia, Ortivus and, most recently, Biotage AB (publ.) where he held the role of CFO between 2003 and 2011.

Shares: 14,247

7 Stefan Fraenkel

Born 1972.

Senior 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: 19,583¹

11 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: 17,760

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: 26,215¹

8 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: 61,853

12 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: 13,009

¹ Includes shareholding of next of kin and/or legal entities.

Group's statement of comprehensive income

SEK THOUSAND	Note	2013	2012
	1–4		
Total revenues	6–7	2,176,694	1,923,161
Cost of goods and services sold		–892,733	–882,782
Gross profit		1,283,961	1,040,379
Sales and administration expenses	15	–898,225	–961,144
Research and development expenses		–455,689	–401,645
Non-recurring items	8	–	–37,095
Other operating revenue	10	23,624	345,869
Other operating expenses	11	–20,203	–40,970
Operating profit/loss	9, 12, 14, 16, 19, 31	–66,532	–54,606
Financial income	17	14,303	7,314
Financial expenses	18	–71,186	–57,800
Financial items – net		–56,883	–50,486
Profit/loss before tax		–123,415	–105,092
Income tax expense	20	30,459	4,209
Profit/loss for the year		–92,956	–100,883
Other comprehensive income¹			
<i>Items that will not be reclassified to profit/loss</i>			
Actuarial gains / losses on defined benefit plan		2,010	–1,200
<i>Items that may be reclassified subsequently to profit/loss</i>			
Translation difference		368	2,021
Cashflow hedge		1,862	–6,494
Comprehensive income for the year		–88,716	–106,556
Earnings/loss per share (SEK) ²		–0.35	–0.38
Earnings/loss per share after full dilution (SEK) ²		–0.35	–0.38
Number of shares (ordinary)		270,389,770	265,226,598
Average number of shares		265,266,117	265,226,598
Number of C-shares (in treasury)		–	4,408,260
Number of ordinary shares (in treasury)		4,688,948	–
Number of shares after full dilution		270,389,770	265,226,598
Average number of shares after full dilution		265,266,117	265,226,598

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".

Group balance sheet

SEK THOUSAND	Note	2013-12-31	2012-12-31
ASSETS	1-4		
Fixed assets			
Intangible fixed assets	21	4,637,028	4,533,366
Tangible fixed assets	22	125,779	125,585
Financial fixed assets	24	2,010	4,381
Deferred income tax assets	25	24,408	–
Total fixed assets		4,789,225	4,663,332
Current assets			
Inventories	26	725,950	700,368
Accounts receivable, trade	27, 30	414,465	343,244
Other receivables	27	66,281	40,480
Prepaid expenses and accrued income	28	78,302	102,126
Liquid funds	29, 30	445,097	456,951
Total current assets		1,730,095	1,643,169
TOTAL ASSETS		6,519,320	6,306,501

SEK THOUSAND	Note	2013-12-31	2012-12-31
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital		148,362	147,948
Other capital contribution		4,867,254	4,847,632
Other reserves		–55,908	–60,148
Retained Earnings		–97,849	3,448
Net result		–92,956	–100,883
Shareholders' equity referring to the owners of the Parent company		4,769,244	4,837,997
LIABILITIES			
<i>Long-term liabilities</i>			
Deferred income tax liabilities	25	297,802	318,281
Other liabilities	30, 32	795,699	610,190
Provisions for pension obligations	31, 33	9,141	31,233
Total long-term liabilities		1,102,642	959,704
<i>Short-term liabilities</i>			
Accounts payable	30	239,098	104,488
Current tax liabilities		6,539	4,060
Other liabilities	30	82,479	104,765
Accrued expenses and prepaid revenues	34	319,318	295,487
Total short-term liabilities		647,434	508,800
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		6,519,320	6,306,501
Pledged assets – Group			
Pledged assets	35	200,000	200,000
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, January 1, 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					
Cashflow hedge	-	-	-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 / repurchase 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
Shareholders' equity, 1 January 2013	147,948	4,847,632	-60,148	-97,435	4,837,997
Comprehensive income					
Net profit/loss for the year	-	-	-	-92,956	-92,956
Other comprehensive income					
Cashflow hedge	-	-	1,862	-	1,862
Actuarial loss	-	-	2,010	-	2,010
Translation differences	-	-	368	-	368
Total comprehensive income	-	-	4,240	-92,956	-88,716
Transactions with shareholders					
Issue / repurchase of shares	414	-	-	-414	-
Share based compensation	-	13,246	-	-	13,246
Sales of ordinary shares	-	6,717	-	-	6,717
Sum transactions with shareholders	414	19,963	-	-414	19,963
Shareholders' equity, Dec 31 2013	148,362	4,867,595	-55,908	-190,805	4,769,244

Swedish Orphan Biovitrum's share capital at year-end was SEK 148,363,001 shared at 270,389,770 shares with a par value of around SEK 0.55. A share issue of 754,912, C shares was completed in 2013, then all 5,163,172 class C shares have been converted into ordinary shares. The Company holds 4,688,948 ordinary shares in treasury at balance sheet date. The ordinary shares carry one vote per share. These shares represent 1.8 per cent of the total number of shares in the company.

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.

	2013	2012
Net profit/loss referable to share-holders of the Parent company	-92,956	-100,883
Average number outstanding ordinary shares (thousands)	265,266	265,227
Earnings per share before dilution (SEK per share)	-0.35	-0.38

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.

	2013	2012
Net profit/loss referable to share-holders of the Parent company	-92,956	-100,883
Average number outstanding ordinary shares for calculation of earnings per share after dilution (thousands)	265,266	265,227
Earnings per share after dilution (SEK per share)	-0.35	-0.38

Group cash flow statement

SEK THOUSAND	2013	2012
Operations		
Profit/loss for the year	-92,956	-100,883
Adjustment for items not affecting cash flow	258,441	468,614
Cash flow from operations before change in working capital	165,485	367,731
Change in working capital		
Decrease (+) / Increase (-) in inventories	-25,582	193,351
Decrease (+) / Increase (-) in operating receivables	-73,399	32,876
Increase (+) / Decrease (-) in operating liabilities	118,885	-188,485
Cash flow from operations	185,389	405,473
Investment activities		
Investment in intangible fixed assets	-384,175	-62,847
Investment in tangible fixed assets	-25,976	-5,456
Divestment tangible fixed assets	143	4,547
Divestment of short term financial assets	2,489	-600
Divestment of short term assets	2,899	-2,899
Cash flow from investment activities	-404,620	-67,255
Financing activities		
Issue of bond	200,000	600,000
Sale of shares	6,717	-
Repayment of bank loan	-	-700,000
Cash flow from financing activities	206,717	-100,000
Net change in liquid funds	-12,514	238,318
Liquid funds at beginning of year	456,951	219,043
Exchange rate differences in liquid funds	660	-310
Liquid funds at end of year	445,097	456,951

Supplementary data to the Cash flow statement – Group

SEK THOUSAND	2013	2012
Interest paid and received		
Interest received	4,489	2,329
Interest paid	60,412	42,247
Adjustments for items not affecting cash flow		
Amortisation/depreciation and write down of assets	307,621	454,298
Write-down of financial asset	–	3,000
Capital gain/loss from divestment of tangible fixed assets	2,952	925
Pensions	–20,080	55
Cost share programmes	13,246	5,870
Arexis, see note 37	–	34,000
Deferred tax	–46,474	–23,160
Other items	1,176	–6 374
	258,441	468,614

Parent company statement of comprehensive income

SEK THOUSAND	Note	2013	2012
	1-4		
Total revenues	6-7	1,841,881	1,640,506
Cost of goods and services sold		-889,838	-813,252
Gross profit		952,043	827,254
Sales and administration expenses	15	-532,707	-446,006
Research and development expenses		-450,599	-390,362
Non-recurring items	8	-	-37,095
Other operating revenues	10	32,813	347,018
Other operating expenses	11	-19,462	-35,375
Operating profit/loss	9, 12, 14, 16, 19, 31	-17,912	265,434
Result from participation in Group companies	13	2,288	1,065
Financial income	17	42,149	37,648
Financial expenses	18	-70,229	-52,072
Financial items – net		-25,792	-13,359
Untaxed reserves	5	1,101	-73,373
Group contribution		241	-
Profit/loss before tax		-42,362	178,702
Income tax expense	20	34,714	-147,116
Profit/loss for the year		-7,648	31,586

Parent company statement of comprehensive income

SEK THOUSAND	2013	2012
Profit/loss for the year	-7,648	31,586
<i>Items that may be reclassified subsequently to profit/loss</i>		
Cashflow hedge	1,862	-6,494
Comprehensive income for the year	-5,786	25,092

Parent company balance sheet

SEK THOUSAND	Note	2013-12-31	2012-12-31
ASSETS	1–4		
Fixed assets			
Intangible fixed assets	21	934,747	638,543
Tangible fixed assets	22	115,635	119,953
Shares in Group companies	23	4,058,468	4,058,305
Financial fixed assets	24	621	3,110
Deferred tax	25	37,052	2,317
Total fixed assets		5,146,523	4,822,228
Current assets			
Inventories	26	664,587	617,942
Accounts receivable	27	193,297	184,365
Current receivables	27	52,266	31,356
Receivables from Group companies		728,061	955,346
Prepaid expenses and accrued revenues	28	68,546	96,605
Cash and bank balances	29	373,503	276,462
Total current assets		2,080,260	2,162,076
TOTAL ASSETS		7,226,783	6,984,304

SEK THOUSAND	Note	2013-12-31	2012-12-31
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
<i>Restricted equity</i>			
Share capital		148,363	147,948
Statutory reserve		800,257	800,257
Total restricted equity		948,620	948,205
<i>Non-restricted equity</i>			
Share premium reserve		4,123,896	4,110,650
Profit/loss carried forward		556,735	516,985
Net profit/loss for the year		–7,648	31,586
Total unrestricted equity		4,672,983	4,659,221
Total shareholders' equity		5,621,603	5,607,426
<i>Untaxed reserves</i>			
Tax allocation	5	–	1,101
Total untaxed reserves		–	1,101
Liabilities			
<i>Long-term liabilities</i>			
Other liabilities	32	790,775	607,825
Total long-term liabilities		790,775	607,825
<i>Current liabilities</i>			
Accounts payable		219,500	90,153
Liabilities to Group companies		299,422	336,983
Tax liabilities		828	1,771
Other liabilities		60,160	94,743
Accrued expenses and prepaid revenues	34	234,495	244,302
Total current liabilities		814,405	767,952
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		7,226,783	6,984,304
Pledged assets			
– Parent company			
Pledged assets	35	200,000	200,000
Contingent liabilities	36	–	–

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 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/repurchase 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	4,110,650	548,571	5,607,426
Shareholders' equity, 1 Jan 2013	147,948	800,257	4,110,650	548,571	5,607,426
Cashflow hedge	–	–	–	1,862	1,862
Issue/repurchase of shares	415	–	–	–415	–
Sale of ordinary shares	–	–	–	6,717	6,717
Share based compensation	–	–	13,246	–	13,246
Comprehensive income for the year	–	–	–	–7,648	–7,648
Shareholders' equity, 31 Dec 2013	148,363	800,257	4,123,896	549,087	5,621,603

Sobi's share capital at year-end was SEK 148,363,001 shared between 270,389,770 shares with a par value of around SEK 0.55. A share issue of 754,912, C shares was completed in 2013, then all 5,163,172 class C shares have been converted into ordinary shares. The number of ordinary shares in treasury amounted to 4,688,948 at year end. All shares issued at the reporting date are ordinary shares. The ordinary shares carry one vote per share. These shares represent 1.8 per cent of the total number of shares in the company.

Parent company cash flow statement

SEK THOUSAND	2013	2012
Operations		
Loss for the year	-7,648	31,586
Adjustment for items not affecting cash flow	87,636	272,529
	79,988	304,115
Tax paid		
Cash flow from operations before change in working capital	79,988	304,115
Change in working capital		
Decrease (+) / Increase (-) in inventories	-46,645	98,903
Decrease (+) / Increase (-) in operating receivables	228,202	-138,001
Increase (+) / Decrease (-) in operating liabilities	26,703	23,148
Cash flow from operations	288,248	288,165
Investment activities		
Acquisition of subsidiaries ¹	-163	-43,139
Fusion and liquidation of subsidiaries	-	464
Divestment short-term financial assets	2,489	-
Investments in intangible fixed assets	-384,133	-28,485
Investments in tangible fixed assets	-19,061	-16,040
Divestment of tangible fixed assets	2,944	472
Cash flow from investment activities	-397,924	-86,728
Financing activities		
Loan – Raising	200,000	600,000
Sale of shares	6,717	-
Amortization of loans	-	-700,000
Cash flow from financing activities	206,717	-100,000
Net change in liquid funds	97,041	101,437
Liquid funds at beginning of year	276,462	175,025
Liquid funds at end of year	373,503	276,462

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	2013	2012
Interest paid and received		
Interest received	4,489	1,800
Interest paid	59,455	36,519
Adjustments for items not affecting cash flow		
Amortisation/depreciation and write down of assets	112,731	85,668
Capital gain/loss from divestment of fixed assets	12	422
Revaluation of deferred tax	-35,836	135,202
Cost share programmes	13,246	5,870
Arexis, see note 37	-	34,000
Other items	-2,517	11,367
	87,636	272,529

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.

The company has been listed as a mid-cap company on the Stockholm stock exchange (now NASDAQ OMX Stockholm) since 15 September 2006. As per 2 January 2014, Sobi moved to the Large Cap listing on the NASDAQ OMX Stockholm Stock Exchange.

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 certain financial assets and liabilities (including derivative instruments) measured at fair value.

New and amended standards 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 in two categories. This classification is based on whether or not the items can be reclassified to an item in the income statement (reclassification adjust-

ments). The change does not address the matter of which items are to be included in "Other comprehensive income".

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 applied the new standard for the financial year beginning on 1 January 2013. The introduction of the standard will only have a limited effect on the consolidated financial statements and mainly with respect to disclosure requirements. None of the other IFRS or IFRIC interpretations that have not yet entered into force are expected to have a material impact on the Group.

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. The Group stopped applying the corridor approach on 1 January 2012 and the introduction of the amended standard only had a limited impact on the Group's financial statements.

New standards, amendments and interpretations to existing standards which have yet been applied by the Group.

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. In connection with the publication of the rules for hedge accounting, the International Accounting Standards Board (IASB) has decided to leave the deadline for compulsory application of IFRS 9 open until all three parts (classification and valuation, impairment and hedge accounting) have been established.

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 share-

holding 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 Group has applied the acquisition method for business combinations. 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 if 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. 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. In internal reporting to the CEO only one segment is used.

>> Note 2, cont.**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 (SEK) 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 when 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, when it is received, if 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"). In addition to EBIT (operating profit), EBITA is also reported, which reflects the earning capacity of the operational activities of the company.

EBITA represents operating income before amortisation of intangible assets 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

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

Intangible fixed assets**Amortisation of intangible fixed assets**

Amortisation of product rights and acquired R&D is charged to sales and administrative expenses. Software and IT projects in progress are charged to sales and administrative expenses.

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.

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. In practice, this means that the expenditure is not capitalised until such time as the US Food and Drug Administration (FDA) or European Commission (EC) approval is obtained. Cur-

>> Note 2, cont.

rently there are no development projects that are in phase for activation. Amortisation is done 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:

<i>Machinery and technical equipment</i>		
Laboratory equipment and other investments	3–7 years	
<i>Other major investments,</i>		
for example redevelopment of property	5–20 years	
<i>Equipment, tools, fixtures and fittings</i>		
Computers, servers and other major		
computer hardware items	3–5 years	
Furniture, fixtures and fittings	5–10 years	
<i>Buildings and land</i>		
Buildings	20 years	
Land	Indeterminate useful life	

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 instruments

A financial instrument is a contract that gives rise to a financial asset in a company and a financial liability or an equity instrument in another company. Financial instruments also include, for example, contract-based rights to receive cash, such as accounts receivable.

The Group classifies its financial assets in the following categories:

- 1) Loan receivables and accounts receivable
- 2) Financial assets measured at fair value through profit or loss (including derivatives not classified as hedging instruments)
- 3) Other financial liabilities
- 4) Available-for-sale financial instruments (including derivatives classified as hedging instruments).

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.

Financial instruments are recognised on the trading date at fair value plus transaction costs. This applies to all financial assets not recognised at fair value through profit or loss. Financial instruments measured at fair value through profit or loss are initially recognised at fair value, while related transaction costs are recognised through profit or loss.

On each reporting occasion, the company evaluates whether there are objective indications of impairment of a financial asset. If impairment of asset's value is indicated, the value is written

>> **Note 2, cont.**

down and the impairment loss is recognised in the statement of comprehensive income.

Financial assets reported in the balance sheet include, on the assets side, cash and cash equivalents and accounts receivable. Liabilities and shareholders' equity include accounts payable, equity instruments and borrowings.

1) 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 items with maturities more than twelve months from the balance sheet date, which are instead classified as fixed assets. The Group's loans and accounts receivable consist of accounts receivable 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 any necessary provisions for impairment. The maturities of accounts receivable are short and they are therefore initially recognised at nominal amounts with no discount. Any bad debt impairment, which is assessed on an individual basis, is recognised in operating expenses.

2) Financial assets measured at fair value through profit or loss (including derivatives not classified as hedging instruments)

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 it was acquired principally for the purpose of being sold in the short term. Assets in this category are classified as current assets if they are expected to be sold within 12 months, otherwise they are classified as fixed assets.

Derivatives are classified in this category if they have not been identified as hedges. Changes in value of derivatives held to reduce transaction risk in operational activities are recognised in operating profit and derivatives that are held to minimise transaction risks in financial activities are recognised in net financial items.

Derivatives are either recognised as assets or liabilities, depending on whether the fair value is positive or negative. When there are liabilities in this category, they are recognised in the same way as the assets.

3) Other financial assets

This category contains loans and accounts payable. Liabilities in this category are measured at amortised cost using the effective interest method.

Borrowing is initially recognised at fair value, net after transactions costs. Borrowing is subsequently recognised at amortised cost and any difference between the amount received and

the repayment amount is recognised through profit or loss over the duration of the loan, using the effective interest method.

Borrowing is classified as current liabilities unless the Group has an unconditional right to defer payment of the debt until at least 12 months after the balance sheet date.

4) Available-for-sale financial assets (including derivatives classified as hedging instruments)

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

A change in value in a financial asset in this category is recognised in 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 from financial instruments. This category includes derivative instruments identified as hedges. These are either recognised as assets or liabilities depending on whether the fair value is positive or negative. Hedge accounting for derivatives is described in the section below.

Derivative instruments and hedging measures

Derivative instruments, in the case of the Group, are used to hedge the risk of exchange rate fluctuations and to cover interest risks in the company's financing. All derivatives are assigned a market value and the market values are reported in the balance sheet, both initially and at subsequent revaluation. The accounting method for the gain or loss which occurs in connection with revaluation depends on whether the derivative is identified as a hedging instrument and if so, on the nature of the hedged item.

The Group identifies derivatives as hedging instruments as follows:

- a) Fair value hedges
- b) Cash flow hedges
- c) Net investment hedges

The entire fair value of a derivative that is a hedging instrument is classified as a fixed asset or long-term liability when the hedged item's remaining maturity is longer than 12 months, and as a current asset or current liability if the hedged item's remaining maturity is less than 12 months. Derivative instruments held for trading are always classified as current assets or current liabilities.

a) Fair value hedges

Changes in fair value of a derivative that has been identified as a fair value hedge are recognised through profit or loss together with changes in fair value of the hedged asset or liability.

b) Cash flow hedges

The effective portion of changes in fair value of a derivative instrument identified as a cash flow hedge is recognised in other comprehensive income. The gain or loss pertaining to the ineffective portion is recognised immediately through profit or loss. Accumulated equity is returned to profit or loss in the periods in which the hedged item affects profit/loss. If a hedging instrument expires or is sold, or if the hedge no longer meets the criteria for hedge accounting and accumulated gains or losses from the hedge are in found equity, the gains/losses on the hedge remain in equity and are simultaneously recognised through profit or loss at the same time as the forecast transaction is finally recognised through profit or loss.

c) Net investment hedges

Hedges for net investments in foreign operations are recognised in the same way as cash flow hedges, i.e., the effective portion is recognised in other comprehensive income and the ineffective portion is recognised through profit or loss. Accumulated gains and losses in equity are recognised through profit or loss when the foreign operations are fully or partially divested.

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.

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

>> Note 2, cont.

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 Sobi 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 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.

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 or shareholders' equity.

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 obligation to make additional contributions. The Group's earnings are charged with the costs as and when the benefits are earned.

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

Sobi primarily has defined contribution pension commitments and these commitments are insured through 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 recognised 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 2005–2013 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 and Collectum. 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

>> Note 2, cont.

the vesting period. Valuation of the Employee Share programmes are based on commonly accepted models. For the valuation of the Performance shares in the Share programmes the Monte Carlo simulation has been used.

Remuneration in connection with terminated employment

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

Contingent liabilities

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

Parent company's accounting principles

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

Employee benefits/defined benefit plans

When calculating defined benefit pension plans, the parent company complies with the Swedish law safeguarding pensions and the Swedish Financial Supervisory Authority's instructions, as compliance with these is a prerequisite for exercising the right to tax deductions. The parent company also complies with FAR's recommendation redR4. The most important differences compared with the IAS 19 rules concern how the discount factor is established, 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.

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 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 2012.

Note 3

Financial risk management

Financial risks and risk management

Through its operations, Sobi is exposed to various kinds of risks that may impact the company's results and financial position. The risks can be divided into operational risks and financial risks. Financial risks relate to a potential negative impact on the financial position resulting from changes in the financial risk factors. Below is a description of the financial risk factors that are deemed the most significant for Sobi, and the management of them. Operational risk is also described in a separate section in the Director's report.

Financial risk is managed at the central level by Sobi's treasury department, which is also responsible for providing solutions for liquidity management and supporting the business in finance-related issues.

The finance policy, which is set by the Board of Directors, establishes the rules and the division of responsibilities between the Board of Directors, the CEO, the CFO, the central finance department and other Group companies. The Board has appointed an Audit Committee tasked with, among other things, working on the structure and content of the finance policy and, if necessary, suggesting changes to the Board. The main objective of the finance policy is to maintain a low level of financial risk and to manage risk in a reliable way. During the year the finance policy was updated extensively.

Financial risk factors

Currency risk – transaction exposure

Transaction exposure is the risk of changes in exchange rates impacting the financial results in a negative way during the period until the transaction is settled. This risk is managed by matching all transactions in the respective currency and using financial instruments such as currency forward contracts to limit any net exposure with sufficient risk in relation to a set parameter.

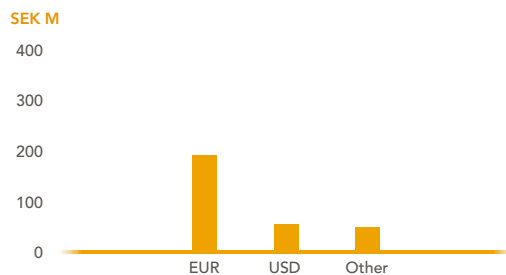
Limiting transaction exposure for future, not yet recognised, transactions, may be necessary if the net exposure for a period of one month exceeds a set amount.

The currencies with the highest excess and deficits are shown in the graph below. The amounts shown in the graph represents the net amount that has to be revaluated. Transaction exposure as per 31 December 2013 amounted to SEK 291 M (510) and has

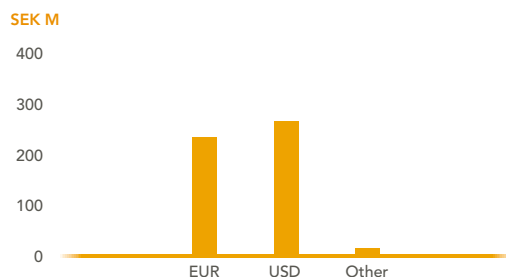
>> Note 3, cont.

been calculated as exposed net flow. A deviation of one percentage point, either way, would impact the profit and loss before taxes with SEK 3 M (6).

Transaction risk



■ Transaction exposure, 2013



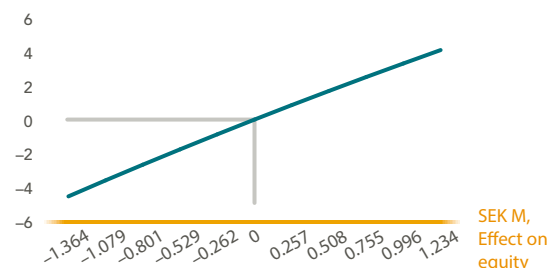
■ Transaction exposure, 2012

Currency risk – translation exposure

Translation exposure is the risk that fluctuations in exchange rates will impact shareholders' equity negatively when the foreign subsidiaries' balance sheets and income statements are translated into Swedish krona. This risk is considered to be low and is therefore not managed. The following graph shows the Company's sensitivity to foreign currency translation effects on foreign subsidiaries' balance sheets and income statements are translated into Swedish krona. The chart shows, for example, that the translation effect on the Group's equity would amount to about SEK 0.3 MSEK if strengthened by 1 per cent.

Translation risk

Currency changes in SEK in %



Interest risk

Interest risk is the risk of negative effects from changes in interest rates, both on profits through changes in general interest rates and on instruments with fixed interest rates through changes in market values. Changes in market values are considered to be acceptable as Sobi's general principle is to minimise volatility in net interest income/expense.

Sobi's financing sources consist primarily of equity, cash flow from operations and borrowings. In the case of interest-bearing borrowings, the Group is exposed to interest rate risk. Sobi's long-term financing consists of a bond loan with variable interest which will mature on 26 June 2017. In 2013 the loan was increased by SEK 200 M and, as of 31 December 2013, the loan amount was SEK 800 M. Sobi has managed the interest risk relating to this loan by fixing the interest rate with interest swaps maturing on 26 June 2015, in which the flows are matched with the bond.

Sensitivity to the effect of changes in interest rates on profits is measured by assuming a sustained interest rate change of 1 percentage point. As of 31 December 2013 such a change would have had an annual impact on net financial items of SEK 0 M (0). Sobi's interest-bearing liabilities as of 31 December 2013 amounted to SEK 798 M and for most of these liabilities Sobi pays a fixed rate, which means that there is no interest rate risk.

Credit risk

Credit risk is the risk of losses if counterparties do not fulfil their commitments. Credit risk can be divided up into accounts receivable credit risks and financial credit risk.

Sobi's credit risk is mainly associated with accounts receivable. As of the closing date, these amounted to SEK 414.5 M, of which SEK 144.6 M represents overdue receivables. See note 27 for information regarding overdue accounts receivable. Sobi's

customers are primarily hospitals and government agencies, which means that the governments in the respective countries provide a substantial portion of the financing. If Sobi deems that a claim will not be honoured, provisions must be made. As of 31 December 2013, such provisions amounted to SEK 10.4 M. Normally there is no collateral for accounts receivable credit risk.

Credit reports are taken up both in distribution agreements and in individual transactions 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.

Sobi has established principles that limit the size of the financial credit risk. To further limit the financial credit risk, financial transactions are primarily with banks with a high official credit rating.

Liquidity risk

Liquidity risk relates to the risk that Sobi will not be able to secure sufficient financing on acceptable terms or meet its payment obligations due to factors beyond Sobi's control. The liquidity risk is managed through a number of directives. Both short-term and long-term forecasts of the Group's liquidity are compiled on an ongoing basis to ensure that there will be sufficient cash funds available to meet the needs of ongoing operations. Investment of any surplus liquidity should 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 Standard & Poor's or an equivalent rating from another rating institute. A high level of liquidity means that the investments can be converted into liquid funds at any given time. There is also a directive on maintaining a liquidity reserve based on a percentage of annual sales. The liquidity reserve consists of bank balances, short-term investments and the unutilised portion of granted credit facilities.

The following table 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.

>> Note 3, cont.

Maturity analysis

	Less than 1 year	1–2 year	2–5 year	More than 5 year
As per 31 December 2013				
Bond ¹	52,735	52,735	879,103	–
Derivatives	–	5,939	–	–
Borrowings	–	–	–	–
Accounts payable	239,098	–	–	–
Other liabilities	22,897	4,924	–	–
As per 31 December 2012				
Bond ²	41,400	41,400	703,500	–
Derivatives	11,077	–	–	–
Borrowings	–	–	–	–
Accounts payable	104,488	–	–	–
Other liabilities	1,113	23,365	–	–

¹ The interest rate is calculated based on an interest rate of 6.6 per cent, the interest rate is non discounted.

² The interest rate is calculated based on an interest rate of 6.9 per cent, the interest rate is non discounted.

Capital risk

Sobi's goal regarding capital structure is to be able to generate a good yield for shareholders and benefits to other stakeholders, and to retain an optimal capital structure in order to keep the cost of capital down. The capital structure can be adapted according to the needs that arise by changing the dividend to shareholders, repaying capital to shareholders, issuing new shares or selling assets to reduce the debt.

The capital is assessed based on the Group's equity ratio. Sobi's goal is an equity ratio of at least 40 per cent. The equity ratio as of 31 December 2013 was as follows:

	2013	2012
Shareholders' equity	4,769,244	4,837,997
Total assets	6,519,320	6,306,501
Equity ratio	73.2%	76.7%

Financial instruments carried at fair value

The following table shows financial instruments carried at fair value by valuation method. The different levels have been defined as follows:

- **Level 1:** Quoted prices in active markets for identical assets or liabilities
- **Level 2:** Inputs other than quoted prices included in level 1 that are observable for the asset or liability
- **Level 3:** Inputs for the asset or liability that are not based on observable market data.

As per 31 december 2013	Level 1	Level 2	Level 3	Total
Financial liabilities available for sale				
Derivatives used for hedging	–	5 939	–	5 939
Total liabilities	–	5 939	–	5 939

As per 31 december 2012	Level 1	Level 2	Level 3	Total
Financial liabilities available for sale				
Derivatives used for hedging	–	11 077	–	11 077
Total liabilities	–	11 077	–	11 077

The fair value of the derivative is based on the net present value of the expected difference between the expected market rate and Sobi's fixed swap rate for the remaining duration of the swap discounted with current market rate. See note 30.

Note 4

Important estimates and assumptions for accounting purposes

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 2013, Sobi's goodwill amounted to SEK 1,648 M (1,605). The impairment tests carried out did not show any impairment loss.

Acquired development projects

The Group assesses periodically for impairment of acquired development projects in accordance with the policy described in note 2. The evaluation of impairment requires that certain estimates must be made. These assumptions are specified in 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 5–15 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.

>> Note 4, cont.

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

Other stock mainly consists of ReFacto, and Multiferon. The production of ReFacto has two components: 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 pharmaceutical 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.

When revenue is recognised, each agreement is interpreted separately and the company makes an assessment of the remaining undertaking. See also note 2 on recognising licence fee and milestone revenues.

Taxes

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.

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	2013	2012
Tax allocation 2008	–	920
Tax allocation 2009	–	181
	–	1,101

All tax allocations were reversed during the year.

Note 6

Distribution of revenues

GROUP	2013	2012
Total revenues by major type of income		
Product sales	1,557,661	1,332,160
Co-promotion revenues	–	12,021
Manufacturing and contract development	491,943	436,033
Royalty revenues	127,090	129,798
Licensing and milestone revenues	–	13,149
	2,176,694	1,923,161
Revenues by regions¹		
Europe ²	1,544,261	1,331,852
MENAR ³	55,126	38,461
North America	550,176	512,919
Other	27,131	39,929
Total revenues	2,176,694	1,923,161

>> Note 6, cont.

PARENT COMPANY	2013	2012
Total revenues by major type of income		
Product sales	1,222,848	1,049,505
Co-promotion revenues	–	12,021
Manufacturing and contract development	491,943	436,033
Royalty revenues	127,090	129,798
Licensing and milestone revenues	–	13,149
	1,841,881	1,640,506
Revenues by regions¹		
Europe ⁴	1,426,528	1,129,401
MENAR ³	38,425	27,468
North America	363,391	465,117
Other	13,537	18,520
Total revenues	1,841,881	1,640,506

¹ The geographical distribution is based on where the end customer is located.

² Net sales in Sweden amounted to SEK 107M (115).

³ Middle East, North Africa and Russia

⁴ Net sales in Sweden amounted to SEK 107 M (78).

Sales by key product

SEK M	2013	2012
Kineret	561,689	484,661
Orfadin	365,901	356,689
Other core products	84,364	79,588
Core Products	1,011,954	920,938
Current portfolio	545,707	411,301
Co-promotion revenues	–	12,021
Partner Products	545,707	423,322
Manufacturing revenues	491,943	435,954
Royalty revenues	127,090	129,798
ReFacto	619,033	565,752
Other revenues	–	13,149
Total revenues	2,176,694	1,923,161

Note 7**Segment reporting**

The Group reports one operating segment, sales of pharmaceuticals. 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, where to Sobi has net sales of SEK 619 M (566), corresponding to 29 percent (30) of the company's total revenues. Sobi has not had any other customer for which revenue exceeds 10 percent of the company's total revenues in 2012 and 2013. The majority of fixed assets are in Sweden; no fixed assets amounting to any material value are abroad.

Note 8**Non-recurring items**

GROUP	2013	2012
Additional purchase price regarding Arexis	–	–34,000
Other	–	–3,095
	–	–37,095
PARENT COMPANY	2013	2012
Additional purchase price regarding Arexis	–	–34,000
Other	–	–3,095
	–	–37,095

Note 9**Depreciation/amortisation and write-down of intangible and tangible fixed assets**

GROUP	2013	2012
Depreciation according to plan by type of asset		
Capitalised software expenses	–3,869	–3,380
Patents and licenses	–52,850	–56,142
Product rights	–218,177	–211,272
Land and buildings	–334	–1,798
Plant and machinery	–11,361	–3,880
Equipment, tools, fixtures and fittings	–17,044	–14,875
Cars	–1,319	–682
	–304,954	–292,029
Depreciation according to plan by function		
Cost of goods and services sold	–19,248	–21,117
Sales and administration expenses	–284,861	–268,829
Research and development expenses	–845	–2,083
	–304,954	–292,029
Write-downs by type of asset		
Product rights	–	–150,764
Patents and licenses	–2,667	–
Equipment, tools, fixtures and fittings	–	–11,505
	–2,667	–162,269
Write-downs by function		
Sales and administration expenses	–2,667	–162,269
	–2,667	–162,269

>> Note 9, cont.

PARENT COMPANY	2013	2012
Depreciation according to plan by type of asset		
Capitalised software expenses	-3,869	-3,444
Patents and licenses	-1,585	-2,055
Product rights	-76,864	-48,891
Land and buildings	-334	-1,798
Plant and machinery	-10,864	-3,880
Equipment, tools, fixtures and fittings	-16,547	-25,600
	-110,063	-85,668
Depreciation according to plan by function		
Cost of goods and services sold	-19,248	-21,117
Sales and administration expenses	-90,030	-62,468
Research and development expenses	-785	-2,083
	-110,063	-85,668
Write-downs by type of asset		
Patents and licences	-2,667	-
	-2,667	-
Write-downs by function		
Sales and administration expenses	-2,667	-
	-2,667	-

Note 10

Other operating revenues

GROUP	2013	2012
Cost forwarded to partners	-	8,821
Exchange rate gains on operating receivables/liabilities	20,895	20,980
Divestment of the co-promotion rights	-	307,480
Other	2,729	8,588
	23,624	345,869

PARENT COMPANY	2013	2012
Exchange rate gains on operating receivables/liabilities	19,150	20,980
Further invoiced costs to partners	-	8,821
Further invoiced costs to subsidiaries	10,934	-
Divestment of the co-promotion rights	-	307,480
Other	2,729	9,737
	32,813	347,018

Note 11

Other operating expenses

GROUP	2013	2012
Exchange rate losses on operating receivables/liabilities	-17,419	-39,578
Divestment of fixed assets	1,271	-
Reimbursed foreign VAT	-	20
Other	-4,055	-1,412
	-20,203	-40,970

PARENT COMPANY	2013	2012
Exchange rate losses on operating receivables/liabilities	-16,678	-35,395
Divestment of fixed assets	1,271	-
Reimbursed foreign VAT	-	20
Other	-4,055	-
	-19,462	-35,375

Note 12

Expenses for operational leasing

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

	GROUP		PARENT COMPANY	
	2013	2012	2013	2012
Within 1 year	4,342	2,898	689	113
Between 1 and 5 years	5,238	5,023	502	727
	9,580	7,921	1,191	840
Leasing costs for the year:	6,080	5,218	832	651

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

	GROUP		PARENT COMPANY	
	2013	2012	2013	2012
Within 1 year	58,509	56,917	56,305	54,220
Between 1 and 5 years	268,722	284,593	267,832	282,602
Later than 5 years	121,490	179,320	121,490	179,320
	448,721	520,830	445,627	516,142
Leasing costs for the year:	57,889	88,810	54,364	85,379

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	2013	2012
Dividends from subsidiaries	2,288	1,368
Write-down of shares in subsidiaries	–	–303
	2,288	1,065

Note 14

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

Average number of employees

GROUP	2013	of which men	2012	of which men
Sweden	394	38%	385	40%
Denmark	10	10%	11	19%
Finland/Baltics	8	44%	11	36%
Norway	9	30%	9	44%
United Kingdom	20	56%	16	69%
France	20	37%	18	39%
Germany	19	39%	17	47%
Italy	13	37%	11	36%
Spain	12	46%	11	45%

GROUP	2013	of which men	2012	of which men
Russia	5	40%	3	33%
Central Eastern Europe	14	33%	14	36%
USA ¹	19	65%	8	59%
United Arab Emirates ²	3	75%	0	100%
Belgium ³	0	29%	–	–
Total	546	42%	514	40%

¹ Employed as of July 2012

² Employed as of October 2012

³ Employed as of December 2013

Salaries, other remunerations and social security expenses

GROUP AND PARENT COMPANY	2013		2012	
	Salaries and remunerations	Social security costs	Salaries and remunerations	Social security costs
Parent company	278,384	149,090	243,143	126,689
(of which pension cost ¹)		(31,499)		(40,831)
Subsidiary	129,150	32,580	110,259	31,053
(of which pension cost)		(9,599)		(11,013)
Group total	407,534	181,670	353,402	157,742
(of which pension cost ¹)		(41,098)		(51,844)

¹ Of the Group's and Parent company's pensions costs, SEK 1 M (1) 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

	2013		2012	
	Board and CEO	Other employee	Board and CEO	Other employee
Parent company				
Salaries and benefits	14,085	264,299	16,881	227,084
(of which bonuses, etc.)	(1,102)	(23,093)	(838)	(17,087)
Subsidiaries				
Salaries and benefits	10,831	118,319	10,209	100,050
(of which bonuses, etc.)	(2,889)	(14,466)	(818)	(6,665)
Group total	24,916	382,618	27,090	327,134
(of which bonuses, etc.)	(3,991)	(37,559)	(1,656)	(23,752)

Remuneration policy 2013

The remuneration policy approved at the 2013 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.

>> Note 14, cont.

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 predetermined 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 2013 Geoffrey McDonough received SEK 4.3 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 per cent 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 2013 variable salary amounted to SEK 1.1 M.

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 per cent of annual gross salary for Geoffrey McDonough's future pension benefits. Pensionable salary in 2013 was SEK 4.3 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.

Fixed and variable salaries

All 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 per cent of which is company objectives and 30 per cent individual goals. The maximum individual levels are between 20–50 per cent of basic salary.

For other employees, the variable salary is based on company objectives between 50 per cent to 100 per cent and remaining part on individual goals. Variable salary levels for these individuals are

between 10–30 per cent 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 per cent 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 4.3 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 per cent 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 individuals with contribution percentages exceeding 27 per cent. Members of management who are employed abroad are covered by different pension plans, depending on the country of employment.

Remuneration and other benefits for the Board, CEO and other senior executives¹

	Basic pay/ fees	Variable remunera- tion	Pension cost	Other benefits	Financial instrument	Other remunera- tion	Total
2013							
Chairman of the Board²	2,386	–	–	–	–	–	2,386
Other board members³							
Helena Saxon	358	–	–	–	–	–	358
Hans Schikan	372	–	–	–	–	–	372
Adine Grate Axén	333	–	–	–	–	–	333
Lennart Johansson	373	–	–	–	–	–	373
Hans Wigzell	333	–	–	–	–	–	333
Matthew Gantz	381	–	–	–	–	–	381
Chief Executive Officer							
Geoffrey McDonough	3,240	1,102	1,080	1,096	3,031	–	9,549
Other senior management⁴	16,601	4,078	3,905	442	3,784	200	29,010
	24,377	5,180	4,985	1,538	6,815	200	43,095

¹ The table shows the company's costs (excl. social charges).

² Bo Jesper Hansen's employment and his salary have no relation to his position as chairman of the board.

³ Information regarding the directors fees can be found in the Corporate Governance Report.

⁴ "Other senior management" refers to Swedish Orphan Biovitrum's management team consisting of 12 persons other than the CEO as of 31 December 2013.

>> Note 14, cont.

Remuneration and other benefits for the Board, CEO and other senior executives⁵

	Basic pay/ fees	Variable remunera- tion	Pension cost	Other benefits	Financial instrument	Other remunera- tion	Total
2012							
Chairman of the Board¹	854	–	–	–	–	7,937	8,791
Other board members²							
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	1,040	1,364	–	7,242
Other senior management⁴	19,406	2,387	6,702	371	2,154	2,801	33,821
	25,043	3,225	7,702	1,411	3,518	10,738	51,637

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.

⁵ Table shows the company's costs (excluding social security costs).

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

	2013	2012
Parent company and subsidiaries		
Parent company		
Salaries and remunerations	38,110	43,375
(of which bonuses etc.)	(5,380)	(6,026)
Pension cost	4,985	7,597
Number of persons		
(excl. union representatives)	12	15
Subsidiaries		
Salaries and remunerations	10,831	10,769
(of which bonuses etc.)	(2,889)	(818)
Pension cost	1,322	1,142
Number of persons	10	10
Group		
Salaries and remunerations	48,941	54,144
(of which bonuses etc.)	(8,269)	(6,844)
Pension cost	6,307	8,739
Number of persons		
(excl. union representatives)	22	25

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.

Share programme 2011

At the 2011 Annual General Meeting, 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. Provided that the above mentioned 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").

>> Note 14, cont.

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 2011, the total shareholder return for the Sobi common share must amount to at least 15 per cent 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 per cent 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 13.93 on the allotment date, volatility of 37.0 per cent and a risk free interest rate of 1.82 per cent.

Share programme 2011

	Number of Performance shares	Number of Matching shares	Value
Other senior management, 8	257,323	42,574	2,299,107
Sum	257,323	42,574	2,299,107

Long-term incentive programme for CEO Geoffrey McDonough

Extraordinary General Meeting on 24 August 2011 approved the Board's proposal for the introduction of a performancebased 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

- a) For any allotment of Performance shares to be possible the share price must have increased by more than 15 per cent 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).
- b) 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.
- c) 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).

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.

>> Note 14, cont.

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 they invest in Sobi shares and on condition that they remain employed throughout the vesting period. Provided that the above mentioned requirements are met, the employees may receive Sobi shares free of charge equivalent to the number of shares the employee invested in under the Share Programme 2012 ("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 on the Sobi common share (the share price development adjusted with respect to dividends), during a three-year period 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 per cent 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 performance 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 the volume-weighted average share price of SEK 21.99 on the allotment date, volatility of 38.0 per cent and a risk free interest rate of 0.92 per cent.

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
Other senior management, 10	402,863	98,835	5,807,206
Sum	402,863	98,835	5,807,206

Share Programme 2013

The 2013 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 above mentioned 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 2013 ("executive matching shares") as well as additional Sobi shares depending on whether targets set by the Board of Directors for value creation are met ("executive 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 2013, the total shareholder return for the Sobi common share must amount to at least 15 per cent during the performance period.

A long-term, performance-based share programme ("All Employee Programme") was adopted at the Annual General Meeting on 26 April 2013. The All Employee Programme covers permanent employees of Sobi who receive the opportunity for allocation of common shares in Sobi on condition that they remain employed during the entire vesting period. Provided that the above-mentioned requirements are met, the employees may receive Sobi shares free of charge equivalent to the number of shares the employee invested in under Share Programme 2013 (employee matching shares) as well as additional Sobi shares depending on whether targets set by the Board of Directors for value creation are met ("employee 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 taking dividends into account), during a three year period 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 2013, the total shareholder return for the Sobi common share must amount to at least 15 per cent during the performance period.

The value of the matching shares and performance shares in Share Programme 2013:1 & 2 and the All Employee Programme has been calculated as follows.

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 performance 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 performance period. Important input data in the model for Share Programme 2013:1 were a volume-weighted average share price of SEK 42.62 on the allotment date, volatility of 43.0 per cent and a risk free interest rate of 0.96 per cent, and for Share Programme 2013:2, a volume-weighted average share price of SEK 65.00 on the allotment date, volatility of 39.9 per cent and a risk free interest rate of 1.14 per cent.

Share programme 2013

	Number of Performance shares	Number of Matching shares	Value
Other senior management, 11	328,972	82,114	9,977,157
Sum	328,972	82,114	9,977,157

>> Note 14, cont.

Expensing of Share programme 2011, 2012 and 2013 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 2011	2011-12-15	2014-12-15	88,658	489,529	36	13,93	6,63	5%	578,187
Share programme 2012, Leadership programme	2012-05-21	2015-05-14	157,507	491,316	36	21,99	9,02	5%	649,120
Share programme 2012, Staff programme	2012-06-25	2015-05-14	–	–	36	–	12,24	5%	23,900
Share programme 2013:1	2013-05-16	2016-05-15	300,244	674,684	36	42,62	19,69	5%	974,928
Share programme 2013:2	2013-11-15	2016-11-14	15,655	27,347	36	65,00	29,70	5%	43,002

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	2013	2012
Board		
Men	5	5
Women	2	2
	7	7
CEO and other senior executives		
Men	8	6
Women	4	6
	12	12

Note 15

Remuneration and reimbursement

GROUP	2013	2012
PwC		
Auditing assignments ¹	-3,371	-3,491
of which auditing in addition to audit assignment	(-697)	(-1,441)
Tax assignments	-3,675	-2,643
Other assignments	-1,542	-1,400
	-8,588	-7,535
Other auditor		
Auditing assignments	-	-
PARENT COMPANY	2013	2012
PwC		
Auditing assignments ¹	-2,302	-2,981
of which auditing in addition to audit assignment	(-697)	(-1,441)
Tax assignments	-3,392	-2,590
Other assignments	-1,274	-1,350
	-6,968	-6,921

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	2013	2012
Raw materials and consumables	-645,909	-606,760
Other external costs	-668,998	-687,405
Personnel costs	-624,119	-534,203
Depreciation and write-downs	-307,621	-454,298
Other operating expenses	-20,203	-40,970
	-2,266,850	-2,323,636
PARENT COMPANY	2013	2012
Raw materials and consumables	-637,051	-536,981
Other external costs	-655,636	-663,630
Personnel costs	-467,726	-400,436
Depreciation and write-downs	-112,731	-85,668
Other operating expenses	-19,462	-35,375
	-1,892,606	-1,722,090

Note 17

Financial income

GROUP	2013	2012
Interest income, miscellaneous	4,489	2,329
Result from short-term investments	1,333	3,880
Exchange rate gains/losses on short term receivables	5,284	548
Revaluation of financial asset	3,085	-
Other	112	557
	14,303	7,314
PARENT COMPANY	2013	2012
Interest income, group companies	29,291	35,300
Interest income, miscellaneous	4,489	1,800
Exchange rate gains/losses on short term receivables	5,284	548
Revaluation of financial claims	3,085	-
	42,149	37,648

Note 18

Financial expenses

GROUP	2013	2012
Interest expenses, bank loan	-51,787	-34,365
Interest expenses, miscellaneous	-8,625	-7,882
Exchange rate difference liabilities	-7,399	-11,307
Financing expenses	-3,375	-4,246
	-71,186	-57,800
PARENT COMPANY	2013	2012
Interest expenses, bank loan	-51,787	-34,365
Interest expenses, miscellaneous	-7,668	-2,154
Exchange rate difference liabilities	-7,399	-11,307
Financing expenses	-3,375	-4,246
	-70,229	-52,072

Note 19

Exchange rate differences affecting operating profit/loss

GROUP	2013	2012
Exchange rate differences affecting operating profit/loss	3,476	-18,598
	3,476	-18,598
PARENT COMPANY	2013	2012
Exchange rate differences affecting operating profit/loss	2,472	-14,415
	2,472	-14,415

Note 20

Income tax

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

GROUP	2013	2012
Tax expense/income for the year	-14,983	-7,608
Adjustment of taxes related to previous years	-1,032	-11,343
Total tax reported for the Group	-16,015	-18,951
<i>Deferred tax relating to:</i>		
Pensions	-4,367	-2,324
Change in tax allocation reserve and excess depreciation	-21,375	21,537
Internal profit in inventories	-16,122	25,183
Depreciation of intangible assets	34,253	6,586
Capitalisation of tax loss carry forwards	35,552	-28,815
Revaluation of deferred tax	17,060	-
Other	1,473	993
Total deferred tax reported for the Group	46,474	23,160
Total tax reported for the Group	30,459	4,209
PARENT COMPANY	2013	2012
Tax expense/income for the year	35,746	-135,773
Adjustment of taxes related to previous years	-1,032	-11,343
Total tax reported for the Parent company	34,714	-147,116

Reconciliation of actual tax

GROUP	2013	2012
Pre-tax profit	-123,415	-105,092
Tax on the basis of prevailing tax rate for Parent company	27,151	27,639
Effect of foreign tax rates	-9,038	-2,955
Non reported taxable income	-	-2,362
Other non-deductible expenses	-5,357	-44,376
Non-taxable income	629	5,180
Interest on tax allocation reserve	-386	-535
Adjustment of tax previous years	-1,032	-11,444
Non valued tax asset	-	-44,501
Effect of changed tax rate	-	-77,563
Deferred tax assets not previously reported	18,492	-
Reported actual tax	30,459	4,209
PARENT COMPANY	2013	2012
Pre-tax profit	-42,363	178,702
Tax on the basis of prevailing tax rate for Parent company	9,320	-46,999
Non reported taxable income	-3	-2,362
Other non-deductible expenses	-5,344	-43 716 ¹
Adjustment of tax previous years	-1,032	-11,343
Non-taxable income	1,132	1,805
Non valued tax asset	-	-44 501
Revaluation of deferred tax	30,641	-
Reported actual tax	34,714	-147,116

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

Prevailing tax rate for the Parent company is 22% (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 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	–	803	–	61,637
Write-downs	–	–	–	–150,764 ¹	–	–	–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	1,605,307	281,420	709,487	3,014,758	57,385	15,267	5,683,624
Accumulated depreciation and amortisation	–	–109,146	–227,840	–763,584	–49,688	–	–1,150,258
Net book value	1,605,307	172,274	481,647	2,251,174	7,697	15,267	4,533,366
1 January–31 December 2013							
Net book value – Opening balance	1,605,307	172,274	481,647	2,251,174	7,697	15,267	4,533,366
Additions	–	–	12,447 ³	366,515 ³	–	5,171 ³	384,133
Reclassification of acquisition values	43,000 ²	–	–122,507 ²	–	10,146	–14 940	–84,301
Write-downs	–	–	–2,667 ⁴	–	–	–	–2,667
Depreciation	–	–	–52,850	–218,177	–3,869	–	–274,896
Reclassified Accumulated Depreciations	–	–	84,190	221	–3,018	–	81,393
Net book value – Closing balance	1,648,307	172,274	400,260	2,399,733	10,956	5,498	4,637,028
At 31 December 2013							
Acquisition value	1,648,307	281,420	599,427	3,381,273	67,531	5 498	5 983 456
Accumulated depreciation and amortisation	–	–109,146	–199,167	–981,540	–56,575	–	–1 346 428
Net book value	1,648,307	172,274	400,260	2,399,733	10,956	5,498	4,637,028

¹ Write-downs in 2012 refer 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 these assets do not have any value.

² Reclassification that refers to the acquisition of Arexis

³ Additions refers to milestone Kineret (SEK 366.5 M), Affibody (SEK 10.3 M), Docspace and IFS (SEK 5.2 M), Aloxi (SEK 1.3 M) and other additions (SEK 0.8 M).

⁴ 2013 years write-down refers to project O4CP. Management has deemed that these assets are of no value.

>> Note 21, cont.

PARENT COMPANY	Research & Development	Trademarks & licenses	Product rights	Software and other	IT-software in progress	Total
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	–	803	–	20,275
Reclassification of acquisition value	–	–	–	–1,424	–	–1,424
Depreciation	–	–2,055	–48,891	–3,444	–	–54,390
Net book value – Closing balance	–	82,377	535,896	5,003	15,267	638,543
At 31 December 2012						
Acquisition value	–	168,318	730,058	51,202	15,267	964,845
Accumulated depreciation and amortisation	–	–85,941	–194,162	–46,199	–	–326,302
Net book value	–	82,377	535,896	5,003	15,267	638,543
1 January–31 December 2013						
Net book value – Opening balance	–	82,377	535,896	5,003	15,267	638,453
Additions	–	12,447 ¹	366,515 ¹	–	5,171 ¹	384,133
Reclassification of acquisition value	–	–79,507	–	10,110	–14,940	–84,337
Write-downs	–	–2,667 ²	–	–	–	–2,667
Depreciation	–	–1,585	–76,864	–3,869	–	–82,318
Reclassification of accumulated depreciation	–	84,190	221	–3,018	–	81,393
Net book value – Closing balance	–	95,255	825,768	8,226	5,498	934,747
At 31 December 2013						
Acquisition value	–	101,258	1,096,573	61,312	5,498	1,264,641
Accumulated depreciation and amortisation	–	–6,003	–270,805	–53,086	–	–329,894
Net book value	–	95,255	825,768	8,226	5,498	934,747

¹ Additions in 2013 refer to milestone Kineret (SEK 366.5 M), Affibody (SEK 10.3 M), Docspace and IFS (SEK 5.2 M), Aloxi (SEK 1.3 M) and other additions (SEK 0.8 M).

² 2013 years write-down refers to project O4CP. Management has deemed that these assets are of no value.

>> Note 21, cont.

Intangible assets consist primarily of product rights, goodwill, licences, 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. 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 2 per cent. Sobi's goodwill at 31 December 2013 amounts to SEK 1,648 M (1,605). Completed impairment tests show no impairment of goodwill.

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

Parameter	2013	2012
Growth rate beyond the initial five-year period	2%	0–1%
Discount rate before tax	11.5%	13.6%
Discount rate after tax	9.0%	10.0%

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: 6.5 per cent

Beta: Sobi's development largely follows the general trend on the market and is therefore calculated as 0.9.

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 the 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 market life.

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 2013

Sobi has not made any material write-downs during 2013.

Note 22

Tangible fixed assets

GROUP	Land and buildings	Plant and machinery	Equipment, tools, fixtures and fittings	Cars	Construction in progress	Total
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 ¹	–	–	–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	286,563	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 January–31 December 2013						
Net book value – Opening balance	4,930	34,241	81,181	3,550	1,683	125,585
Entry into service of existing facilities	–	–	–	–	–	–
Additions	–	11,754	4,399	5,238	4,585	25,976
Reclassification of acquisition value	–672	–	3,052	–	–1,683	697
Disposals	–	–	–13	–	–	–13
Depreciation	–334	–8,812	–19,593	–1,319	–	–30,058
Reclassified depreciations	671	–471	3,392	–	–	3,592
Net book value – Closing balance	4,595	36,712	72,418	7,469	4,585	125,779
At 31 December 2013						
Acquisition value	6,728	392,146	201,957	10,448	4,585	615,864
Accumulated depreciation and amortisation	–2,133	–355,434	–129,538	–2,979	–	–490,084
Net book value	4,595	36,712	72,418	7,469	4,585	125,779

¹ 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	Construction in progress	Total
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
Merger of subsidiaries	–	3,242	116	–	10,086
Reclassification of acquisition value	–	–200	–	–	–200
Disposals	–	–6,419	–1,683	–	–8,102
Depreciation	–1,797	–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	–1,797	–560,751	–198,836	–	–761,233
Net book value	4,931	35,362	77,977	1,683	119,953
1 January–31 December 2013					
Net book value – Opening balance	4,931	35,362	77,977	1,683	119,952
Entry into service of existing facilities	–	–	–	–	–
Additions	–	10,915	3,561	4,585	19,061
Reclassification of acquisition value	–2	–	2,647	–1,683	962
Disposals	–	–	–13	–	–13
Depreciation	–334	–8,315	–19,096	–	–27,745
Reclassification of depreciation	–	26	3,392	–	3,418
Write-downs	–	–	–	–	–
Net book value – Closing balance	4,595	37,988	68,468	4,585	115,635
At 31 December 2013					
Acquisition value	6,726	387,170	190,964	4,585	589,445
Accumulated depreciation and amortisation	–2,131	–349,182	–122,496	–	–473,809
Net book value	4,595	37,988	68,468	4,585	115,635

Note 23

Shares in Group companies

PARENT COMPANY	2013	2012
Accumulated acquisition values		
Accumulated acquisition values, opening balance	4,058,305	4,015,630
Acquisitions	163	132
Merger of subsidiaries	–	–293
Additional payment Arexis	–	43,000
Liquidation of subsidiaries	–	–164
	4,058,468	4,058,305
Accumulated write-down		
Opening balance	–	–
This years write-down	–	–
	–	–
Net book value end of period	4,058,468	4,058,305

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, Stockholm, Sweden	100	100,0	3,655,588
SOBI Middle East FZ-LLC, 91193, Dubai, UAE	1,000	100,0	132
Arexis AB, 556573-5130, Stockholm, Sweden	1,000	100,0	402,571
Swedish Orphan Biovitrum Inc., EIN 68-068244, Delaware, USA	1,000	100,0	7
Swedish Orphan Biovitrum S:R:O, 28171276, Prague, Czech republic	1	1,0	8
BVBA Swedish Orphan Biovitrum, 0536.217.087, Brussels, Belgium	100	100,0	162
			4,058,468

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

Note 24

Financial fixed assets

GROUP	2013	2012
Accumulated acquisition values		
Opening balance	4,381	11,410
Write-down of loan and shares	–2,000	–3,000
Financial asset	–371	–
Change in pension commitment	–	–3,727
Other	–	–302
Accumulated acquisition values	2,010	4,381
Book value at end of period	2,010	4,381
PARENT COMPANY	2013	2012
Accumulated acquisition values		
Opening balance	3,110	141,313
Acquisition	–	570
Financial asset	–489	–
Write-down of loan and shares	–2,000	–3,000
Change of deferred tax	–	–135,773
Accumulated acquisition values	621	3,110
Book value at end of period	621	3,110

Note 25

Deferred tax receivables and liabilities

Accounted deferred tax receivables and liabilities

GROUP 2013	Deferred tax receivable	Deferred tax liability	Net
Inventory	18,406	–	18,406
Acquired R&D	–	–37,900	–37,900
Acquired product rights	24,511	–404,498	–379,987
Pensions	2,325	–	2,325
Tax allocation reserve	–	–134,552	–134,552
Other	5,842	–	5,842
Other intangible assets	216,700	–	216,700
Loss carry-forward	35,772	–	35,772
	303,556	–576,950	–273,394
Offsetting	–279,148	279,148	–
Net deferred tax receivable/liability	24,408	–297,802	–273,394

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

For the parent company there are a deferred tax asset on SEK 1.3 M (2.3) for deferred tax on derivat. In 2013 there is also a deferred tax on loss carry-forward amounting to SEK 35.8 M, thus, totally there is a deferred tax asset of SEK 37.1 M in the parent company.

Non accounted deferred tax receivables

GROUP	2013-12-31	2012-12-31
Deductable temporary differences	–	44,501
Deficit for tax purpose	–	–
Total	–	44,501

PARENT COMPANY	2013-12-31	2012-12-31
Deductable temporary differences	–	44,501
Deficit for tax purpose	–	–
Total	–	44,501

The closing balance for tax loss carry-forward refers to Swedish companies. According to tax legislation, this tax-losses can be carried forward indefinitely. The tax-losses are capitalised because the Group believes that it is probably that the remaining deficit will be offset against future taxable profits. The value of deferred tax 2013 has been calculated using a tax rate of 22.0 per cent (22.0).

As a result of a decision announced by the court of appeal on 28 November 2013, Sobi 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 will not appeal the decision. The disputed amount has decreased the company's loss carry forwards. Historically, no deferred tax asset linked to this amount has been recognised. Refer to note 37.

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

GROUP 2013	Amount 1 January	Reported in income statement	Recorded in other com- prehensive income	Translation difference	Amount 31 December
Inventory	34,528	–16,122	–	–	18,406
Acquired R&D	–30,449	–7,451	–	–	–37,900
Acquired product rights	–438,751	58,764	–	–	–379,987
Pensions	7,292	–4,367	–600	–	2,325
Tax allocation reserves/ excess depreciation	–113,177	–21,375	–	–	–134,552
Other	5,380	1,473	–1,011	–	5,842
Other intangible assets	216,700	–	–	–	216,700
Utilisation of loss carry- forward	196	35,552	–	24	35,772
	–318,281	46,474	–1,611	24	–273,394

GROUP 2012	Amount 1 January	Reported in income statement	Recorded in other compre- hensive 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

Note 26

Inventories

GROUP	2013	2012
Raw materials and consumables	16,982	14,768
Work-in-progress	360,060	412,549
Finished products and goods for resale	348,908	273,051
	725,950	700,368

The expenditure for the inventories that was carried as an expense is included in cost of goods sold and amounts to SEK 292,254 thousand (369,905). Provision for obsolescence amounts to SEK 26,470 thousand (32,515).

PARENT COMPANY	2013	2012
Raw materials and consumables	16,982	14,768
Work-in-progress	360,060	412,549
Finished products and goods for resale	287,545	190,625
	664,587	617,942

The expenditure for the inventories that was carried as an expense is included in cost of goods sold and amounts to SEK 289,605 thousand (276,826). Provision for obsolescence amounts to SEK 26,470 thousand (32,515).

Note 27

Accounts receivable and other receivables

GROUP	2013	2012
Accounts receivable	424,907	348,380
Deduction: Provision for decrease in accounts receivable	-10,442	-5,136
Accounts receivable – net	414,465	343,244
Tax receivables	18,048	21,375
Other receivables	48,233	19,105
Total other receivables	66,281	40,480
Total accounts receivable and other receivables	480,746	383,724

PARENT COMPANY	2013	2012
Accounts receivable	203,667	189,433
Deduction: Provision for decrease in accounts receivable	-10,370	-5,068
Accounts receivable – net	193,297	184,365
Tax receivables	17,010	19,065
Other receivables	35,256	12,291
Total other receivables	52,266	31,356
Total accounts receivable and other receivables	245,563	215,721

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

As of 31 December 2012 accounts receivable amounting to SEK 145 M (188) were past due and no write-down was deemed necessary. Provisions for doubtful receivables amounted to SEK 10.4 M (5.1) as of 31 December 2013.

Changes in the provision for doubtful receivables are as follows:

GROUP	2013	2012
Opening balance	-5,136	-19,879
Provision for receivables impairment	-5,306	–
Unused amounts reversed	–	14,743
Closing balance	-10,442	-5,136

PARENT COMPANY	2013	2012
Opening balance	-5,068	3,440
Provision for receivables impairment	-5,302	-1,628
Closing balance	10,370	-5,068

Accounts receivable past due

GROUP	2013	2012
Past due 1–30 days	46,184	81,280
Past due 31–90 days	21,747	21,322
Past due 91–120 days	8,488	5,755
Past due > 121 days	68,225	79,351
	144,644	187,708

PARENT COMPANY	2013	2012
Past due 1–30 days	16,187	24,999
Past due 31–90 days	5,598	7,268
Past due 91–120 days	2,406	1,343
Past due > 121 days	13,638	44,875
	37,829	78,485

Amounts, per currency, for accounts receivables and other receivables

GROUP	2013	2012
SEK	89,877	72,140
NOK	9,887	13,463
DKK	21,642	19,703
USD	81,313	54,084
EUR	219,333	187,434
GBP	37,491	19,400
CZK	6,271	6,852
CHF	1,891	–
PLN	4,075	2,853
AUD	3,700	4,773
Other currencies	5,266	3,022
	480,746	383,724

PARENT COMPANY	2013	2012
SEK	89,877	67,077
NOK	9,689	13,184
DKK	21,642	19,675
USD	28,706	16,759
EUR	70,151	82,536
GBP	6,601	180
CZK	3,970	5,752
CHF	1,891	–
PLN	4,075	2,853
AUD	3,700	4,773
Other currencies	5,261	2,932
	245,563	215,721

Note 28

Prepaid expenses and accrued revenues

GROUP	2013	2012
Accrued royalty revenues	23,728	23,017
Accrued co-promotion revenues	6,372	1,362
Prepaid leasing fees	125	252
Prepaid rents	16,344	14,911
Prepaid insurance expenses	12,666	8,626
Prepaid service and maintenance expenses	–	3,797
Accrued interest income	2,562	–
Prepaid expenses, tech transfer Kineret	–	34,324
Other accrued revenues	1,378	–
Other prepaid expenses	15,127	15,837
	78,302	102,126
PARENT COMPANY	2013	2012
Accrued royalty revenues	23,728	23,017
Accrued co-promotion revenues	5,545	1,362
Prepaid leasing fees	–	136
Prepaid rents	15,270	14,216
Prepaid insurance expenses	11,195	7,575
Prepaid loan expences	–	3797
Accrued interest income	2,562	–
Prepaid expenses, tech transfer Kineret	–	34,324
Other accrued revenues	1,034	–
Other prepaid expenses	9,212	12,178
	68,546	96,605

Note 29

Short-term investments and liquid funds

Specification of security

GROUP	2013		2012	
	Fair value	Book value	Fair value	Book value
Cash and Bank	445,097	445,097	456,951	456,951
	445,097	445,097	456,951	456,951
PARENT COMPANY	2013	2012	Fair value	Book value
Cash and Bank	373,503	373,503	276,462	276,462
	373,503	373,503	276,462	276,462

Note 30

Financial assets and liabilities per category (Group)

	Loans and receivables	Asset at fair value through the profit and loss	Assets available for sale	Total
31 december 2013				
Assets as per balance sheet				
Accounts receivable	414,465	–	–	414,465
Liquid funds	445,097	–	–	445,097
Total	859,562	–	–	859,562
31 december 2012				
Assets as per balance sheet				
Accounts receivable	343,244	–	–	343,244
Liquid funds	456,951	–	–	456,951
Total	800,195	–	–	800,195
	Liabilities at fair value through the profit and loss	Oth. Financial depts	Liabilities available for sale	Total
31 december 2013				
Liabilities as per balance sheet				
Borrowings	–	790,775	–	790,775
Financial leasing	–	6,821	–	6,821
Derivatives	–	–	5,939	5,939
Accounts payables	–	239,098	–	239,098
Other short term liabilities	–	20,750	–	20,750
Total	–	1,057,444	5,939	1,063,383
31 december 2012				
Liabilities as per balance sheet				
Borrowings	–	588,075	–	588,075
Financial leasing	–	3,478	–	3,478
Derivatives	–	–	11,077	11,077
Accounts payables	–	104,488	–	104,488
Other short term liabilities	–	20,000	–	20,000
Total	–	716,041	11,077	727,118

See Note 2 for additional information on what is included in the different categories. Advance payments are excluded from accounts receivable and other receivables because analysis is only required for financial instruments. Accrued social security contributions, etc., are excluded from this table for the same reason.

The company has an unused loan facility amounting to a total of SEK 135 M in the form of a variable credit. Security for the loan consists of a floating charge amounting to SEK 200 M.

Long-term financing consists of a bond loan of SEK 800 M maturing on 26 June 2017. The bond loan is subject to the usual provisions, one of which relates to limits on the Group's net debt in relation to operating profit before interest, tax, depreciation and amortisation (EBITDA), which applies under certain conditions if the Group should take on additional financial liabilities. The loan agreement also contains restrictions regarding any significant change in the ownership structure, the so-called change-of-control, as well as limitation of the dividend. The full terms and conditions for the bond loan are available on the Company's website, www.sobi.com.

Note 31

Employee benefits (pension commitments) after end of employment

The pension commitments are calculated annually on the balance sheet date, based on actuarial calculations. Sobi also has a defined benefit pension plan for the subsidiary in Norway.

The figures below include special payroll tax of reported assets in accordance with IAS 19.

Pension costs are reported under the items: selling expenses, administration expenses and research and development expenses.

In 2013 Sobi dissolved the defined benefit plan which covered around 50 people and the dissolved plan has now been replaced by a defined contribution plan. The defined benefit plan was dissolved by using the plan assets managed by Skandia for the pension obligation for a one-time payment. The Group now has no more obligations for pensions already vested under this plan. The dissolved pension plan yielded a settlement gain of SEK 18.3 M in the second quarter.

Risks

Through its defined benefit pension plan after concluded employment, the Group is exposed to a number of risks, the most common of which are:

Life expectancy assumptions. In most of the pension obligations, the employees covered by the plan will receive life-long benefits and, accordingly, longer life expectancy will result in higher pension liabilities. This risk is the most significant in the case of the Swedish plans where inflation increases result in greater sensitivity to changes in life expectancy assumptions.

Inflation risk. The pension obligations in some of the plans are linked to inflation; higher inflation leads to higher liabilities (even if there is, in most cases, a ceiling for the inflation level to protect the plan against exceptional inflation increases). Most of the plan assets are either not affected by (fixed interest on bonds) or slightly correlated with (shares) inflation, which means that an increase in inflation will also increase the deficit.

Discount rate: a decrease in the interest rate on corporate bonds will have the effect of an increase in the liability of the plan, although this will be partially offset by an increase in the carrying amount of the bonds.

Pension benefits

For white-collar employees in Sweden, the ITP 2 plan's defined benefit pension obligations for retirement pensions and family pensions are insured through Alecta. According to statement UFR3 Classification of ITP plans financed through insurance with Alecta issued by the Swedish Financial Accounting Standards Council, this is a defined benefit plan covering multiple employers. For the 2013 financial year, the Group did not have access to the information necessary to be able to report its proportional part of the plan's obligations this plan, plan assets and expenses, and accordingly, it was been possible to report the plan as a defined benefit plan. The ITP pension plan

insured through Alecta is therefore reported as a defined contribution plan. Premiums for the defined benefit retirement and family pensions are calculated on an individual basis, depending on salary, previously vested pension and the anticipated remaining period of employment. The group's share of the total premiums of the pension plan is insignificant. Expected contributions in the next reporting period for the ITP 2 pension plans insured through Alecta amount to SEK 20.9 M.

The collective consolidation level consists of the fair value of Alecta's assets as a percentage of insurance commitments calculated according to Alecta's actuarial calculation assumptions, which do not correspond to IAS 19. The collective consolidation level will normally be allowed to vary between 125 and 155 per cent. If Alecta's collective consolidation level falls below 125 or exceeds 155 per cent, steps are to be taken to create the necessary conditions to return the consolidation level to the normal interval. In the event of low consolidation, one measure could be to raise the contractual price for taking out a new policy and to increase existing benefits. In the event of a high consolidation level, one measure could be to introduce premium reductions. At the end of 2013 Alecta's surplus in the form of the collective consolidation level amounted to 148 per cent (2012: 129).

The Norwegian pension plan is subject to the Norwegian corporate pension act (Foretaks-pensjonsloven) and the Swedish plan by the Pension Obligations Vesting Act and a consortium agreement. According to the agreement Sobi must allocate enough funds to ensure the future pension obligations.

Both the Swedish and the Norwegian benefit plan is based on final salary.

Changes in the defined benefit pension obligations during the year are as follows:

January–December 2013	Present value of obligation	Fair value of plan assets	Total
At start of year	-144,111	112,878	-31,233
Current service cost	-1,896	-249	-2,145
Interest cost	-1,361	–	-1,361
Gains and losses on settlements ¹	102,945	-84,654	18,291
Remeasurements:			
– excluding amounts included in interest expense/(income)	–	1,393	1,393
– (Gain)/loss from change in demographic assumptions	1,853	-11	1,842
– (Gain)/loss from change in financial assumptions	-416	–	-416
– Experience (gains)/losses	-570	363	-207
Contributions:			
– Employers	5,967	258	6,225
– Plan participants	–	-2,185	-2,185
Exchange differences	1,334	-679	655
Benefit obligation at end of year	-36,255	27,114	-9,141

¹ The defined benefit plan has been replaced with a defined contribution plan. The difference of SEK 18.3 M has not resulted in any cash flow.

>> Note 31, cont.

January–December 2012	Present value of obligation	Fair value of plan assets	Total
At start of year	–140,311	110,265	–30,046
Current service cost	–13,268	–	–13,268
Interest cost/revenue	–4,904	3,845	–1,059
Remeasurements:			
– excluding amounts included in interest expense/(income)	–	–993	–993
– (Gain)/loss from change in demographic assumptions	–10	–56	–66
– (Gain)/loss from change in financial assumptions	–1,339	–643	–1,982
– Experience (gains)/losses	2,280	–	2,280
Contributions:			
– Employers	1,568	14,268	15,836
– Plan participants	12,343	–13,684	–1,341
Exchange differences	–470	–124	–594
Benefit obligation at end of year	–144,111	112,878	–31,233

BREAKDOWN OF THE PENSION OBLIGATION PER COUNTRY	2013	2012
Sweden	–3,903	–19,496
Norway	–5,238	–11,737
Total	–9,141	–31,233

Actuarial assumptions on the balance sheet date

SWEDISH PENSION PLAN	2013	2012
Discount rate, %	3.60	3.00
Expected inflation, %	2.00	2.00
Life expectancy after retirement, men, yrs	19.6	19.6
Life expectancy after retirement, women, yrs	22.8	22.8
NORWEGIAN PENSION PLAN	2013	2012
Discount rate, %	3.70	3.90
Expected inflation, %	2.00	2.00
Life expectancy after retirement, men, yrs	20.4	20.4
Life expectancy after retirement, women, yrs	23.2	23.2

Demographic assumptions

Mortality assumptions are the same as those proposed by the Swedish Financial Supervisory Authority in force from 21 December 2007 for the Swedish pension plans and for the Norwegian plans, the mortality table K2013 BE has been used. As of the balance sheet date, Norway had eight active employees and Sweden had one active employee and one retiree. The retirement age is set at 65 years.

Allocation of asset type

	2013	Quoted in %	2012	Quoted in %
Shares	7,295	100	39,009	100
Bonds	14,023	100	46,842	100
Real estate	796	–	–	–
Other funds	4,740	–	–	–
Other	260	–	27,027	–
Total	27,114		112,878	

Sensitivity analysis

Present value of obligation	36,255
Discount rate –0.5%	39,827
Discount rate +0.5%	33,087
Inflation +0.5%	37,536
Inflation –0.5%	35,139
Life expectancy after retirement –1 year	34,466
Life expectancy after retirement +1 year	37,491

The sensitivity analysis above is based on a change in one assumption only. All other assumptions are held constant. In practice, this is highly unlikely and some changes in the different assumptions may be correlated. When calculating the sensitivity of actuarial assumptions in the defined benefit plan, the same method is used as for calculating the obligation shown in the financial report, i.e., present value of the defined obligation using the so-called projected unit credit method at the end of the reporting period.

Other information

Contributions made to plans for remuneration after terminated employment are expected to amount to SEK 1,661 K (15,322) for the 2014 financial year. The weighted average maturity of the obligation is estimated to be 33.43 years.

Note 32

Other liabilities, long-term

GROUP	2013	2012
Bond	790,775	588,075
Other	4,924	22,115
	795,699	610,190
PARENT COMPANY	2013	2012
Bond	790,775	588,075
Other	–	19,750
	790,775	607,825

The bond loan are presented net of transaction costs from 2013, the comparative figures for 2012 have been adjusted accordingly. Also see note 30 for further information.

Note 33

Provision for pension obligations

	GROUP		PARENT COMPANY	
	2013	2012	2013	2012
Opening balance	31,233	6,719	–	–
Costs incurred	–	–	–	–
Reversed and unused provision	–18,927	–	–	–
Payments	–3,404	–	–	–
Provision this year	239	24,514	–	–
Closing balance	9,141	31,233	–	–

Also see the Group statement of changes in equity and note 31.

	GROUP		PARENT COMPANY	
	2013	2012	2013	2012
Long-term	9,141	31,233	–	–
Short-term	–	–	–	–
Total provisions	9,141	31,233	–	–

Note 34

Accrued expenses and deferred revenues

GROUP	2013	2012
Provision for vacation pay and bonus incl social security contributions	91,026	66,178
Accrued social security contributions	54,830	31,027
Accrued royalty	18,212	3,938
Accrued restructuring cost	6,587	2,858
Accrued manufacturing costs	12,994	30,903
Accrued R&D-costs	31,825	43,566
Accrued Interest	3,213	525
Accrued costs for audit and preparation of statutory accounts	5,254	4,216
Accrued co-promotion	7,259	–
Accrued costs, other	88,118	112,276
	319,318	295,487

PARENT COMPANY	2013	2012
Provision for vacation pay and bonus incl social security contributions	72,751	51,837
Accrued social security contributions	51,367	28,566
Accrued royalty	16,138	3,938
Accrued restructuring cost	6,587	2,858
Accrued manufacturing costs	10,088	22,902
Accrued R&D-costs	31,825	43,566
Accrued Interest	3,213	525
Accrued costs for audit and preparation of statutory accounts	4,188	4,008
Accrued co-promotion	7,259	–
Accrued costs, other	31,079	86,102
	234,495	244,302

Note 35

Pledged assets

GROUP	2013	2012
Contingent liabilities	200,000	200,000
Shares in subsidiaries	–	–
	200,000	200,000

PARENT COMPANY	2013	2012
Contingent liabilities	200,000	200,000
Shares in subsidiaries	–	–
	200,000	200,000

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

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.

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 commercialisation of long-lasting recombinant factor VIII and factor IX haemophilia programs, which was restructured in February 2010. Under the restructured 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 commercialisation 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 North American territory) and all other regions excluding the Sobi territory (the Biogen Direct territory and the Biogen Distributor territory). 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 the manufacturing expenses for clinical supplies of the product, the development expenses for the product from 1 October 2009 through the date on which Sobi is registered as the marketing authorisation holder and certain shared expenses for final regulatory approval and pre-launch activities, and 100 per cent 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 below. In the event that Sobi exercises its option right, amounts under the restructured 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

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 ¹	
			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 ² in the Biogen Distributor territory ³	Net revenue share	10%	50%	Base rate less 15%

¹ 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.

² 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.

³ The Biogen Distributor Territory represents Biogen territories where sales are derived utilising a third-party distributor.

>> **Note 36, cont.**

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 had an ongoing dispute with the Tax Agency regarding the sale of the property Paradiset 14. The Tax Agency expressed to the administrative court, with reference to the tax evasion act, that Sobi should be taxed as if the property had been transferred to its limited partnership at market value. 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 be charged an amount of SEK 232.2 M as revenue in the 2005 tax year. Both the Tax Agency and Sobi appealed to the Administrative Court of Appeal. In their ruling on the 28 November 2013 the Administrative Court of Appeal declared that the basis for levying the tax based on the tax evasion law would be set at SEK 232.3 M. Sobi has decided not to appeal the decision. The company has already reduced its tax loss carry forward by SEK 232.2 M in the tax year 2005. Therefore, no deferred tax asset linked to this amount has been recognised. The company now expects to make a final payment of SEK 0.8 M in 2014. This payment has been accrued in 2013.

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 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, SEK 20 M in 2013 and will pay SEK 21 M in 2014, these are classified as other debt in the balance sheet.

Note 38**Transactions with related parties**

A company related to the chairman of the Board, Orfacare, provides consultation as regards making available, marketing and distribution of drugs for the Swedish Orphan Biovitrum Group in e.g., Switzerland and Austria. Consulting expenses were SEK 3.3 M (2.9) in 2013.

In January 2014 the company prolonged its employment agreement with Bo Jesper Hansen, unrelated to his position as Chairman for the company. The new agreement will enter into effect on 1 May 2014 and is valid until 1 May 2015. See also note 14.

Note 39**Significant events after the reporting date****Sobi moves to Large Cap Index on NASDAQ OMX Stockholm**

On 2 January 2014 Sobi was transferred to the Large Cap category on the NASDAQ OMX Stockholm stock exchange.

Termination of co-promotion activities for Kineret with Savient Pharmaceuticals, Inc.

The US Bankruptcy Court for the District of Delaware has approved the acquisition of Savient Pharmaceuticals, Inc by Crealta Pharmaceuticals LLC. The Court rejected the agreement between Savient and Sobi for co-promotion of Kineret in the US as per January 31, 2014. The agreement will therefore be terminated as per the same date and Sobi will assume all promotion activities previously performed by Savient.

Health Canada approves Alprolix™

Sobi's partner Biogen Idec announced that Health Canada approved Alprolix (Coagulation Factor IX (Recombinant), Fc fusion protein), rFIXFc, for the control and prevention of bleeding episodes and routine prophylaxis in adults, and children aged 12 and older, with haemophilia B. Alprolix is the first approved long-acting haemophilia B therapy and is indicated to prevent or reduce the frequency of bleeding episodes with prophylactic injections scheduled once weekly or once every 10–14 days.

Kiobrina pivotal phase 3 study did not meet primary endpoint

Topline data from the company's pivotal phase 3 study of its enzyme therapy Kiobrina (rhBSSL - recombinant human Bile Salt Stimulated Lipase) showed that rhBSSL did not meet its primary endpoint, growth velocity measured after four weeks of treatment, with no statistically significant improvement in growth velocity in preterm infants treated with rhBSSL compared to placebo. The financial and operational effects of the results are still being investigated.

US FDA approves Alprolix™

Sobi's partner Biogen Idec announced that the US Food and Drug Administration (FDA) approved Alprolix (Coagulation Factor IX (Recombinant), Fc fusion protein), the first recombinant, DNA derived haemophilia B therapy with prolonged circulation in the body. Alprolix is indicated for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with haemophilia B.

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 8 May 2014, for approval.

Stockholm, 1 April 2014

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 1 April 2014

PricewaterhouseCoopers AB

Mikael Winkvist
Authorised Public Accountant

Auditors' 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 2013. 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 2013 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 2013 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 2013.

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 1 April 2014
PricewaterhouseCoopers AB

Mikael Winkvist
Authorised Public Accountant

Annual General Meeting 2014

Annual General Meeting 2014

Swedish Orphan Biovitrum AB will hold its Annual General Meeting on Thursday 8 May 2014 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, 2 May 2014. Shareholders must notify the company of their intention to participate no later than Friday, 2 May 2014 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 by Friday 2 May 2014. Shareholders who wish to register their shares in their own names should inform the nominee well in advance of this date. Such registration may be temporary.

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 2014

Q1 Interim Report, January–March, and Annual General Meeting	8 May 2014
Half Year Interim Report, January–June	18 July 2014
Nine Months Interim Report, January–September	30 October 2014

The annual report can be downloaded in pdf format from www.sobi.com, as can previous annual reports, interim reports and press releases.

Contact details

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Telephone: +46 8-697 20 00
Fax: +46 8-697 23 30
Website: www.sobi.com

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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