

Read more!

Patients guide us

Rare

diseases



CEO and President Geoffrey McDonough summarises the year.

→ page 6

Pioneering in haemophilia

Our long-acting coagulation factors in development will once approved offer the possibility of a step forward in the standard of care for people with haemophilia.

page 24

Growing with partners

Our integrated platform enables access to niche medications for patients in Europe.



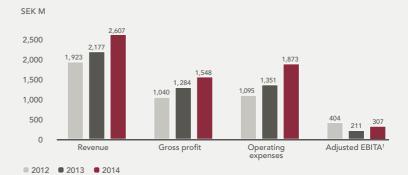
The financial year in brief

- Total revenues 2014 were SEK 2,607 M, an increase of 20 per cent.
- Product revenues were SEK 1,989 M, an increase of 28 per cent.
- EBITA amounted to SEK -43 M. Figures for 2014 include write-downs for Kiobrina® and Multiferon® totalling SEK 350 M.
- Adjusted EBITA, excluding write-downs realting to Kiobrina and Multiferon, was SEK 307 M.
- The gross margin remained stable at 59 per cent.

KEY FIGURES

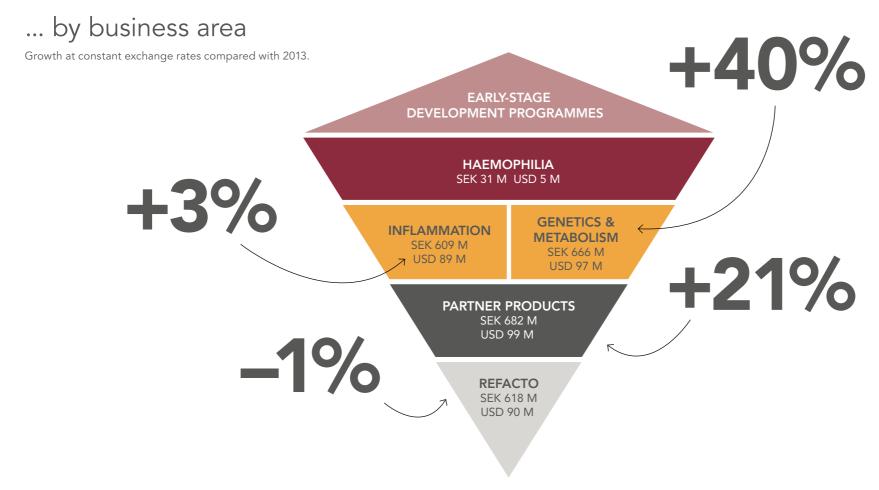
SEK M	2012	2013	2014
Total revenues	1,923	2,177	
Gross profit	1,040	1,284	
Gross margin, %	54	59	
Operating expenses	1,095	1,351	
EBITA	367	211	
Adjusted EBITA	404	211	307
EBIT	-55	-67	-325
Profit/loss for the year	-101	-93	
Earnings per share, SEK	-0.38	-0.35	
Cash flow from operations	406	186	
Equity per share, SEK	18	18	
Equity assets ratio, %	77	73	
Dividend	0.0	0.0	
No. of employees	514	546	589

The figures for 2014 include write-downs of SEK 325 M for Kiobrina and SEK 25 M for Multiferon.



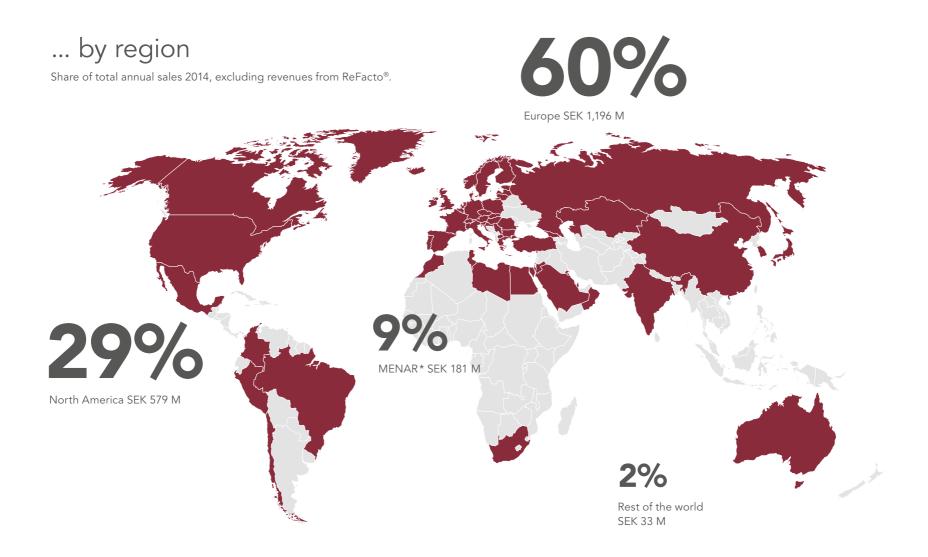
¹ The figures for 2012 include revenues of SEK 308 M from the sale of co-promotion rights to Pfizer.

Our **revenues**...



Total revenues	2013	2014
SEK M	2,177	2,607
USD M	317	380

Exchange rate USD 1 = SEK 6.8577 (average rate for the period).



^{*} Middle East, North Africa and Russia

Business highlights 2014



FIRST QUARTER

- US Food and Drug Administration (FDA) approved Alprolix[®] [Coagulation Factor IX (Recombinant), Fc Fusion Protein].
- Sobi presented Kiobrina Phase 3 top-line results; primary endpoint not met.
- Cometriq® approved in Europe for the treatment of progressive, unresectable, locally advanced or metastatic medullary thyroid carcinoma.
- Health Canada approved Alprolix.
- Sobi received EURORDIS Company Award 2014.

SECOND QUARTER

- Sobi initiated direct sales of Orfadin® in North America.
- Sobi filed for EU approval of Xiapex® for Peyronie's disease.
- Sobi and TiGenix entered partnership for the commercialisation of ChondroCelect.
- Biogen and Sobi published positive topline results from Kids A-LONG Phase 3 paediatric trial for Eloctate[®] [Antihemophilic Factor VIII (Recombinant), Fc Fusion Protein].

- US FDA approved Eloctate.
- Biogen and Sobi announced their intent to donate 1 billion international units of haemophilia clotting factor therapy for humanitarian aid programmes.
- Kirsti Gjellan appointed Senior Vice President Manufacturing Operations.
- Sobi named Company of the Year at the European Mediscience Awards 2014.

Q2



Enabled regulatory submission in the EU.



THIRD QUARTER

- Sobi expanded Haemophilia development portfolio by electing to include a potentially longer-acting haemophilia A candidate (rFVIIIFc VWF-XTEN Heterodimer) in collaboration agreement with Biogen.
- Sobi opened new North American office in Waltham, Massachusetts, USA.

Exclusive commercialisation and development rights for Elocta transferred to sobi

FOURTH QUARTER

- Sobi received positive opinion by the Committee for Medicinal Products for Human Use (CHMP) regarding Xiapex for the treatment of Peyronie's disease, which was followed by approval by the EU Commission in January 2015.
- Sobi exercised opt-in right for Elocta™ (rFVIIIFc).
- Marketing Authorisation Application (MAA) for Elocta filed and validated for review by European Medicines Agency (EMA).
- Orfadin approved in Japan.



CEO's statement

2014 was a pivotal year for Sobi. The commercial portfolio delivered a strong performance, we made some tough decisions regarding our R&D portfolio, and achieved critical milestones in preparation for the potential launch of Elocta and Alprolix, our long-acting factors for the European haemophilia market.

At Sobi we are inspired to pioneer a world in which patients with rare diseases are diagnosed at birth and receive effective and sustainable therapy, enabling them to live full and healthy lives. We aim to develop new medicinal products and therapies and, through close dialogue with relevant stakeholders such as authorities, healthcare providers and patient organisations, to build a sustainable model for ensuring that these products reach patients over a lifetime. Much has been accomplished in the rare disease field in recent years, but there is still much to be done. In Europe and North America alone there are an estimated 60 million people who suffer from approximately 7,000 known rare diseases. Yet there are only about 200 treatments available and even these do not reach all of those in need. It is very clear to all of us here that our mission requires a long-term approach.

Strong performance

In 2014, sales rose 20 per cent, with positive contributions from all parts of the business. ReFacto once again delivered stable earnings. Sales of our main products, Kineret® and Orfadin, rose 8 and 50 per cent, respectively, with the strong performance of Orfadin deriving from taking direct responsibility for direct sales in North America. We also substantially advanced our presence and capabilities geographically, especially in North America, the Middle East and North Africa during the year.

We are also growing in terms of product portfolio. In 2014, our Partner Product portfolio had sales growth of 25 per cent, with seven product launches and continued development of the depth and duration of our partnerships. We have worked to take greater responsibility for the products on behalf of

our partners. One example is our partnership with Auxilium Pharmaceuticals Inc. where we collaborate on the development and commercialisation of Xiapex. This product, intended for treatment of Dupuytren's contracture – a connective tissue deformity of the hand – has demonstrated potential also for the treatment of Peyronie's disease, for which it was approved in Europe in early 2015.

Difficult decisions

The development of medicinal products involves continuous risk, and sometimes involves difficult decisions. In 2014, we made decisions to put our phase 1 study of SOBI002 on clinical hold, and not to proceed with an application for an expanded therapeutic indication for Kepivance®. In addition we discontinued our development of the enzyme replacement therapy Kiobrina for preterm infants. Our phase 3 study to evaluate the impact on the growth and development of preterm infants did not generate the expected results. Our comprehensive and well-conducted study will nevertheless be of great benefit to further research in neonatology. We have gained cuttingedge knowledge that we will use to remain engaged in the field in the future.

Key milestones for Haemophilia

Several critical milestones were achieved in 2014 for our haemophilia programmes, which are being developed in partnership with Biogen. Several authorities, including the US Food and Drug Administration (FDA), approved Eloctate for the treatment of haemophilia A, and Alprolix for haemophilia B. Both products were approved in Canada, Australia and Japan. Positive data from the Kids A-LONG phase 3 study in children with haemophilia A under 12, enabled Biogen to

Positive contributions from all parts of the business.



submit a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA). In November, we opted in and exercised our right to take over the final development and commercialisation of Elocta, which will be the trade name for Eloctate in the EU, in our territory. As a result, we are now in the midst of an exciting pre-launch phase. Elocta will open the door to a market that is ten times larger than our current annual sales, with a product that may positively impact the lives of a significant community. We are preparing for the launch in many ways – strengthening the organisation by recruiting the

best people in the field, engaging in close dialogue with authorities, organisations representing people with haemophilia and other stakeholders, and ensuring that all resources are in place to ensure the earliest possible access for those who could potentially benefit from this new treatment.

We are also in the initial phase of launching a global donation programme in partnership with Biogen and the World Federation of Hemophilia, an initiative which is aimed at providing a more predictable, sustained supply of factor VIII and IX for people with haemophilia in the developing world.

OUTLOOK 20151

For 2015, Sobi expects total full-year revenues to be in the range of SEK 2,800 M to 3,000 M, and the gross margin to be in the range of 58 to 60 per cent. Operating costs are projected to increase as the company continues to prepare for the planned launch of Elocta. Sobi expects EBITA to be in line with the adjusted 2014 level. The outlook for 2015 is based on constant exchange rates and excludes revenue from the potential European launch of Elocta.

¹ The outlook was first published in the 2014 Q4 and FY report on 19 February 2015.

In collaboration with Biogen we have also commenced development of a next-generation long-acting factor for the treatment of haemophilia A utilising the XTEN technology platform. This is an exciting way forward in the treatment of haemophilia, which could yield an even longer-acting replacement factor VIII product and is an indication of our long-term commitment to the field.

Continued development

It is clear that our company will intensify its focus on haemophilia in the coming years. However, Sobi is constantly evolving in a market where there still remains a great need for change and progress. We will continue to create new partnerships to develop and provide medicinal products for other rare diseases aimed at restoring vitality and hope to young lives. Our journey in 2014 shows that we are moving in the right direction. We now have a strong platform from which to launch our haemophilia products and upon which, in turn, we can build new programmes for the future.

Geoffrey McDonough

This is **Sobi**

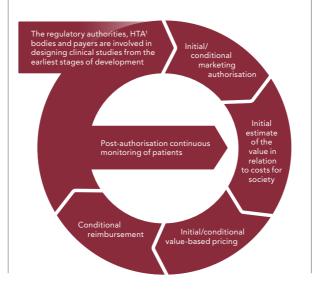
Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is focussed on rare diseases and niche indications, with products owned on a proprietary basis or licensed from partners. Our late-stage development pipeline includes two projects in the field of haemophilia.

Who

Committed to people with rare disease

In Europe and North America alone, there are approximately 60 million people who suffer from some of the approximately 7,000 known rare diseases, the majority of which still remain without treatment. Our strong commitment to improving the quality of life for patients with rare diseases guides us throughout our operations. We strive to be pioneers in creating a world where patients are diagnosed at birth, receive effective and sustainable therapy, and go on to live full and healthy lives within the boundaries of their disease.

Read more on page 10

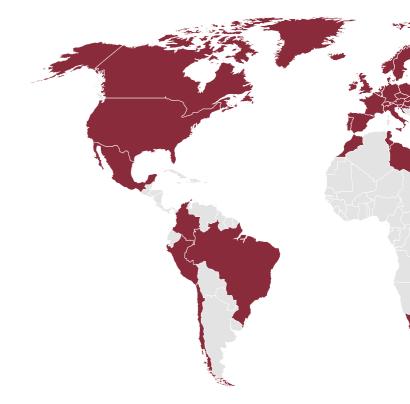


¹ Health Technology Assessment

Where

Growing international presence

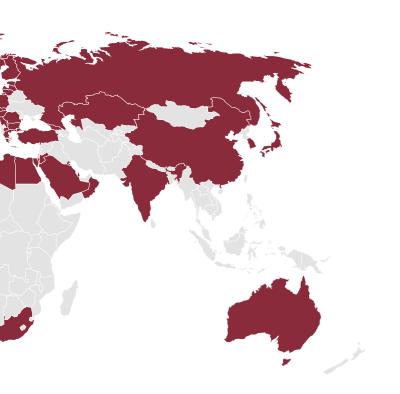
We are expanding our presence. Today, we are represented all over the world. Europe accounts for the largest proportion of sales. In 2014, we established new affiliates in Austria and Switzerland, and increased our presence in the Middle East. We also inaugurated our new North American office in



Waltham, Massachusetts, USA, one of the world's largest biotechnology hubs.

Our organisation spans offices in 24 countries, delivering therapies to patients in 67 countries across the globe.

Read more on page 16

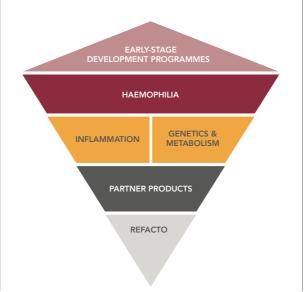


What

Markets a growing portfolio

We are dedicated to rare diseases and have a diversified and growth-oriented commercial product portfolio. Our key therapeutic areas are Inflammation, Genetics & Metabolism and Haemophilia. In partnership, we also market niche and specialty pharmaceuticals in Europe, the Middle East, North Africa and Russia. In addition, Sobi manufactures the drug substance for the haemophilia product ReFacto for the global market.

Read more on page 22

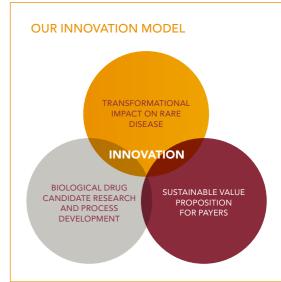


How

Building the future

Our research and development ranges from late-stage pre-clinical research to the development and commercialisation of biologics. It is based on a model in which biological research and process scale-up are integrated into a Patient and Customer-Centric approach to Commercialisation (PC3). By involving relevant stakeholders throughout the innovation process, from the initial generation of an evidence base, through to patient access to therapy and reimbursement, we co-create sustainable solutions for rare disease patients.

Read more on page 38



Strategic priorities

A pioneer in rare diseases, Sobi is well-positioned to build value for patients, society and shareholders in a collaborative and sustainable way.

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 focussing 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 the needs of both patients and society.

Drawing on 35 years of experience in developing biopharmaceutical products (biologics) and 25 years of experience in 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.

Value drivers

- Diversified commercial portfolio focussed on improving cash flow and profitability;
- Focus on efficiently commercialising our proprietary innovative medicines for rare disease patients globally; and
- Business model oriented to building value through partnerships from global early-stage biologics development to late-stage specialty distribution in Europe.



OBJECTIVES IN 2015

- 1. Continue to build an engaged, learning and high-performing organisation.
- 2. Prepare for the successful launch of Elocta.
- 3. Grow portfolio in Europe.
- 4. Build operating momentum for the North American business.
- 5. Increased focus on preclinical development programmes.

LONG-TERM OBJECTIVE

Sobi aims to become a leading international company focussed on biopharmaceuticals for the treatment of rare diseases.

AUTHORISATION AND REIMBURSEMENT OF MEDICINAL PRODUCTS



Pharmaceutical companies have traditionally followed linear models, where each developmental stage of a therapy has been conducted in an isolated and sequential manner, by different parts of the company. Changes in the external environment have required modification of this model, which is now becoming more of a cyclical and ongoing process, starting from the earliest stages and continuing after the therapy is available in the market and to patients. This is a novel dynamic way of working that requires continuous contact with regulators, payers, patients, academics and all other stakeholders involved in the process, as well as an integrated approach from relevant parts of the company throughout every phase of a product's life cycle.

Sobi's business model is based on an integrated and agile approach to product life cycles through cross-functional expertise, cooperation and collaboration – all the way from pre-clinical development through to regulatory evaluation, assessment by healthcare authorities and, ultimately, commercialisation through successful inclusion in local healthcare systems. It is important to Sobi that all stakeholders are involved in all stages of the development process in order to deliver the most meaningful value to both the patient, society and our shareholders.

Business model

¹ Health Technology Assessment

The **patient** journey

We can envision a world in which treatment can be applied to a disease at birth, thereby changing a person's life from that day forward, and where access to the treatment is ensured throughout a person's life. This is the world we want to co-create with the rare disease community.

The power and beauty of Sobi is that we are already living in this world - our treatment of patients suffering from Cryopyrin-associated autoinflammatory syndrome (CAPS) with Kineret is proof of this. Many of CAPS patients have been living all of their lives with Kineret and do not remember the pain, rash and inflammation caused by their disease. This is also true for Hereditary Tyrosinaemia type-1 (HT-1) and Orfadin, where screening is available in many countries so that babies are being treated in the first few weeks of their lives.

Sobi's vision is real. We are not just participating, but contributing, creating and pioneering a world where rare disease patients are diagnosed at birth, receive effective and sustainable therapy, and go on to live full and healthy lives within the boundaries of their disease.

When we ask ourselves why we are working together, the stories that patients tell provide us with the answer.



CHILDHOOD

CAPS encompasses a group of rare autoinflammatary diseases that affect approximately one person in one million individuals worldwide. NOMID is the most severe form of CAPS. After a year of doctor visits, hospital stays, and uncertainty, Quinn was diagnosed with NOMID. Read more about CAPS and NOMID on pages 30-31.

One in a million

DIAGNOSIS AT BIRTH

As patients are being identified earlier, thanks to screening programmes, many are now diagnosed as newborns. For patients with HT-1 this allows for earlier intervention with Orfadin. The need for a liquid formulation of Orfadin to deliver exact doses in the treatment of small children has therefore been identified. Read more on pages 32-33.



EARLY TREATMENT

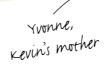
An estimated 350 million people in the world are living with a rare disease, many of whom never get the right diagnosis. And among those who do receive a diagnosis, it is often later in life. Sobi's vision is that the diagnosis should be made early and treatment applied to a disease at the earliest possible stage because many rare diseases cause irreversible and progressive damage if left untreated.

DevelopAKUre

COLLABORATION

Sobi is involved in a unique collaboration DevelopAKUre, led by a consortium of 13 partners across Europe, to develop what we hope could be the first ever treatment for Alkaptonuria (AKU) or Black Bone Disease.

Adolescence





"Life sometimes has different plans and you make the most of it."

KEVIN

Twenty years ago, before treatment was available, less than one third of children born with HT-1 lived past their second birthday¹. Today, a closely managed diet and medical treatment can change the course of this rare disease. With screening and effective treatment, patients can look forward to leading a very different life than that possible in the past.

Kevin is 14 years old and living with HT-1. Entering into his teens, Kevin is taking more responsibility for monitoring his diet and treatment, preparing for an adult life with HT-1 – something few could dream of a generation ago.

¹ van Spronsen FJ, Thomasse Y, Smit GP, et al. Hepatology. 1994;20(5):1187-1191.





PATIENT-ACCESS-CENTRIC RESEARCH AND DEVELOPMENT

The medical needs of patients are always central to Sobi's research and development (R&D) programmes. These include all aspects of commercialisation, from the initial generation of an evidence base for registration, to patient access to medication and reimbursement throughout the entire product life cycle. Sobi's R&D ranges from late-stage pre-clinical research to the development and commercialisation of biopharmaceuticals.

Mid-life

Mature adulthood

Cometriq

MID-LIFE

Cometrig has been approved for the treatment of patients with advanced medullary thyroid cancer unsuitable for surgery, who have few other treatment options. It was approved in the EU in March 2014 for this rare disease.

MATURE ADULTHOOD

Dupuytren's contracture affects 3 to 6 per cent of the adult population in northern Europe. It is a progressive disorder that affects the palm of the hand by forming a rope-like collagen cord that causes the fingers to be drawn in toward the palm of the hand in a fixed position, hindering normal function. See page 35.







LIVING A FULL LIFE

Gaining reimbursement for products is a key part of ensuring that patients get access to treatment. Through cooperation with relevant stakeholders, Sobi was successful in its efforts to secure reimbursement in Hungary and Romania for Yondelis, a treatment for advanced stages of the rare diseases soft-tissue sarcoma and ovarian cancer.

THE HAEMOPHILIA COMMUNITY

Sobi has a long tradition in haemophilia research and treatment, and current activities include two late-stage biological therapies in development and production of the drug substance for ReFacto. As part of the haemophilia community we have a commitment that drives us towards innovations in the treatment of haemophilia, with the simple goal to help give people with haemophilia choices that will help them live the lives they want.

Geographic expansion

Sobi is growing in existing markets with new products and therapies, and in totally new markets. Sobi now has presence in 24 countries, providing treatments to patients all over the world.

INVESTING IN A KEY MARKET

Investing in the US and Canadian markets is key to Sobi's global expansion strategy. Sobi established its North American subsidiary in 2012. On 22 September 2014, Sobi inaugurated its new North American office in Waltham, Massachusetts, USA, one of the world's largest biotechnology hubs. Maintaining an office in Massachusetts provides opportunities for collaboration with some of the best research institutions and universities in the world.

> 2014, Sobi North America had 43

our new North American office.



The **orphan drug** market

Orphan drugs are developed to treat diseases that are rare, often chronic, severely debilitating and potentially life-threatening. 80 per cent of rare diseases have a genetic origin, so they commonly affect children.

Orphan drugs are researched, developed, manufactured and made available in very small volumes compared with medicinal products for more common diseases. This is because the diseases are rare and only affect a small number of people. Most rare diseases still have no treatment.

The history of orphan drugs is one of shared responsibility and of the rare disease community working together to achieve legislation and incentives to support the research and development of treatments. The US Orphan Drug Act was signed in 1983, and was followed by similar legislation in Japan, Australia and the EU, among others. Prior to the creation of the legislation, only a handful of therapies were available to treat rare diseases. Since then, several hundred orphan drugs have been developed and made available to patients who need them. But a great need still exists. There are approximately 7,000 recognised rare diseases, the majority of which still remain without treatment.

That said, in 2014, the European Medicines Agency (EMA) recommended more new orphan medicines for authorisation in the EU than ever before; 17 out of a total of 82 new approved medicines were orphan drugs¹. Similarly, the U.S. Food and Drug Administration (FDA) approved 41 new treatments in 2014, 15 of which were orphan drugs². A key aspect remains to secure that patients can have timely and sustainable access to these newly approved therapies.

The patients

A rare disease, by definition, only affects a small number of patients who may be geographically widespread. Ideally, patients are diagnosed early in their lives and treated by specialist physicians in specialist centres. Since prompt treatment can play a major role in attenuating the progression of the disease, early diagnosis is key, as is early and continued availability of treatment.

Sobi wants to secure that this is the case. Therefore, we need to be sustainable as a company and as part of the healthcare systems. There has been made a political comittment in the EU that states that patients suffering from rare conditions should be entitled to the same quality of treatment as other patients. This means that Sobi and local healthcare systems need to recognise that rare disease patients - while rare - should not be treated as exceptions or aberrations, but as an integral part of our shared commitment. This can only be achieved by a concerted, multi-stakeholder dialogue and engagement, with an objective of finding shared solutions on a sustainable basis.

In the field of rare diseases, patient organisations and patients themselves may often be the best experts in their diseases. Sobi partners with, and supports, a wide range of patient representative organisations, nationally and regionally, to achieve our common goals of advancing the best outcomes for people with rare diseases. We achieve this through research and creating awareness, as well as ensuring that patients have timely and reimbursed access to the treatments they need, as well as educational and support services.



COLLABORATIVE DIALOGUE

Sobi prospectively seeks and fosters opportunities for collaborative dialogue to create sustainable frameworks for including rare disease treatments in healthcare systems. One example is the dialogue provided by the Medicine Evaluation Committee (MEDEV) group of payers, who have established a dedicated task force to explore if the European Commission's Mechanism of Coordinated Access (MoCA) recommendations³ can be developed into a meaningful process for evaluating orphan drugs on a collaborative basis. Sobi has been an active participant in this process and is committed to continuing this work.

In North America, our teams are seeking similar opportunities to make rare disease treatments available to paediatric and adult patients in a collaborative, modern and forward-looking way.

¹ http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_ and_events/news/2015/01/news_detail_002247.jsp&mid=W C0b01ac058004d5c1

² Associated Press, 2 January 2015

³ http://ec.europa.eu/enterprise/sectors/healthcare/ competitiveness/process_on_corporate_responsibility/ platform_access/index_en.htmComplex situation in Europe

An integrated approach

A close collaboration between all stakeholders is a crucial element of securing the best outcomes for patients and their families.

Sobi believes that, if the ultimate aim is to create sustainable solutions so that new medicinal products actually reach the patient, it makes most sense to seek these solutions collaboratively and as early as possible in the development of a new therapy. We are committed to understanding and supporting the patient needs at all stages of the patient journey, and engaging with healthcare professionals, academics, patient associations, Health Technology Assesment (HTA) bodies and payers to ensure that our products are developed and continuously supported in a way that give the patients the best chance for timely access and sustained benefit. We refer to this as Patient and Customer Centric approach to Commercialisation (PC3).

Collaborating cross-functionally to give early input to the development programmes through continuous engagement with various stakeholders provides an

WHAT ARE RARE DISEASES AND ORPHAN DRUGS?

The definition of a rare disease and an orphan drug, intended to diagnose, prevent or treat rare diseases, varies from region to region. In the EU, a disease is defined as rare when it affects fewer than 1 in 2,000 individuals. To benefit from orphan status, the disease also has to be life threatening or chronically debilitating. In the US, a disease is defined as rare when it affects fewer than 200,000 Americans. Some examples of severe or life-threatening rare diseases are haemophilia, ovarian cancer and rare metabolic disorders, such as Hereditary Tyrosinaemia type 1 and Urea Cycle Disorders.

opportunity for early assessment of the incremental value that our programmes may add to patients and society. Where patients, expertise and experts are both rare and geographically scattered, this approach is vital to success. Sobi enables this through our principal way of working, which takes a fully integrated and patient-oriented approach across the entire lifecycle of the portfolio. We believe that this supports our vision and mission and also creates a solid basis to increase predictability within our business.



Ensuring that the patient voice is heard

Peter L. Saltonstall, President and CEO of the National Organization for Rare Disorders (NORD), an umbrella organisation in the US that advocates on behalf of people with rare diseases.

How has the market for orphan drugs developed in the US?

Since the foundation of NORD in 1983, when the Orphan Drug Act was passed by the US Congress, about 450 drugs have been approved for rare diseases. The US Food and Drug Administration (FDA) has been flexible and responsive to the needs of patients when approving new treatments. In 2014, 35 per cent of the drug products approved by the FDA were orphan drugs. The FDA has made clear that while it seeks to be flexible, it will only approve a drug for a rare disease if it is proven to be both safe and effective, which is the standard for all new drugs. We try to work closely with the FDA in expediting the approval of new drugs and in educating FDA staff on the special needs of patients with rare diseases.

Can anything else be done to facilitate the process?

One method is to further develop the FDA's partnership with the European Medicines Agency (EMA). In partnership with the European Organisation for Rare Disorders (EURORDIS), we encourage close contact between the FDA and the EMA around the approval process. Each agency must, of course, maintain its own independence, but close communication helps everyone, including patients who want access to new medicines as quickly as possible.

Are there any other issues to consider in the US?

There are many things that we need to keep in mind in our efforts to improve access to treatments for rare diseases. In the US, individual states have autonomy with regard to how they reimburse for certain treatments. A patient's health insurance might provide adequate coverage in one state, but not in another. We are doing everything we can to ensure that patients have access to the drugs they need.

What are you doing as a national advocacy organisation?

There are about 30 million Americans who live with one or more of the 7,000 known rare diseases. So our challenge is vast. To reach patients with all of the new treatments that have been approved, we have begun to work more locally. In every state in which we are represented, we work to establish partnerships with government agencies, organisations and businesses to ensure that the patient voice is heard. We also conduct Patient Assistance Programs that provide patients who are uninsured or underinsured with access to treatment. These programmes are sponsored by drug companies. NORD pioneered these kinds of programmes and is the leading provider of them. Partnerships with companies such as Sobi are a key factor in this development.



A diverse growing business platform

Sobi markets a growing portfolio of 50 products, including 44 partner products. We also manufacture the drug substance for ReFacto on behalf of Pfizer.

OUR 20 LARGEST BRANDS

Aloxi®

Ammonaps®

Ammonul®

Betapred™

ChondroCelect

Collatamp®

Cometria

Defibrotide

Erwinase®

Ferriprox®

Fosinopril

Kepivance

Kineret

Megestrol

Orfadin

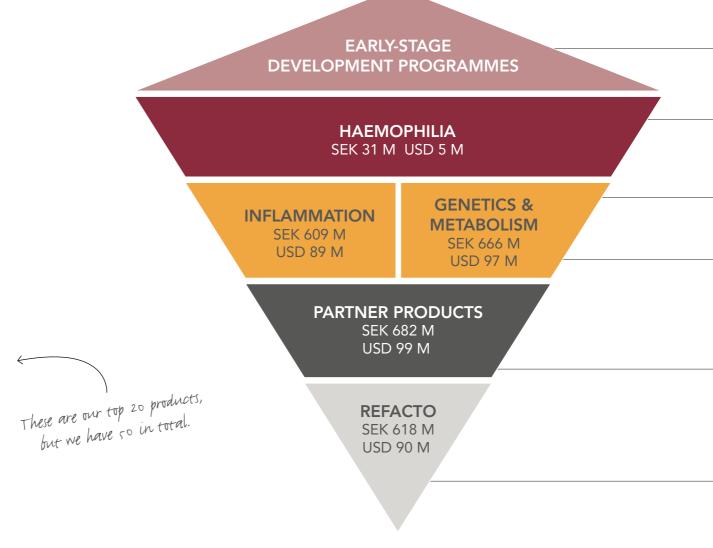
Ravicti®

Ruconest®

Willfact®

Xiapex

Yondelis



2014 revenues. Exchange rate USD 1 = SEK 6.8577 (average rate for the period).

EARLY-STAGE DEVELOPMENT PROGRAMMES

Sobi's innovation model is based on three fundemental questions; Is there a patient need? Is it possible to develop a treatment? Will the treatment create value for the patient and healthcare system? Read more on pages 38-41.

HAEMOPHILIA

Sobi's development of two long-acting coagulation factors, together with partner Biogen, offers the potential to significantly improve the standard of care for people with haemophilia. Read more on pages 24-29.

GENETICS & METABOLISM

Sobi provides treatments for certain inborn errors of metabolism that, if left untreated, can be life-threatening. Read more on pages 32-33.

INFLAMMATION

Sobi's Inflammation business area is engaged in providing a treatment called Kineret for inflammatory and auto-inflammatory diseases. Read more on pages 30-31.

PARTNER PRODUCTS

Sobi offers small and mid-sized pharmaceutical and biotechnology companies a cost-efficient and integrated platform for the commercialisation of their products in Europe, the Middle East, North Africa and Russia. Read more on pages 34-36.

REFACTO

Sobi has been manufacturing the drug substance for the haemophilia product ReFacto for the global market for Pfizer for many years. Read more on page 37.

Developing a leading haemophilia platform

Sobi's delelopment of two long-acting coagulation factors together with partner Biogen offers the potential to significantly improve the standard of care in haemophilia. The ongoing commercialisation and development of the Elocta/Eloctate (rFVIIIFc) and Alprolix (rFIXFc) haemophilia programmes is a milestone not only for Sobi and Biogen, but also for people with haemophilia all over the world. This is the first time in almost 20 years that a new type of treatment is being developed. During 2014, Sobi continued to develop the infrastructure and capabilities required for the potential launches in Sobi's territory; Europe, North Africa and Russia as well as parts of the Middle East.

Long-acting clotting factor therapies have the potential to improve clinical outcomes due to their longer half-life, which means that they can potentially provide increased protection against bleeding episodes in prophylactically treated patients, possibly even with fewer injections. We anticipate this, once the products are approved, will increase the treatment choices for people with haemophilia as well as their quality of life. Surveys conducted by Sobi among

European haemophilia caregivers show that reduced dosing frequency and good efficacy profiles are ranked as two of the most desirable improvements compared with conventional therapies.

Conventional therapies

In Sobi's territory recombinant products account for 57 per cent of the current market and plasma products for the remaining 43 per cent¹. Over the past decade, there has been a gradual shift from plasma-based clotting factors to recombinant clotting factors; and from ondemand treatment of bleeding episodes to preventative, prophylactic regimes. Conventional clotting factors require frequent injection regimes, which usually involve three injections per week for prophylaxis. This can be challenging, particularly for small children, when the burden of the treatment becomes too high. This may create "gaps" where people are not well protected.





CURRENT ESTIMATED MARKET VALUE¹



The current estimated market value in Sobi's territory is USD 3.7 billion.

¹ Marketing Research Bureau, 2011 includes all patients (mild, moderate or severe).



Brian O'Mahony, Chief Executive of the Irish Haemophilia Society and the President of the European Haemophilia Consortium (EHC)

Involving patients for better outcomes

What are the key issues that are top of mind for you and for the haemophilia community today?

Security of supply and also safety is always going to be important for the community, and although we have had an excellent safety record over the past 20 years, the risks posed by inhibitors is a continuing issue. Equal access to treatment across Europe has also become increasingly important, because this still varies a lot from country to country. In addition, with shrinking health budgets, health economics

and pricing is becoming increasingly important. Patients can no longer assume that they will receive the quantity of treatment that they need without economic considerations. This could have strong healthcare access implications.

New innovations such as long-acting factors and, eventually, gene therapy will offer great possibilities, but we are very concerned that the treatments will not reach everyone who needs them. Just because something is available doesn't mean that it is being used. Plasma and recombinant-based treatments have been available for more than 20 years, but there is still a great difference in the standard of care across Europe, and many patients are receiving nowhere near what they need to secure optimal outcomes.

One of the current focus areas for the European Haemophilia Consortium (EHC) is tenders and procurement procedures. Why is that and what are the critical aspects that need to be addressed?

I have been an advocate of properly organised national tender systems for many years. To be successful, the process has to involve both clinicians and patient representatives, because this provides a holistic view of available treatments. Governments care about cost of treatment, and cost must be considered, but safety, quality and efficacy must come first.

The EHC recently performed a European-wide study which showed that not only do you get better outcomes by involving patient representatives and clinicians, but you actually also lower the total cost of haemophilia treatment. That in itself should interest governments and healthcare systems. It's what we have been saying for years, but it is great to have data to prove it.

What are your expectations of companies, authorities, healthcare providers and other stakeholders engaged in the haemophilia community for the future?

Cooperation. Only through mutually respectful partnerships can we understand where each stakeholder is coming from and together form the future for the community. If we give mixed messages, we cannot expect decision-makers to reach the best outcomes on behalf of the community. There are always going to be challenges; availability of treatment, safety, costs, questions about orphan market exclusivity etc. Open and honest dialogue is key.

Collaboration on post-market surveillance is one example of how we can move forward together. We cannot just say that haemophilia treatment works, we need to prove it.

We have come a long way in the past decades, but we should never become complacent. When you achieve something you should stop and celebrate, but then you move on to the next step. There is still a lot to do to ensure adequate and equal treatment across Europe and beyond.



WANT TO KNOW MORE?

Scan the QR-code to see an interview with Brian O'Mahony.



Sobi's team of haemophilia experts

Sobi has intensified efforts to develop the infrastructure and build the capabilities required to support the successful launch of Elocta in Sobi's territory. The organisation includes best in class subject matter experts, clinical academic specialists and leaders as well as functional experts in commercialisation and patient access. In addition resources are being continuously developed in Sobi's regions throughout the EMENAR territory (Europe, Middle East, North Africa and Russia).

The current estimated market value for haemophilia A and B in Sobi's territory is USD 3.7 billion. Haemophilia A accounts for the largest proportion, approximately USD 3.3 billion.

Patient-centric approach

Sobi has extensive experience in producing, distributing and marketing orphan medications for rare diseases in Europe. The final drug product for Elocta will be manufactured by Biogen in the US and, if approved in the EU, transported to Europe, where Sobi will assume responsibility for packaging and distribution to markets in the Sobi territory. In the process of bringing the product to Sobi territory, Sobi is proactively engaging with relevant national and international stakeholders such as patient organisations, healthcare providers, authorities and payers.

Sobi engages with umbrella patient organisations both globally and in Europe, as well as local organisations respresenting people with haemophilia. This work spans European, Middle Eastern, North African and Russian haemophilia organisations and includes the World Federation of Hemophilia (WFH) and the European Haemophilia Consortium (EHC).

About Sobi's haemophilia product candidates

Elocta and Alprolix are investigational recombinant, clotting factor replacement therapies for haemophilia A and B, respectively. They are based on Fc fusion technology, which uses a naturally occurring process that slows the breakdown of IgG1 (a protein normally found in the body) and cycles it back into the bloodstream. This technology is believed to enable the factor proteins to remain active in the body for a longer period of time. Fc fusion technology has been used for more than 15 years, and Sobi and Biogen are the only companies to apply the technology for the treatment of haemophilia.

Compared with most other markets for rare diseases served by Sobi, the haemophilia market is in terms of size and market value - larger and more competitive, with several treatment options available for people with haemophilia today. In addition to Sobi and Biogen's long-acting products, Baxter, Novo Nordisk, CSL Behring and Bayer are also engaged in research and development of new treatments.

Sobi had no direct sales of haemophilia products in 2014. The revenue generated derived from royalty payments from sales in Biogen territories and amounted to SEK 30.9 M.

Agreement with Biogen

Biogen has full responsibility for development activities and costs in the haemophilia programmes as well as manufacturing. In November 2014, Sobi exercised its opt-in right to take over final development and commercialisation of Elocta for Sobi's territory: Europe, Russia, North Africa and some Middle Eastern countries. Biogen holds development and commercialisation rights for the rest of the world.

Upon EU regulatory approval of Elocta, Sobi will be liable to repay approximately half of the development and manufacturing costs for Elocta/Eloctate incurred by Biogen. For Sobi to meet the repayment obligation, the base royalty structure will be adjusted during a repayment period. Sobi receives an initial royalty rate of 2 per cent on sales of Eloctate in Biogen territories. The agreement is reciprocal with adjusted royalties beginning at the time of the first commercial sale of Elocta in Sobi territory. Upon full repayment, at the latest by mid 2020, the base 12 per cent cross-royalty structure will apply. All financial terms in the agreement between the companies are described in detail in Note 19, page 91.



Sobi's legacy in haemophilia

Through his work back at the beginning of Sobi's haemophilia research Peter Lind has contributed to bringing a novel product (ReFacto) to the market, laying an important foundation for the company and a long-term platform for growth and sustainability.

What was the aim of the project?

In 1985, we started a project at Kabi-Vitrum and KabiGen with the ambition to create a new recombinant form of coagulation factor VIII. In these early stages of DNA cloning, my team and I worked on expressing the gene (cDNA) for human coagulation factor VIII in an effort to isolate a homogenous product.

What was ground-breaking in your research?

Understanding recombinant protein expression was an evolving new area of research and we applied the latest advancements in the field. We saw opportunities to refine and define the molecule and its expression of what finally became the B-domain deleted FVIII (FVIII-SQ), discovering the basis for ReFacto. We then continued on to select and characterise the high expressive cell lines needed for production process development and manufacturing of the product on a larger scale.

How is this research connected to the haemophilia programmes Sobi now has?

The cloning and expression of the coagulation factor VIII cDNA was a joint project with Biogen, Inc. The project with Biogen was concluded in 1986, but the work continued in Sweden leading to ReFacto. A new collaboration began in 2005 with Syntonix to develop a manufacturing process for recombinant factor IX. Syntonix was later acquired by Biogen and we once again became partners. The collaboration agreement was also extended to include their factor VIII programme which employed the same B-domain deleted FVIII that we pioneered.

Haemophilia milestones



2006

An agreement between Syntonix and Biovitrum (later to become Sobi) covering the development and manufacturing of

rFIXFc is signed. Any possible development within haemophilia A is also included in the agreement.

1983

Sobi's work on recombinant factor development started as a Kabi-Vitrum financed operation to Biogen, Inc. The aim being to clone the gene (cDNA) for human coagulation factor VIII (FVIII).

1984

Genentech clones the gene (cDNA) for human FVIII.

1986-1987

The expression on human recombinant FVIII in mammal cells is built up in a small scale. Kabi-Vitrum is granted a patent for the B-domain deleted forms of FVIII, which came to form the base for the development of ReFacto.

2008

The phase 1/2a study begins with the ambition to establish the safety and pharmacokinetic (PK) parameters of rFIXFc following a single intravenous injection.

2007

Biogen acquires Syntonix and the collaboration in which Sobi has already initiated the development of rFIXFc manufacturing process, is transferred to Biogen.

Sobi manufactures the material for the first in human phase 1/2a rFIXFc studies.

2010

Phase 1/2a study of rFVIIIFc is completed. rFVIIIFc demonstrated safety and efficacy in PTP haemophilia A subjects.

Phase 3 study of rFIXFc (B-LONG) was initiated to assess the safety, efficacy and PK in PTPs with severe haemophilia B.

The phase 3 study (A-LONG) was initiated to assess the safety, efficacy and PK of rFVIIIFc in PTPs with severe haemophilia A.



2012

A-LONG and B-LONG are completed and the patients are offered the opportunity to transfer to long-term follow-up studies

(ASPIRE for haemophilia A and B-YOND for haemophilia B). The primary efficacy and safety objectives are met.

Two global paediatric clinical studies regarding rFVIIIFc in haemophilia A and rFIXFc in haemophilia B are initiated, Kids A-LONG and Kids B-LONG respectively.

Biogen submits a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for the use of rFIXFc (Alprolix) in the treatment of haemophilia B.

2009

The rFIXFc phase 1/2a clinical study was completed. rFIXFc demonstrated safety and efficacy in previously treated (PTPs) haemophilia B subjects.

Data supported investigation of rFIXFc in a phase 3 study in PTPs haemophilia B.

The rFVIIIFc phase 1/2a study in PTPs with severe haemophilia A was initiated.

1983 1984 1987

1989

2005 2006

2007

2008

2009

2010

2011

2012

2013

Biogen submits a BLA to the FDA for the use of rFVIIIFc (Eloctate) in the treatment of haemophilia A. The leading scientific journal Blood publishes online detailed clinical study data for Eloctate (haemophilia A). The New England Journal of Medicine publishes

detailed clinical study data for Alprolix (haemophilia B).

June 2014

The FDA approves Eloctate [Antihemophilic Factor VIII (Recombinant), Fc Fusion Protein) for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with haemophilia A.



March 2014

Health Canada approve Alprolix [Coagulation Factor IX (Recombinant), Fc fusion protein] for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with haemophilia B.

July 2014

An open-label study to determine the safety and efficacy of rFIXFc in previously untreated patients (PUP) with severe haemophilia B (PUPs B-LONG) commences. First sales of Eloctate are recorded in Biogen territory.

April 2014

Biogen and Sobi announce results from the Kids A-LONG phase 3 clinical study. The study meets the primary objectives and the paediatric results enable a Marketing Authorisation Application (MAA) for rFVIIIFc to the European Medicines Agency (EMA).

September 2014

Sobi expands its haemophilia development portfolio by including a potentially longer-acting haemophilia A candidate (rFVIIIFc VWF-XTEN Heterodimer) in collaboration with Biogen.

May 2014

Biogen and Sobi announce the intent to donate one billion International Units (IU) of clotting factor over ten years to support the treatment of haemophilia in developing countries.

First sales of Alprolix are recorded in Biogen territory. Sobi receives first royalty payment.

October 2014

Biogen submits a MAA for Elocta (rFVIIIFc) in Europe.

EMA validates the MAA for Elocta. An open-label study to determine the safety and efficacy of Elocta in untreated males with severe haemophilia A commences (PUPs A-LONG).

November 2014

Sobi exercises its opt-in right for the final development and commercialisation of Elocta in Europe, North Africa, Russia, and some Middle Eastern markets. Sobi makes a payment to Biogen of USD 10 million, which will be held in escrow pending the EU regulatory approval of Elocta.

2015 - ANTICIPATED MILESTONES

- Completion of the Kids B-LONG study (presented February 2015).
- Potential filing of rFIXFc in EU.
- Potential European regulatory approval of Elocta.
- Biogen and Sobi make first donations to the World Federation of Hemophilia (WFH) intended for people with haemophilia in countries with limited access to treatment.

See page 49 for more information on the humanitarian aid donation.

ABOUT HAEMOPHILIA A AND B

Haemophilia is a rare disorder in which the clotting ability of the blood is impaired. Haemophilia A affects one in 5,000 male births each year, while haemophilia B affects one in 25,000. Both types of haemophilia occur less often in females. According to the World Federation of Hemophilia (WFH), an estimated 142,000 people worldwide are identified as living with haemophilia A and 28,000 people are identified as living with haemophilia B1. Several more have not been identified and have no access to treatment.

People with haemophilia can experience bleeding episodes that may cause pain, irreversible joint damage and life-threatening haemorrhages. Regular injections of factor VIII or IX can restore the clotting process and prevent bleeding episodes.

2013 2014

¹ World Federation of Hemophilia. Annual Global Survey 2012. http://www1.wfh.org/publications/files/ pdf-1574.pdf. Accessed January 28, 2014.

Meeting an unmet need

Sobi's Inflammation business area is engaged in providing treatment in the form of Kineret for Rheumatoid arthritis as well as the autoinflammatory diseases Cryopyrin-associated autoinflammatory syndrome (CAPS) and Neonatal onset multisystem inflammatory disease (NOMID) in children. NOMID is the most severe form of CAPS.

Autoimmune diseases, such as Rheumatoid arthritis (RA), occur when the body's immune system mistakenly attacks certain components of the body's tissues, perceiving them as harmful and foreign. Autoinflammatory diseases are distinguished by inflammation triggered for unknown reasons by the innate immune system in multiple tissues of the body. Many autoinflammatory diseases have symptoms that are chronic from childhood or infancy, including CAPS.

Kineret is Sobi's largest product in terms of revenues, and for which Sobi has the global rights. In 2014, Kineret reported revenues of SEK 609.3 M, accounting for 23 per cent of the company's revenue.

At the end of 2013, the European Commission approved Kineret for treatment of the rare disease CAPS in adult patients and in children from eight months and older. In 2014, the CAPS treatment was launched in a number of major EU markets. The CAPS indication was also approved in Australia and Israel.

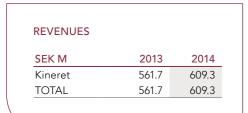
Following the 2012 US approval of Kineret for NOMID, Sobi is continuing to expand awareness of the medication throughout the US. In 2014, the increased frequency of collaborations with physicians currently prescribing Kineret enhanced awareness of patients suffering from RA or NOMID who may be suitable for Kineret treatment. In addition, a patient support programme for Kineret - KineretKare aimed at providing product reimbursement support, was initiated in the U.S.

WHAT IS KINERET?

Indication: Rheumatoid arthritis (RA), Cryopyrin associated periodic syndrome (CAPS) and Neonatal onset multisystem inflammatory disease (NOMID). RA is an autoimmune inflammatory disease caused by deficiencies in theimmune system that leads to stiff joints and chronic and debilitating pain. The disease affects about 1 per cent of the population in Europe and the US. CAPS encompasses a group of rare autoinflammatory diseases that affect approximately one person per one million worldwide. CAPS diseases are characterised by a number of inflammatory responses such as fevers, rash, joint pain, headaches, conjunctivitis and many other symptoms. In its most severe form, NOMID, the disease is also associated with chronic meningitis, hearing loss, craniofacial abnormalities, bone lesions and increased

Product description: Kineret (anakinra) is a recombinant protein drug used to treat RA. CAPS in adults as well as children from eight months and older in the EU, and patients with NOMID in the US. A PARTY KINGTON Geographic market: Global. Sobi holds a global license

for manufacturing and sales of the product.







Karen Durrant, President of the The Autoinflammatory Alliance

Increasing knowledge about autoinflammatory diseases

Sobi and the Autoinflammatory Alliance are collaborating to advance awareness of autoinflammatory diseases to move closer to the joint vision of early diagnosis and access to treatment.

How would you describe the Autoinflammatory Alliance and what are your objectives?

The Autoinflammatory Alliance is a non-profit public charity based in the US dedicated to promoting awareness, proper diagnosis and treatment, and improved care for people with CAPS or other autoinflammatory diseases.

We provide resources and materials to educate and inform medical professionals, patients and others about autoinflammatory diseases, because earlier diagnosis means that the right treatments can be started at an earlier stage, thereby helping prevent more serious effects from systemic inflammation resulting from these conditions. Furthermore, helping the patient to understand their disease empowers them to seek better care and treatment. We also manage online patient communities that have enabled patients from around the world to connect with each other.

Autoinflammatory Alliance has developed a comparative chart. Could you describe it?

One of our most successful and beneficial projects has been the development of our Comparative Chart of Autoinflammatory Diseases. It has the known autoinflammatory diseases arranged with the genetics, systemic findings, symptoms and pertinent labs for each condition, along with a photo. For medical professionals, this has facilitated comparison of the various diseases, providing up-to-date information so they can consider these diseases when diagnosing their patients. It has become the leading resource and educational tool for doctors worldwide on autoinflammatory diseases.

This benefits patients, since many more people have been diagnosed after the patients themselves, and the doctors, have learned more about these diseases. Some patients go undiagnosed for years, maybe even decades, or have been misdiagnosed with other conditions before the correct disease was identified, and have suffered greatly. Our goal is for doctors to consider these diseases when they observe certain symptoms in their patients.

Sobi has given an unrestricted grant, which we have used to develop an interactive version of the comparative chart to provide further information and to disseminate this knowledge in the community.

Sobi's grant also helped us to develop, promote and host autoinflammatory picnics at four locations in the US. The picnics were a special opportunity for families to come together and meet others with autoinflammatory diseases.



PICNIC HIGHLIGHTS

The Autoinflammatoriy Alliance organised Picnic Days at four locations in the US. Scan the QR code to view a film of the highlights from these events.

Delivering on our promise to patients

Inborn errors of metabolism represent a large class of genetic diseases that includes disruptions to the metabolism. Left untreated, these diseases can result in permanent damage or death. However, treatment can provide successful results, especially if the diagnosis is made early in life.

For many years, Sobi has been involved in delivering the treatment of Hereditary Tyrosinaemia type 1 (HT-1), a severe, genetic disease where the body lacks the ability to break down the amino acid tyrosine. Sobi's product Orfadin, together with the appropriate diet, is an essential part of HT-1 treatment.

In Sobi's Genetics & Metabolism business area, Orfadin is the largest product and is Sobi's second largest product overall in terms of revenues. Importantly Orfadin is also Sobi's legacy orphan drug product and exemplifies our dedication and way of engaging with the rare disease community. In 2014, Orfadin reported revenues of SEK 547.9 M, an increase of 50 per cent, accounting for 21 per cent of the company's revenue. The main driver behind this increase was Sobi's decision to assume direct responsibility for the distribution of Orfadin in the US and Canada as of 1 April 2014.

Continued engagement for HT-1 patients

Twenty years ago, before treatment was available, less than one third of children born with HT-1 lived past their second birthday¹. Over the past decades, the previous course of the disease has been dramatically changed and the majority of the people living with the HT-1 diagnosis, and receiving therapy, are growing up to become teenagers and adults. Sobi continues to invest in active life cycle management (LCM) activities for Orfadin, thereby further improving the lives of HT-1 patients.

Maintaining a strong patient-centric approach is crucial to Sobi's mission, and Sobi is continuously developing in initiatives informed by the needs of patients, care providers and healthcare professionals.

REVENUES

SEK M	2013	2014
Orfadin	365.9	547.9
Other	84.4	118.5
TOTAL	450.3	666.4

COLLABORATING TO FIND UNIDENTIFIED HT-1 PATIENTS

New-born screening for HT-1 is not as established in Russia as in many other European countries. Only a very small group of patients have been diagnosed. In Russia, an ongoing selective screening is being carried out for Gaucher's disease, the symptoms some of which are similar to HT-1. Sobi supported the re-evaluation of negative Gaucher's disease samples, checking for markers of HT-1 disease. In 2014, the project was piloted and from 22 unconfirmed diagnosis samples, one patient with chronic HT-1 was immediately identified, thus providing hope that additional patients will be diagnosed and gain access to proper treatment as the project expands.



¹ van Spronsen FJ, Thomasse Y, Smit GP, et al. Hepatology. 1994;20(5):1187-1191.

- As more countries have introduced new-born screening for HT-1 it has become apparent that there is a need to improve accuracy and administration of doses for the smaller children. Adults need a higher dosing, for whom Sobi is developing a higher strength capsule. The LCM activities therefore relate to new strengths and new dosage forms.
- Collaborating with the HT-1 community, Sobi has identified adherence to treatment and diet as one area that requires further support. During the year, Sobi has been involved in the co-development of tools aiming to address such adherence challenges.
- In conjunction with the launch of Orfadin in the US, Sobi introduced Orfadin4U™ – a comprehensive support programme for patients and their caregivers, including product and reimbursement support, as well as a call centre to assist with any questions patients or their caregivers might have.

Urea Cycle Disorders

Sobi also provides therapies for Urea Cycle Disorders (UCD) in the Genetics & Metabolism business area. These products - Ammonaps, Ammonul and Ravicti recorded revenues totalling SEK 118.5 M in 2014, representing a year-on-year increase of 40 per cent.

Urea Cycle Disorders is a group of serious conditions in which patients suffer from deficiencies in the enzymes required to remove ammonia from the blood stream.

WHAT IS ORFADIN?

Indication: Hereditary Tyrosinaemia type-1 (HT-1). People with HT-1 have problems breaking down an amino acid called tyrosine. Toxic by-products are formed and accumulate in the body, which can cause liver failure, renal dysfunction and neurological complications. In the most common form of the disease, symptoms arise within the first six months of the child's life.

Product description: Orfadin (nitisinone) blocks the breakdown of tyrosine, thereby reducing the amount of toxic by-products in the body. However, tyrosine remains in the body and patients must therefore maintain a special diet in combination with Orfadin

Geographic market: Global.



GENETICS & METABOLISM MILESTONES 2014

- Sobi assumed direct sales and distribution responsibility for Orfadin in the US and Canada.
- Sobi launched Orfadin4U in the US.
- Ravicti, a new treatment alternative for UCD, made available for Named Patient Use in the Middle East.
- Ammonul included in Middle East and Saudi Arabia emergency treatment protocols for the treatment of acute hyperammonaemia on Named Patient Use.
- First scientific article from the DevelopAKUre clinical development programme published in Annals of Rheumatic Disease.

Key partner for commercialisation of niche medicines

Sobi offers small and mid-sized pharmaceutical and biotechnology companies a cost-efficient and integrated platform for the commercialisation of their products in Europe, the Middle East, North Africa and Russia. The European market consists of nearly 40 countries with a broad range of supply chain demands, patient needs, healthcare traditions and medical standards, as well as more obvious differences in languages, cultures and payment systems. Accordingly, companies entering Europe are often faced with two difficult options: either charging more for their products, which might slow down or even remove the opportunity to receive reimbursement for the product, or not making the medication available at all in the specific country. Either decision will impact those in need of the medications - the patients, who risk being without the treatment that could give them a better life, and possibly even a chance of survival. Creating a cost-efficient platform for the provision of products intended for a limited number of patients is therefore important and can directly affect the availability of these niche medications to European patients.

Cost-efficient platform

Based on more than 25 years of experience, Sobi offers small and mid-sized pharmaceutical and biotechnology companies a cost-efficient and integrated platform for the commercialisation of their products in Europe, Middle East, North Africa and Russia. Sobi's partnership offering is based on efficient distribution capacity and extensive market knowledge. The partnerships span over many years and include strategies for regulatory approval, pricing and reimbursement, as well as preparations for the launch of additional and/or subsequent marketing activities, tender management and logistics. The main objective is to help meet important medical needs in various therapeutic areas so that each patient receives optimal treatment.

During 2014, the partner platform has demonstrated that Sobi can also support the filing of products in the EU, a future valuable asset in building the late-stage pipeline portfolio.

New additions to the portfolio in 2014

The high level of activity in Sobi's partner portfolio also continued during 2014.

In collaboration with US partner Exelixis, Inc., Sobi announced in March that Cometriq was authorised by the European Commission for the treatment of patients with progressive, unresectable, locally advanced or metastatic medullary thyroid cancer.

In 2013, Sobi signed a ten-year partnership agreement with Auxilium Pharmaceuticals. Inc. for the development and commercialisation of Xiapex for the treatment of patients with Dupuytren's contracture in 71 European, Asian and African countries, becoming Marketing Authorisation Holder in Europe in April 2014. In June, Sobi and Auxilium submitted an application to the EMA for an expansion of the indication for Xiapex to also include Peyronie's disease, which is caused by collagen-rich patches of scar tissue that develop along the shaft of the penis under the skin. The Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion for the use of Xiapex in Peyronie's disease in December 2014, and in January 2015, Xiapex was approved for the treatment of Peyronie's disease in the EU.

REVENUES

SEK M	2013	2014
Partner products	545.7	682.2
TOTAL	545.7	682.2

In 2014, Sobi also entered into a new partnership with TiGenix NV for the commercialisation of Chondro-Celect, a cell-based, first-in-class medicinal product for articular cartilage repair.

Strong development of sales

While the continued strong growth of Partner Products is partly the result of new agreements signed in 2013 and 2014, such as the Valeant portfolio and Xiapex, all parts of the product portfolio contributed to the positive trend. The portfolio comprised 44 different medicinal products from a total of 29 partners. For the full-year, total revenues for Partner Products amounted to SEK 682.2 M, with an annual growth rate of 25 per cent.

WHAT IS XIAPEX?

Indication: Dupuytren's contracture is a condition where one or more fingers are bent forwards toward the palm and cannot be fully straightened. It is caused by a thickening of the tissues under the skin of the palm that form 'cords' pulling down on the fingers. Xiapex is intended for use in patients with cords in their palms that are sufficiently thick that they can be felt through the skin. As of January 2015, Xiapex is also approved for the treatment of Peyronie's disease in the EU.

Product description: Xiapex (collagenase clostridium histolyticum), is a pharmacological treatment for Dupuytren's contracture and may be an alternative to invasive and often complicated surgery for patients. Xiapex is administered by local injection directly into the Dupuytren's cord.

Geographical market: Sobi holds the exclusive rights to commercialise Xiapex for the treatment of Dupuytren's contracture and Peyronie's disease in 71 Eurasian and African countries. Sobi is Marketing Authorisation Holder (MAH) for Xiapex in the 28 EU Member States, as well as Norway and Iceland.

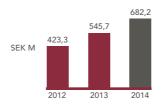
WHAT IS YONDELIS?

Indication: Yondelis is used to treat patients with advanced soft tissue sarcoma, a type of cancer that develops in the soft, supporting tissues of the body. It is used when treatment with anthracyclines and ifosfamide (other anticancer medicines) is no longer effective, or in patients who cannot be administered these medicines.

Product description: Yondelis is a powder that is dissolved to make a solution for infusion (administered via a drip directly into the vein). It contains the active substance trabectedin.

Geographical market: Nordics, Central and Eastern Europe.

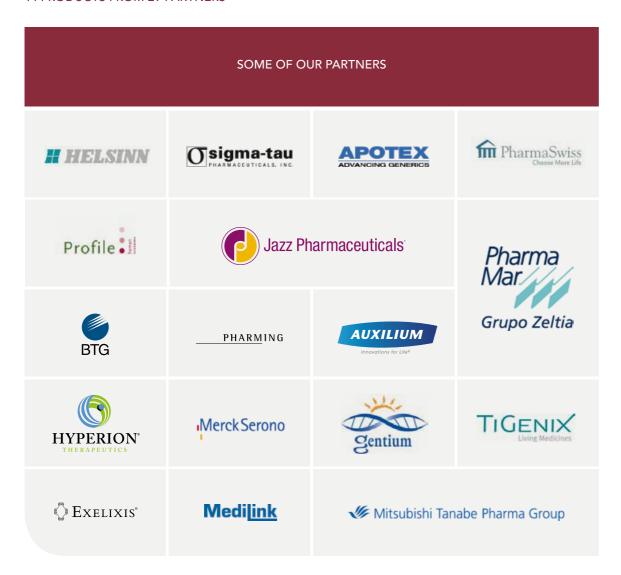
REVENUES TREND FOR PARTNER PRODUCTS, 2012-2014



PARTNER PRODUCTS -**MILESTONES 2014**

- Cometriq approved in Europe for the treatment of progressive, unresectable, locally advanced or metastatic medullary thyroid carcinoma.
- Sobi filed for EU approval of Xiapex for the treatment of Peyronie's disease and received positive opinion by the CHMP.

44 PRODUCTS FROM 29 PARTNERS



PARTNER PRODUCTS LARGEST PRODUCTS

Aloxi

Ammonaps

Ammonul

Betapred

ChondroCelect

Collatamp

Cometriq

Defibrotide

Erwinase

Ferriprox

Fosinopril

Kepivance

Kineret

Megestrol

Orfadin

Ravicti

Ruconest

Willfact

Xiapex

Yondelis

Manufacturing: many important functions

The development of manufacturing expertise and capacity remains a key strategic area for Sobi. Sobi has been manufacturing the drug substance for the haemophilia product ReFacto for the global market on behalf of Pfizer for many years.

A cost-effective manufacturing process plays a key role in being and remaining competitive. Sobi works in collaboration with its extensive manufacturing supplier network to both achieve continuous improvements in production - in the manufacturing process itself and in the analyses and forecasts that are undertaken to ensure that production meets the relevant needs at the right time while maintaining high quality. Manufacturing also includes other important aspects, such as quality assurance, technological development, research and development collaboration and harmonising product delivery with patient value. Sobi engages in continuous dialogue with patients on how packaging can be developed to facilitate use.

Agreement with Pfizer

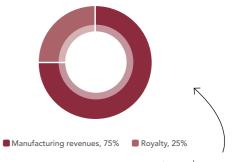
Sobi has been manufacturing the drug substance for the haemophilia product ReFacto since 1998 on behalf of Pfizer, which then sells the finished product all over the world.

As the global supplier, Sobi receives manufacturing revenues and royalties on Pfizer's sales of ReFacto. The supply agreement will remain effective until 2020, with an option to extend, and the royalty agreement applies until 2016/2017. The collaboration with Pfizer is based on Sobi's extensive experience and expertise in the development and manufacturing of recombinant protein drugs.

Developments in 2014

ReFacto has continuously contributed to Sobi's revenues over the years. In 2014, total revenues for ReFacto (manufacturing and royalties) amounted to SEK 618.2 M, unchanged compared with the preceding year. Manufacturing revenue was SEK 465.9 M, while royalty revenue was SEK 152.2 M. In 2013, revenues included SEK 65.8 M for the delivery of validation batches.

REVENUES BY CATEGORY



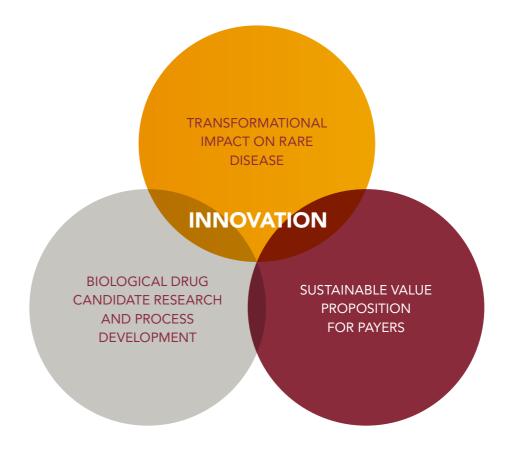
Read more about how our manufacturing plays an important role in research & development on page 42.

SALES					
SEK M	2010	2011	2012	2013	2014
Manufacturing revenues	388.0	451.7	436.0	491.9	465.9
Royalty revenues	109.7	123.3	129.8	127.1	152.2
TOTAL	497.7	575.0	565.8	619.0	618.2

The patient journey guides innovation

The medical needs of patients are always central to Sobi's research and development (R&D) programmes. These include all aspects of development, from the initial generation of an evidence base through patient access to medication and reimbursement throughout the entire product lifecycle.

Sobi's R&D ranges from late-stage pre-clinical research to the development and commercialisation of biopharmaceuticals. It is based on a model in which biologics development and process scale-up are integrated into a modern Patient and Customer-Centric approach to Commercialisation (PC3). By being a fast and flexible organisation, Sobi can apply knowledge of patient needs throughout the entire R&D process.





TRANSFORMATIONAL IMPACT IN RARE DISEASE

Sobi's innovation model revolves around the patient journey for a rare disease patient. The disease areas we are committed to and working with represent various degrees of diagnostic awareness and standards of care. Whether it is an area with little disease awareness and no current treatment options, or an area with established disease knowledge and advanced standard of care, it is important to acknowledge our role in

progressing the understanding of the disease, the medical management and the outcome of the patients on treatment. We define unmet needs of patients by collaborating with patients and caregivers and by continuously studying treatment outcomes. The impact we wish to make is a transformative one - one that will substantially alter the course of the rare disease patient's life from that day on.

BIOLOGICS RESEARCH AND PROCESS DEVELOPMENT

Sobi's own platform for R&D enables the use of innovative methods that integrate biological research, process scale-up and fullscale development throughout the process of commercialisation. The benefits of the platform are that it can be an interface between new discoveries, can integrate research and development processes and can offer benefits of scale that are appropriate for different projects with the overall objective of maximising the 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 the quality assurance of external products and technology transfer. The platform can also be integrated with other external partners in various partnership projects.





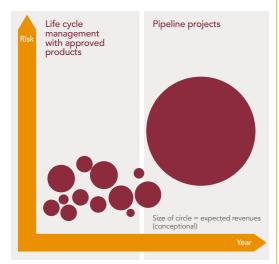
SUSTAINABLE VALUE PROPOSITION FOR PAYERS

Sobi is keen to involve all the stakeholders in the development process, including regulatory authorities, those responsible for value assessments and the relevant pricing and reimbursement systems, together with patient organisations and care providers. The purpose of this is to identify their views on the value

and the contribution that projects in development can bring in relation to the benefits for patients and society. By identifying stakeholders involved at each stage of the patient journey, optimal outcomes are secured for all in a sustainable way and ideally the development and availability can be speeded up.

PIPELINE OF RARE DISEASE BIOLOGICS

BALANCING RISK + ALLOCATION OF CAPITAL



Sobi incrementally invests when key risks are reduced at each stage of development. Sobi balances the financial investment in its R&D portfolio by spreading investments between lifecycle products with limited risk and potential, and products in the pre-clinical and clinical phase with higher risk and major potential.

Evolution in the R&D portfolio

2014 was an eventful year for Sobi's R&D portfolio. While new milestones were achieved bringing the haemophilia programmes closer to the market, three of the pipeline programmes – Kiobrina, Kepivance and SOBI002 – met setbacks. At year-end, in addition to the late-stage haemophilia projects, a number of lifecycle projects such as Orfadin Oral Suspension and early-stage projects remained in the portfolio.

Although the anticipated outcomes were not reached for some key pipeline projects during 2014, Sobi remains focussed on areas of unmet medical need, such as developing treatments for children and infants (as exemplified by Kiobrina) and how quality of life can be improved for people with advanced cancer (as exemplified by Kepivance). Sobi believes in the importance of sharing results with the scientific community, even if the findings are negative. The knowledge developed by Sobi in conjunction with various projects can be used to advance research with the ultimate goal of improving the life of patients.

Development of the innovation model

Following the setbacks in the portfolio in 2014, efforts to identify new projects have intensified. A cross-functional team has been formed with members from R&D, Manufacturing, Commercialisation, Business Development and Patient Access - with responsibility for identifying and managing new requirements, and creating an even more effective innovation model.

Manufacturing capabilities are key

Sobi's biologics production know-how and process scale-up capabilities fill an important function in the company's development work. Following Sobi's dynamic business model, manufacturing and scale-up capabilities play a key role already in early development projects, facilitating the continuous inclusion of production and product quality aspects as well as other activities, such as necessary tech transfers, throughout the R&D process.

These capabilities also enable evaluation, planning and implementation of process and product changes and ensure compliance with global regulatory submissions and approvals, thereby continuously improving efficiency and performance throughout the product life cycle. This model of close collaboration facilitates an agile and continuous process that ensures early sustainable access to treatments.

Expanded areas of application

A key area for Sobi is to explore the potential of already authorised medications by investigating them for other uses or in new applications. Kineret, a medicine originally indicated for the treatment of Rheumatoid arthritis (RA), is now also indicated for the treatment of Cryopyrin associated periodic syndrome (CAPS) in the EU and its most severe form Neonatal onset multisystem inflammatory disease (NOMID) in the US. The new liquid formulation for Orfadin, developed for the treatment of children with Hereditary Tyrosinaemia type-1, is currently under review by the European Medicines Agency. All expanded areas of application originate from reported need from patient representatives and caregivers.

PIPELINE

Indication	Project	Partner	Pre-clin.	Phase 1	Phase 2	Phase 3	Reg.
Haemophilia A	rFVIIIFc	Biogen					
Haemophilia B	rFIXFc	Biogen					
Hereditary Tyrosinaemia type 1	Orfadin Oral suspension	Sobi					
Hereditary Tyrosinaemia type 1	Orfadin 20mg capsule	Sobi					
Alkaptonuria	Nitisinone	DevelopAKUre					
Complement factor C5	SOBI002*	Affibody					
Enzyme replacement therapy	SOBI003	Sobi					
IL-1-driven disease	IL-1 Affibody	Affibody					
Pipeline projects LCM with approved products Submitted for regulatory review							
Currently on clinical hold							
Currently on clinical hold							

A sustainable model for high-quality patient care

Sobi's strong commitment to improving the quality of life of patients with rare diseases is at the heart of the company's operations.

Ideally all stakeholders should be engaged in ongoing dialogue around a medicinal product - legislators, paying agencies, clients and patients - in order to understand their different needs, from the first phases of development for a new drug candidate and onward through the product's entire life cycle. Creating an effective model for such dialogue is crucial to Sobi's ability to create sustainable solutions for shareholders, employees, the healthcare systems that pay for the products and, not least, the patients.

Sobi's materiality analysis

Sobi's materiality analysis is an important tool for prioritisations in the business strategy, communication and stakeholder dialogue. The three most important aspects are patient health and safety, access to healthcare and medicines, and engagement with patient organisations.

The materiality analysis is based on the aspects listed under the GRI (Global Reporting Initiative Index) Reporting Framework's requirements for

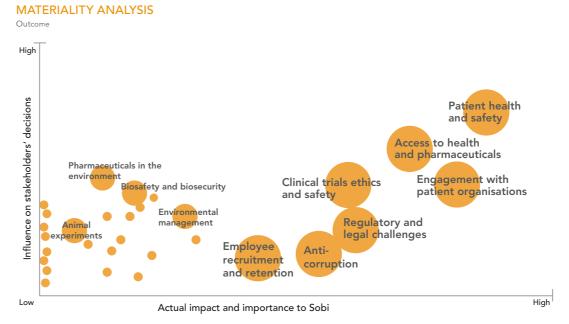
READ MORE ON OUR WEBSITE

In addition to the material areas described on pages 42-45, Sobi works proactively with several other relevant aspects, including environmental activities.

There are also areas that are crucial for the pharmaceutical industry in general, but are currently of limited relevance to Sobi's operations:

- biosafety; and
- pharmaceuticals in the environment.

Information about these areas is available at www.sobi.com/About-Sobi/Corporateresponsibility



The vertical axis shows the importance that stakeholders attach to various aspects relating to Sobi and the pharmaceutical industry. The horisontal axis shows Sobi's own assessment in relation to the actual business strategy and operations

engaging industry stakeholders, combined with Sobi's own analysis of issues raised by the media and other companies in the industry. Representatives of a number of strategic functions within Sobi evaluated the listed areas in which Sobi has real impact through its products, services and relationships, and where such impact arises within the operations. The process resulted in a number of relevant aspects that reflect Sobi's financial, environmental and social impact and/ or that affect judgements and decisions made by key stakeholder groups.

In 2013, via a survey and targeted interviews, a broader group of internal and external stakeholders was invited to prioritise the relevant aspects and themes identified. The result was a map of the areas that are of material importance to Sobi's external stakeholders, and that are strategically important to Sobi as a company. By weighing the views of stakeholders, the company's strategy and risk profile, and the actual impact Sobi identified the most prioritised issues. The priorities remain unchanged for 2014.

Patient health and safety

Maintaining patient safety is Sobi's most important task. Products are evaluated by international and national regulators according to rigorous, established and harmonised standards before they are granted marketing authorisation. Sobi continuously examines, analyses and balances patient benefits and risks. This includes both marketed products and medicinal products under development.

In clinical applications, Sobi always adheres to the Declaration of Helsinki's ethical principles for medical research involving human subjects. Sobi's employees ensure compliance with both internal and external rules in all clinical studies in which Sobi is a sponsor, and the potential side effects of pharmaceuticals are identified in collaboration with physicians and patients. For the products marketed by Sobi, there is an effective system for collecting, processing and reporting adverse effects and other safety information to drug regulatory authorities in accordance with international laws and regulations. All employees are responsible for reporting product complaints and any side effects of Sobi's products of which they may be aware. Employees receive annual training in this area.

The reporting obligation is regulated in a Standard Operating Procedure (SOP), with which Sobi's employees agree to comply. Sobi regularly updates this SOP to reflect changes in legislation and best practice.

Access to healthcare and medicines

Sobi sees the need for an integrated approach to ensure that patients can access the innovative medicinal products developed by the company, and can achieve the best possible results from the treatment. As a result, the patient journey, from diagnosis and treatment to ongoing care and long-term results, is an important aspect in Sobi's prioritisations. The objective is to identify where the greatest value can be created for patients and their care providers, by reducing time to diagnosis, improving diagnostic precision, developing monitoring tools and understanding the barriers that must be overcome in order to achieve sustainable health outcomes.

By creating and maintaining a dialogue with various stakeholders, including government agencies, Sobi operates on the basis of a sustainable model for how medicinal products are delivered. This is called the Patient and Customer-Centric approach to Commercialisation (PC3).

Engagement with patient groups

Learning that a child has a serious or even life-threatening rare disease can be overwhelming for both the child and the child's family. Since these diseases are rare, knowledge about them may also be inadequate, even among health professionals. Sobi cooperates with a number of patient organisations and engages in active dialogue in order to understand their needs and develop a mutual understanding of how the specific rare disease manifests itself and is best treated. In 2014. Sobi received the European rare disease patient organisation, EURORDIS, Company Award for its contributions to patients with rare diseases, and the European Mediscience Award as a result of the company's ethical stance and social initiatives.

Although medical knowledge of rare diseases is generally increasing, it often differs between geographical areas, even when treatments are already available. Sobi works to facilitate the transfer of knowledge in healthcare and, in collaboration with expert medical groups, has developed several extensive training programmes for healthcare providers who treat patients with rare diseases. Several of these training programmes are now certified by public healthcare providers.

Regulatory and legal challenges

Sobi operates in a highly regulated environment and must adhere to laws and regulations in both research and marketing. There is a general trend today towards greater awareness of liability issues and legal risks and thus, also, increased transparency requirements. Companies are expected to record more information about legal processes and, in the pharmaceutical industry, the requirements for transparency in relation to clinical results have become much stricter. Sobi welcomes this transition and works continuously to maintain its own, and its business partners', standards of transparency.

A new regulatory environment has also developed around marketing authorisation and the pricing of medicines. Applications for marketing authorisation are now often conducted in a step-by-step process, which can result in conditional approvals that must be followed up and continually evaluated. Medicines are priced according to new and more complex models. This is creating challenges for the entire pharmaceutical industry, but Sobi's approach is well-suited to navigating and meeting the requirements in this new environment.

TRADE COMPLIANCE

Compliance with trade laws and regulations is an important matter to Sobi. Both new and current markets are constantly evaluated and the organisation is trained to be aware of related risks and "red flags". The order management team have routines and processes to ship the correct product to the correct market. The process also includes restricted party screening and orders to sanctioned countries cannot be shipped without a proper approval.

Ethical issues and safety in clinical studies

All clinical studies sponsored by Sobi are conducted and reported in accordance with applicable laws and the international standard, Good Clinical Practice (GCP). Before a clinical study commences, it is subject to 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 conducted.

Most of Sobi's clinical studies are conducted by contract research companies, in collaboration with physicians and patients. Sobi's outsourcing process is governed by internal Standard Operating Procedures (SOPs). Ultimate responsibility for the strategy, quality and integrity, including implementation and maintenance of quality control systems, and the reporting of a study, always lies with Sobi as a sponsor. Sobi publishes information on www.clinicaltrials.gov regarding the clinical studies that it sponsors. In 2014, there were no breaches of the legislation or standards aimed at protecting the health and safety of people taking part in clinical studies.

Anti-corruption

Sobi's Code of Conduct addresses corruption and bribery. Risk analyses are conducted in every country in which Sobi operates, and issues including bribery legislation and business ethics are reviewed. To raise employee awareness of the rules that apply in the countries where they work, various countries are ranked in regard to transparency. In the compliance area, guidelines have been issued for healthcare and training has been carried out to establish an ethical business standard for transparent sales and non-sales activities, and regarding relationships with the medical profession, care providers, payers and patient organisations. In 2014, work was focussed on preparations for the anticipated launch of haemophilia products.

Recruitment and retention

Sobi is a knowledge-intensive company. Employees are expected to meet high expectations, which is essential for building an innovative and high-performing corporate culture and thereby create value for various stakeholders. Work with recruitment, integration, leadership and process management has been particularly important in 2014 in conjunction with efforts to strengthen the organisation in preparation for the anticipated launch of haemophilia products planned for the end of 2015.

Sobi strives to create a performance-based culture, based on individual accountability, thereby helping the company to address our competitive market and to achieve ambitious objectives. A critical factor in this work is to set and continuously monitor individual goals that are linked to the strategic business objectives. At Sobi, employees and managers work together to define new goals every year, and they are monitored at specific times during the year. Individual employees are appraised not only on their degree of goal achievement, but how their goals are achieved. It is vital that Sobi's values are observed.

Competitive terms of employment are a prerequisite for recruiting and retaining high-calibre employees. Sobi endeavours to offer competitive salaries and benefits. These are determined individually and adapted to the local labour market. For every employee to understand how their own work contributes to the company's mission, Sobi has a strong corporate culture with common goals and transparent communication. Efforts to strengthen the corporate culture are particularly important in the transition that Sobi is currently undergoing in building the enforced haemophilia business.

Providing continuous professional development for all employees is crucial for the development of the product portfolio, and being able to launch and sell our products successfully. A large proportion of Sobi's training courses are web-based and individual.

Of the total number of employees in 2014, 43 per cent were men and 57 per cent were women. The corresponding figures for the Executive Leadership and Board of Directors were 67/33 per cent and 62/38 per cent, respectively (excluding employee representatives). All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

Supply chain

Sobi sells and markets a wide range of products, 50 products to 67 countries, many of which are small volumes to a limited number of patients. Since biologics are sensitive and often require cold chain to ensure product integrity and quality, having full control of the entire supply chain is vital – from manufacturing to when the product reaches the patient. Sobi interprets sales patterns and prepares long-term forecasts for each product in order to place timely orders with the manufacturers. The single most important responsibility is to ensure that patients never risk being without their medication, which could be life-threatening. Sobi has therefore built up a robust supply chain. In Europe, when pharmacies and clinics order products, these orders are normally managed by Sobi's logistics partners who perform customer service and ship the products within 24 hours from a local warehouse. In the US, home delivery is an important part of the patient support programmes and is increasingly provided by Sobi through dedicated partners. All local warehouses are, in turn, continuously refilled according to sales forecasts, with products from Sobi's central warehouse in Nijmegen in the Netherlands. Supplies of medications to hospitals or pharmacies in ex-EU/ex-US markets often require substantial trade compliance controls, document preparations and transport monitoring, and are managed through Sobi's central supply chain team and shipped out of Sobi's central warehouse. Sobi's 24/7/365 Emergency

Service will then use all the resources it has at its disposal to supply the product as soon as possible to the hospital.

Procurement

Sobi purchases materials, goods and services from more than 1,000 suppliers. Establishing good relationships with these suppliers promotes sustainability and responsibility within the business. Sobi strives to apply consistent rules to all suppliers based on the Sobi Code of Conduct. Sobi's purchasing is mainly conducted in two categories: products governed by international and national regulatory requirements and standards, and products of a general nature for all companies 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 assessments. In the second category, Sobi procures goods at the best terms and balances price and quality, with consideration for the relevant industry's standards of responsibility. Sobi's suppliers are primarily based in Europe and the US.



"The so called transparency initiative has been in place in the pharmacertificat industry in France for about a year. For those of us in the field, it has had a major impact on our dayto-day work. Sobi France has established a system that manages and collects data and automatically transfers this to the authorities on a daily basis. It ensures that we maintain complete traceability of payments and expenses to external stakeholders. One of the positive effects of this transparency is the high level of trust we experience in customer meetings, enabling us to engage in an open and equal dialogue."

Alexandra Pruvot Medical Science Manager, France

Continued strong trend for Sobi's share

During the year, the market price of the Sobi share increased by 19 per cent, reaching an all-time high of SEK 94.75 on 3 July 2014, while the lowest price paid was SEK 65.00 on 26 March 2014. The Sobi share is listed on Nasdaq Stockholm, under the company name Swedish Orphan Biovitrum and included in both the OMX Stockholm Large cap and Pharmaceuticals & Biotechnology sector index, which rose 15.7 and 27.9 per cent respectively in 2014.

Share capital

Total shares outstanding as of 31 December 2014 amounted to 270,785,950 of which 270,389,770 were ordinary shares and 396,180 were Class C shares, corresponding to a total of 270,429,388 votes. The ordinary shares carry one vote per share, and Class C shares 1/10 of a vote per share. The new issue of Class C shares during the year will be used to hedge commitments under Sobi's incentive programmes. At year end the share capital was SEK 148,580,386, distributed between 270,785,950 shares with a par value of approximately SEK 0.55.

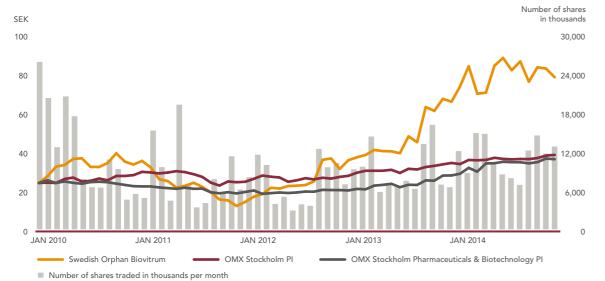
	2013		201	4
	High	Low	High	Low
1st quarter	42.50	36.60	87.20	65.00
2nd quarter	43.30	36.80	89.65	65.55
3rd quarter	65.75	40.30	94.75	72.40
4th quarter	70.25	50.25	88.00	65.25

Market price for the Sobi share in 2014

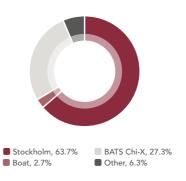
Shareholder categories

31 Dec. 2014	Percentage of capital
Foreign shareholders	30.7
Swedish shareholders	69.3
Of which:	
Institutions	65.3
Private persons	4.0

Sobi share price and trading volume 2010-2014



Trading places



Source: Euroclear

Shareholders

The number of shareholders at year-end totalled 12,955 (10,153). The holding of the largest shareholder, Investor, remained unchanged at 39.8 per cent. Swedish legal entities, including institutions and funds, owned 69.3 per cent of the shares at year-end. There were several additions to the list of the 15 largest shareholders, including Swedbank Robur fonder and Biotech Target N.V.

Treasury shares held by Swedish Orphan Biovitrum AB (publ) at year-end totalled 3,674,140 A shares and 396,180 C shares. During the year, 1,014,808 shares were used for allotment under a performance-based long-term share programme.

Sobi has launched several share-based incentive programmes for senior executives and other employees. For more information, see Note 12 on pages 84-85.

Analyst coverage

Bank of America MI	Rick Aldridge		
Carnegie	Kristofer Liljeberg		
Danske Bank	Mattias Häggblom		
Deutsche Bank	Richard Parkes		
Goldman Sachs	Eleanor Fung		
Handelsbanken	Peter Sehested		
Jefferies	Eun K. Yang		
Kepler Chevreux	Richard Koch		
Nordea Securities	Erik Hultgård		
Pareto Securities	Yilmaz Mahshid		
RX Securities	Samir Devani		
SEB	Lars Hevreng		
Swedbank	Johan Unnerus		

Largest shareholders at 31 December 2014¹

Shareholder	Number of A shares	Number of C shares	Share capital, %	Share votes, %
Investor AB	107,594,165	0	39.73	39.79
Goldman Sachs & Co, W9	9,924,677	0	3.67	3.67
Skandinaviska Enskilda Banken S.A., W8IMY	9,558,832	0	3.53	3.53
Swedbank Robur fonder	8,996,159	0	3.32	3.33
Catella Fondförvaltning	7,807,466	0	2.88	2.89
AMF – Försäkring och Fonder	7,510,110	0	2.77	2.78
Handelsbanken Fonder AB RE JPMEL	6,998,110	0	2.58	2.59
Biotech Target N.V.	6,825,749	0	2.52	2.52
State Street Bank and Trust OMNIBUS	5,359,622	0	1.98	1.98
Afa Försäkring	4 768 869	0	1.76	1.76
Swedish Orphan Biovitrum AB (publ)	3,674,140	396,180	1.50	1.37
Fourth Swedish National Pension Fund	4,008,853	0	1.48	1.48
CBNY-Norges Bank	3,783,532	0	1.40	1.40
Gladiator	3,215,000	0	1.19	1.19
JPM Chase NA	3,150,166	0	1.16	1.6
Total 15 largest shareholders	193,175,450	396,180		
Other	77,214,320			
TOTAL	270,389,770	396,180	·	

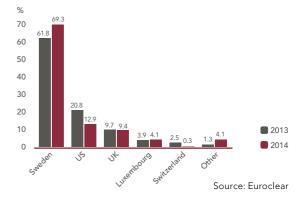
¹The shareholders are presented as they appear in the shareholder register held by Euroclear Sweden AB. The list may therefore not show shareholders whose shares have been registered in the name of a nominee, through the trust department of a bank or similar institution.

Source: Euroclear

Brief facts, the Sobi share

Listing	Nasdaq Stockholm
Number of shares (A+C-shares)	270,785,950
Market capitalisation	SEK 18.05 billion
Ticker	SOBI
ISIN	SE0000872095
CUSIP	870321106

Shareholders by country



FOR MORE INFORMATION REGARDING SOBI AMERICAN DEPOSITARY RECEIPTS (ADR), PLEASE CONTACT

US Depositary: BNY Mellon Shareowner services

P.O. Box 30170

College Station, TX 77842-3170, USA

E-mail: shrrelations@cpushareownerservices.com

Toll Free in the USA: +1-888-269-2377 International dialing: +1-201-680-6825

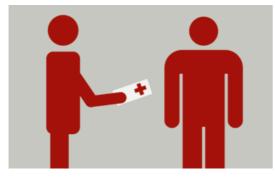
COMMUNICATION WITH SHAREHOLDERS

For more up-to-date information about the Sobi share, please visit www.sobi.com or call +46 (0)8 697 20 00, to contact Jörgen Winroth, Head of Investor Relations.

Five-year summary

Income statement, SEK M	2010	2011	2012	2013	2014
Total revenues	1,906.7	1,910.8	1,923.2	2,176.7	2,607.0
Gross profit	1,221.0	974.6	1,040.4	1,284.0	1,547.8
EBITDA	344.8	131.3	399.7	241.1	-11.7
EBITA	290.9	49.5	367.0	211.0	-43.4
EBIT	-10.3	-318.6	-54.6	-66.5	-325.0
Profit/loss for the year	-104.5	17.9	-100.9	-93.0	-267.8
Capital, SEK M	2010	2011	2012	2013	2014
Total assets	7,069.5	6,699.5	6,306.5	6,519.3	6,370.7
Capital employed	6,302.7	6,016.1	5,747.8	5,864.6	5,612.6
Equity	4,342.4	4,963.4	4,838.0	4,769.2	4,522.9
Investments	1,934.1	45.1	68.3	410.2	183.2
Cash and cash equivalents	38.5	219.0	457.0	445.1	519.1
Net debt	1 162.7	481.0	143.0	352.5	298.4
Cash flow, SEK M	2010	2011	2012	2013	2014
Cash flow from operations before change in working capital	249.7	118.3	367.7	165.5	299.4
Cash flow from operating activities	-215.1	102.9	405.5	185.4	233.7
Cash flow from investing activities	-1,884.3	-43.8	-67.3	-404.6	-183.5
Cash flow from financing activities	1,881.7	121.6	-100.0	206.7	20.0
Net change in cash and cash equivalents	-217.7	180.7	238.3	-12.5	70.2
Key figures, %	2010	2011	2012	2013	2014
Gross margin	64.0	51.0	54.1	59.0	59.4
Return on capital employed	-0.2	-5.3	-0.9	-1.1	-5.8
Return on equity	-2.4	0.4	-2.1	-2.0	-5.9
Equity ratio	61.4	74.1	76.7	73.2	71.0
Debt/equity ratio	62.8	35.0	30.4	36.7	40.9
Share overview, SEK	2010	2011	2012	2013	2014
Earnings per share	-0.47	0.07	-0.38	-0.35	-1.01
Equity per share	20.5	18.7	18.2	17.6	16.7
Dividend	0.0	0.0	0.0	0.0	0.0
Cash flow per share	-1.1	0.7	0.9	0.0	0.3









DONATION FOR AN **IMPORTANT PURPOSE**

It is estimated that only about 25 per cent of people with haemophilia worldwide receive regular treatment. To contribute to a long-term improvement of this situation, Sobi and Biogen have announced an intention to donate one billion International Units (IU) of clotting factor for humanitarian aid in developing countries over the next ten years.

Sobi and Biogen hope that this will help enable a predictable, sustained humanitarian supply of factor therapy with a goal to improve the quality of care and outcomes for people with haemophilia living in developing countries.

WANT TO KNOW MORE?

Scan the QR code to find out more about the donation.



Directors' Report

Highlights 2014

Financial Highlights

- Total revenues were SEK 2,607.0 M (2,176.7), an increase of 20 per cent.
- Revenues from Key Therapeutic Areas were SEK 1,306.6 M (1,012.0), an increase of 29 per cent.
- The gross margin was 59 per cent (59).
- EBITA was SEK -43.4 M (211.0).
- Other operating expenses were negatively impacted by impairment losses of SEK 324.9 M relating to the Kiobrina research project, and SEK 25.2 M relating to Multiferon. In total SFK 350.1 M
- The loss for the year amounted to SEK –267.8 M (–93.0), representing a loss per share of SEK -1.01 (-0.35).
- Cash flow from operating activities amounted to SEK 233.7 M (185.4).

Business Highlights

- Sobi exercised its opt-in right to take over final development and commercialisation of Elocta (rFVIIIFc) in Sobi's
- Biogen submitted a Marketing Authorisation Application for Elocta in Europe.
- The Board elected to include XTEN, a potentially longer-acting haemophilia A candidate, in the agreement with Biogen.
- Sobi became Marketing Authorisation Holder for Xiapex
- Sobi signed a new partnership agreement with TiGenix for the commercialisation of ChondroCelect.
- Sobi assumed direct responsibility for Orfadin in North
- The phase 3 study for Kiobrina did not meet its primary endpoint.
- Cometriq was approved in Europe.
- Xiapex received a positive opinion for the treatment of Peyronie's disease.

Key figures

SEK M	2014	2013
Operating revenues	2,607.0	2,176.7
Gross profit	1,547.8	1,284.0
Gross margin	59%	59%
EBITA	-43.4	211.0
EBIT	-325.0	-66.5
Net profit/loss for the period	-267.8	-93.0
Earnings/loss per share, SEK	-1.01	-0.35

See page 48 for a five-year summary of revenues, costs and results.

Sobi's operations

Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Haemophilia, Inflammation and Genetic Diseases. We also market a portfolio of specialty and rare disease products in collaboration with various partner companies in Europe, the Middle East, North Africa and Russia.

In 2014, the company generated revenues through:

- Product sales of proprietary products, and royalty revenues from Biogen's sales of the drugs Eloctate and Alprolix.
- Product sales in Europe, Middle East, North Africa and Russia of products for which Sobi holds the distribution and/or licensing agreements.
- Manufacture of the drug substance for ReFacto AF®/ Xyntha® and royalties from Pfizer's global sales of ReFacto AF/Xyntha.

Operating revenues

In 2014, total revenues increased to SEK 2,607.0 M (2,176.7). Sales of products in Key Therapeutic Areas rose 29 per cent and the Partner Products portfolio increased 25 per cent. The trend for manufacturing and royalties in ReFacto was in line with 2013.

SEK M	2014	2013
Key Therapeutic Areas	1,306.6	1,012.0
Partner Products	682.2	545.7
ReFacto	618.2	619.0
Total revenues	2,607.0	2,176.7

Gross margin

The gross margin was 59 per cent (59).

Expenses

Operating expenses rose 37 per cent to SEK 1,912.7 M (1,374.1). The increase was due to impairment losses of SEK 324.9 M for Kiobrina and SEK 25.2 M for Multiferon, as well as increased costs associated with preparations for the anticipated launches of the haemophilia programmes. The operating expenses were also affected by costs relating to the long-term incentive programmes of SEK 51 M. There is no cash flow impact of these programmes.

Sales and administrative expenses increased to SEK 1,031.5 M (898.2). The increase was due to higher costs for marketing/commercialisation, medical personnel and personnel to achieve marketing authorisation for the medical products in the current portfolio, preparations for the anticipated launches of the haemophilia programmes, and increased investments in the North American operations. The increased costs were also affected by a negative currency impact of about 4 per cent compared with 2013, related to the EUR and USD. Research and development expenses rose 10 per cent to SEK 500.5 M (455.7), reflecting the costs for the discontinuation of Kiobrina and the anticipated launch of Elocta.

Other operating revenues and expenses amounted to SEK –340.8 M (3.4), which consists mainly of the writedowns for Kiobrina and Multiferon.

Earnings

EBITA amounted to SEK –43.4 M (211.0). The amounts for 2014 include the impairment of Kiobrina and Multiferon. Excluding these impairment losses, EBITA amounted to SEK 306.7 M. Amortisation of intangible fixed assets amounted to SEK 281.6 M (277.6). EBIT amounted to SEK –325.0 M (–66.5).

Net financial items

Net financial items for 2014 amounted to SEK 6.4 M (–56.9). Financial income of SEK 69.8 M (14.3) mainly comprised exchange-rate gains, while financial expenses of SEK 63.4 M (71.2) mainly consisted of interest-related expenses.

Taxes

In 2014, the current tax expense amounted to SEK –19.4 M (–16.0), and deferred tax amounted to SEK 70.2 M (46.5). Total tax for the Group amounted to SEK 50.7 M (30.5).

Other comprehensive income

Other comprehensive income totalled SEK 5.1 M (4.2), and consisted of cash flow hedging relating to the bond loan and to revaluation of the pension obligation.

Cash flow and investments

Cash flow from operations amounted to SEK 233.7 M (185.4). Non-cash items amounted to SEK 567.2 M (258.4), net, mainly attributable to the amortisation of product rights and licences, and impairments losses for Kiobrina and Multiferon, which were slightly offset by the reversal of deferred tax.

Cash flow from investing activities amounted to SEK –183.5 M (–404.6). Decisions to exercise Sobi's opt-in right to take over the final development and commercialisation of Elocta in Sobi's territory, and to include XTEN in Sobi's agreement with Biogen, accounted for the largest investments during the year and impacted cash flow by SEK 124.7 M.

An increase in working capital had an impact of SEK –65.7 M (19.9) on cash flow. Stock increased, mainly for Kineret, but also for Partner Products. Accounts receivable also increased, reflecting sales growth during the year. Current liabilities also increased, mainly a result of personnel costs and increased discounts for, primarily, products in the US.

Financial position

At 31 December 2014, cash and cash equivalents amounted to SEK 519.1 M (445.1).

Sobi has a bond loan amounting to SEK 800 M, with maturity in 2017. The bond loan runs subject to a variable interest rate of 3-month STIBOR +500 basis points, which, through interest-rate swaps, was converted to a fixed rate, at an average of 6.6 per cent. The bond loan is listed on Nasdaq Stockholm.

At 31 December 2014, net debt amounted to SEK 298.4 M, compared with SEK 352.5 M at 31 December 2013.

Equity

At 31 December 2014, consolidated shareholders' equity totalled SEK 4,522.9 M, compared with SEK 4,769.2 M at 31 December 2013.

Parent Company

The Parent Company's mission is to develop, register, distribute and market medications for rare diseases. In 2014, revenues for the Parent Company totalled SEK 2,328.3 M (1,841.9). Operating income amounted to SEK 196.8 M (–17.9). The loss for the year was SEK –120.7 M (–7.6). The figures for 2014 include an impairment loss of SEK 177.4 M on the holding in Arexis relating to Kiobrina and group contribution of SEK 158.8 M. At 31 December 2014, cash and cash equivalents amounted to SEK 392.4 M (373.5). Equity amounted to SEK 5,510.4 M (5,621.6) at 31 December 2014, whereby the difference is attributable to the results during the year and the costs associated with the company's share programme.

Five-year summary

SEK M	2014	2013	2012	2011	2010
Operating revenues		2,176.70	1,923.20	1,910.80	1,906.70
Cost of goods and services sold		-892.7	-882.8	-936.3	-685.7
Research and development expenses	-500.5	-455.7	-401.6	-555.7	-558.8
Operating profit/loss	-325.0	-66.5	-54.6	-318,6	-10,3
Financial items, net		-56.9	-50.5	-52.2	-82.2
Profit/loss for the year	-267.8	-93.0	-100.9	17.9	-104.5
Earnings/loss per share ¹ , SEK		-0.35	-0.38	0.07	-0.47
Earnings/loss per share after full dilution ¹ , SEK		-0.35	-0.38	0.07	-0.47
Number of shares, in thousands	270,390	270,390	265,227	265,227	212,181
Equity ratio	71.0%	73.2%	76.7%	74.1%	61.4%

¹ Earnings/loss per share have been adjusted for the rights issue completed in June 2011.

Sales

Key Therapeutic Areas

Products in Sobi's Key Therapeutic Areas – Inflammation, Genetics & Metabolism and Haemophilia (Kineret, Orfadin, Ammonaps, Ammonul, Ravicti Eloctate and Alprolix) amounted to SEK 1,306.6 M (1,012.0), representing growth of 29 per cent. The increase at constant exchange rates was 22 per cent. The main exchange rate drivers were the EUR and USD.

Total sales of Kineret rose 8 per cent to SEK 609.3 M (561.7). Growth was mainly driven by price increases in the US and higher sales volumes in Europe.

Total sales of Orfadin rose 50 per cent to SEK 547.9 M (365.9). Reassuming direct sales for the product in North America from Rare Disease Therapeutics (RDT) as of 1 April, as well as continued growth in Middle East, North Africa and Russia, accounted for the increase. On 1 January 2015, Sobi will also assume distribution responsibility for Orfadin in Latin America. The registration of Orfadin in Japan generated a milestone payment of SEK 4.8 M. In 2014, Sobi's business partner Biogen was granted approval for both Eloctate and Alprolix in several markets. In 2014, Sobi thus received royalties on Biogen's sales of these products, on Alprolix as of May, and Eloctate as of July. Revenues for the full-year amounted to SEK 30.9 M (0), corresponding to royalties of 2 per cent on sales of Eloctate and Alprolix, respectively, in Biogen's territories. Furthemore, Sobi received a milestone payment of SEK 10.7 M from Biogen in conjunction with Alprolix receiving regulatory approval.

Partner Products

Total sales of products in our partner portfolio amounted to SEK 682.2 M (545.7). Sobi signed a new partnership agreement with TiGenix for the commercialisation of ChondroCelect, a cell-based medicinal product for the repair of articular cartilage in the knee. Cometrig was approved in Europe for the treatment of progressive, unresectable, locally advanced or metastatic medullary

thyroid cancer. The Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA) adopted a positive opinion on the use of Xiapex for the treatment of adult men with Peyronie's disease. Total revenues for Partner Products rose 25 per cent. Growth in the portfolio was mainly driven by Xiapex, Ruconest and the Valeant portfolio.

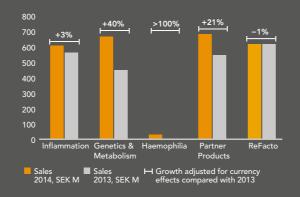
Sales increased for the three largest products: Xiapex rose more than 100 per cent to SEK 125.9 M (48.0); Kepivance rose 5 per cent to SEK 88.6 M (84.2); and Yondelis rose 13 per cent to SEK 82.5 M (73.3).

ReFacto

Total revenues for ReFacto, derived from manufacturing and royalties, amounted to SEK 618.2 M (619.0). Total manufacturing revenues declined 5 per cent to SEK 465.9 M (491.9). In 2013, revenues included an amount of SEK 65.8 M for extra deliveries of validation batches.

Total royalty revenues rose 20 per cent to SEK 152.2 M (127.1). In February 2012, Sobi and Pfizer extended their supply agreement for ReFacto AF/Xyntha until 31 December 2020, with an option to renew.

Revenues by product category



Revenues by product category

SEK M	2014	2013
Inflammation: Kineret	609.3	561.7
Genetics & Metabolism: Orfadin	547.9	365.9
Genetics & Metabolism: Other		84.4
Haemophilia	30.9	0
Key Therapeutic Areas	1,306.6	1,012.0
Partner Products	682.2	545.7
Manufacturing revenues		491.9
Royalty revenues	152.2	127.1
ReFacto	618.2	619.0
Total revenues	2,607.0	2,176.7

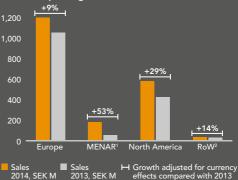
Product sales by region

(Excluding ReFacto manufacturing and royalty revenues)

SEK M	2014	2013	Change
Europe		1 052.3	14%
MENAR ¹		55.1	228%
North America	578.9	423.1	37%
RoW ²	33.0	27.1	22%
Total	1,988.8	1 557.7	28%

¹ Middle East, North Africa and Russia

Revenues per region



¹ Middle East, North Africa and Russia

² Rest of the world

² Rest of the world

Products per business line

Key Therapeutic Areas	Partner Products	ReFacto
Inflammation	Aloxi	Manufacturing
Kineret	Betapred	Royalty
Genetics & Metabolism	${\sf ChondroCelect}$	
Orfadin	Comteriq	
Ammonaps	Ferriprox	
Ammonul	Kepivance	
Ravicti	Ruconest	
Haemophilia	Valeant portfolio	
Eloctate	Xiapex	
Alprolix	Yondelis	
	Others	

Development

Sobi's development projects include two pipeline programmes, rFVIIIFc and rFIXFc in haemophilia. There are also preclinical development projects and projects focussed on the further development of existing products. In 2014, the phase 3 study of Kiobrina was terminated, as well as a programme to expand the indication for Kepivance. A decision was also made to suspend the phase 1 study of SOBI002 following the observation of transient and mild side effects in the study.

Positive results regarding efficacy and safety for Kids A-LONG, Biogen's and Sobi's phase 3 study in children for the drug candidate Eloctate (rFVIIIFc) for haemophilia A

In April 2014, Sobi and Biogen announced positive results from the phase 3 study for Kids A-LONG, which evaluated the safety, efficacy and pharmacokinetics (measurements of how long the medication remains in the body) of Eloctate in previously treated children under twelve with severe haemophilia A.

Eloctate was generally well tolerated and no inhibitors (neutralising antibodies that may interfere with the activity of the therapy) were detected. Data from the paediatric phase 3 study of Eloctate showed that prophylaxis with twice-weekly dosing resulted in low bleeding rates in children under twelve. The study met the primary endpoint and the data enabled a Marketing Authorisation Application in the EU, which was submitted in October, 2014. The European Medicines Agency (EMA) requires the inclusion of paediatric study data in an initial marketing application for a new haemophilia therapy. The European trade name for Eloctate will be Elocta.

An equivalent study of Alprolix (rFIXFc) for children under 12 with severe haemophilia B, Kids B-LONG, was ongoing at year-end. Alprolix is Biogen's prolonged circulating recombinant factor IX medicine for haemophilia B therapy, for which Sobi has an opt-in right.

Regulatory approval for Alprolix

In March 2014, Health Canada was the first regulator to approve Alprolix [Coagulation Factor IX (Recombinant), Fc Fusion Protein] for the control and prevention of bleeding episodes, as well as routine prophylaxis for adults and children older than 12 with haemophilia B. This approval was followed during the year by approvals in the US, Australia and Japan.

Regulatory approval for Eloctate

In June 2014, the US Food and Drug Administration (FDA) was the first regulator to approve Eloctate [Antihemophilic Factor VIII (Recombinant), Fc Fusion Protein] for the control and prevention of bleeding episodes, manage bleeding during surgical procedures as well as routine prophylaxis in adults and children older than 12 years with haemophilia A. This approval was followed during the year by approvals in Canada, Australia and Japan.

Expanded haemophilia development portfolio

In September 2014, Sobi decided to include a potentially longer-acting haemophilia A candidate, based on XTEN

technology (rFVIIIFc-VWF-XTEN Heterodimer), in its collaboration with Biogen. The molecule is currently in the pre-clinical phase of development. The decision was associated with a payment to Biogen totalling approximately USD 7 M.

Cometriq approved in Europe for the treatment of progressive, unresectable, locally advanced or metastatic medullary thyroid cancer.

In March 2014, Cometriq (cabozantinib) was approved for the treatment of adult patients with progressive, unresectable locally, advanced or metastatic medullary thyroid cancer (MTC). In accordance with the terms of the agreement for commercialisation and distribution between Exelixis and Sobi, Sobi will support the commercialisation of Cometriq in the EU for the approved indication until the end of 2019.

Kiobrina's phase 3 study did not meet primary endpoint

In March 2014, Sobi announced data from the company's phase 3 study of Kiobrina (rhBSSL – recombinant human bile salt stimulated lipase), called the "LAIF study." The primary endpoint of the study – growth velocity measured after four weeks of treatment with rhBSSL – was not met. Preterm infants treated with rhBSSL showed no statistically significant improvement in terms of growth velocity compared with placebo groups.

Marketing Authorisation Holder for Xiapex in Europe

In April 2014, Sobi and Auxilium Pharmaceuticals, Inc. announced that Sobi had become the Marketing Authorisation Holder (MAH) for Xiapex (collagenase clostridium histolyticum) in 28 EU countries, as well as Norway and Iceland. Xiapex is an innovative biopharmaceutical used to treat Dupuytren's contracture. In 2015, Xiapex was also approved by the European Commission for the treatment of Peyronie's disease.

No application to expand Kepivance indications

In autumn 2014, the company decided not to pursue an application for an additional indication for Kepivance. After careful review and analysis of available data, Sobi concluded that in such a setting the benefits/risk of Kepivance do not sufficiently support a Marketing Authorisation Application for treatment of oral mucositis in connection with head and neck cancer.

Suspended phase 1 study of SOBI002

In the third-quarter, a decision was made to place the phase 1 study of SOBI002 on hold after observing mild and transient adverse events at the low dose levels during the trial. The company is working to understand the data in more detail.

Other information

Signed partnership agreement with TiGenix for the commercialisation of ChondroCelect

In April 2014, Sobi announced that the company had acquired the right to market and distribute ChondroCelect, a cell-based medicinal product for articular cartilage repair, from TiGenix NV. ChondroCelect was the first cell-based product to receive approval in Europe. Sobi will continue to market and distribute the product where it is available, but also work to increase patient access to the product in a much larger area, including the EU, Norway, Russia, Switzerland, Turkey as well as countries in the Middle East and North Africa.

Subsidiaries in Switzerland and Austria

One new subsidiary in Switzerland, Swedish Orphan Biovitrum AG, and one in Austria, Swedish Orphan Biovitrum GmbH, were established during the year.

Change in management

In 2014, Kirsti Gjellan was appointed Senior Vice President Manufacturing Operations. Kirsti Gjellan was previously employed at global pharmaceutical company Pfizer, where she was Managing Director and Site Leader at the Strängnäs biotechnology site for Pfizer Health AB and a Board member of Pfizer Health AB.

Strengthened Board

The Board of Directors was strengthened by the election of Annette Clancy at the Annual General Meeting.

Environmental information

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

Sobi's production facilities in Stockholm and Umeå have permits for hasardous operations for facilities that produce organic substances through industrial-scale biological reactions. Compliance with permit conditions is reported annually in environmental reports to the local authorities. In Solna, Sweden, 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 conditions for this permit mainly relate to emissions to water and include a requirement to adjust the pH of process water. In 2014, no breaches of the conditions were reported by any of the facilities.

The company also has an import permit for animal by-products from the Swedish Board of Agriculture, and a permit for handling flammable products. Sobi also has a permit to work with radioactive substances from the Swedish Radiation Safety Authority. In 2014, no such activities were performed. Although adaptation to current regulations has not, to date, affected Sobi's competitiveness or operations negatively, the company cannot predict the impact of future regulations.

Share capital and ownership

Sobi's share capital at the end of the year amounted to SEK 148,580,386 distibuted into 270,785,950 shares with with a quota value of approximately SEK 0.55, of which 270,389,770 ordinary shares and 396.180 C shares. The ordinary shares carry one vote per share and the class C shares carry 1/10 of a vote per share. Investor AB, the single largest shareholder in Sobi, held a total of 107,594,165 shares, representing 39.79 per cent of the votes and 39.73 per cent of the capital.

Share repurchases

At the Annual General Meeting held on 8 May, 2014 Sobi's Board of Directors was authorised to repurchase the issued Class C shares for hedging the long-term incentive programme. The Annual General Meeting also resolved to approve the Board's proposal on transfer of the shares. On 31 December 2014, Sobi held 3,674,140 ordinary shares and all 396,180 Class C shares in treasury.

Sobi's values

Sobi promotes a good working environment. Sobi strives to comply with all health and safety-related laws and requlations and therefore conducts systematic work environment efforts that integrate environmental and quality awareness. The company has also worked actively for several years to raise awareness of the company's values among all employees throughout the organisation. The values are described below.

Sobi's values are appropriately reflected by the word "CARE":

Collaborative – I contribute to innovations and the results-oriented work of our teams - both within and between various company functions, and with external

Accountable – I take responsibility for my results and focus on consistently meeting my commitments.

Respectful – My approach to employees and customers is based on reliability and trust, where the integrity of my relationships is supported by candid feedback.

Engaged – I make a positive contribution to the company's results through the energy I put into my work, by sharing my experience, and by actively making the most of our opportunities.

Compliance with the company's values is evaluated every year in Sobi's evaluation process (see Note 12). Sobi acknowledges and rewards performances above and beyond the ordinary by individual employees and teams who put the company's values into practice in various ways.

Employees

In 2014, the average number of employees was 589 (546), of whom 389 (394) were based in Sweden. Salaries and other remuneration amounted to SEK 522.8 M (407.5), of which the Parent Company accounted for SEK 297.4 M (278.4).

Of the total number of employees in 2014, 43 per cent were men and 57 per cent women. All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

Guidelines and remuneration 2014

The 2014 Annual General Meeting (AGM) adopted the following guidelines for remuneration to senior executives.

Guidelines for remuneration to senior executives

The Board of Directors proposes that the AGM resolves to approve the Board's proposed guidelines for remuneration to the company's senior executives according to the following, and for the period until the 2015 AGM. Senior executives in this context refers to Swedish Orphan Biovitrum's CEO and the managers reporting to the CEO from time to time, who are also included in the company's management, as well as Board members who have signed employment or consulting contracts.

Motives

Sobi aims to offer competitive terms, enabling the company to recruit and retain competent personnel. The remuneration of senior executives is to consist of fixed salary, variable salary, pension and other benefits. Long-term incentive programmes may be offered in addition to the above and will subsequently be submitted to the AGM for approval. Remuneration is primarily based on the position,

performance and the company's, or individual's, fulfilment of predetermined targets.

Fixed salary

The fixed salary for the CEO and other senior executives is to be competitive and aims to reflect the demands and responsibilities of the position. The fixed salary for the CEO and other senior executives is revised once a year.

Variable salary

The variable salary for the CEO and other senior executives is to be based on the company's fulfilment of predetermined targets. These targets are to promote the Company's/Group's development, value creation and financial growth over time, and are designed in a manner that does not encourage excessive risk-taking. The variable salary may amount to not 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 other senior executives.

Long-term incentive programmes

Long-term incentive programmes may constitute a complement to fixed and variable salary. Programme participants are nominated on the basis of various factors, including expertise, performance and retention of key employees in the company. The outcome is dependent on the fulfilment of certain predetermined performance requirements. The aim of long-term incentive programmes should be to create a long-term commitment to Sobi, to give participants an opportunity to share Sobi's long-term success and value creation and to create opportunities for attracting and retaining senior executives and key employees, see Note 12.

Other remuneration and terms of employment

Pension benefits for the CEO and the other senior executives should primarily comprise defined-contribution pension plans, but may also be defined-benefit plans under collective agreements.

Fixed salary during notice periods and severance payment, including payments for any restrictions on competition, shall, in total, not exceed an amount equivalent to the

fixed salary for two years. The total severance payment for all members of the Executive Leadership Team is to be limited to the existing monthly salary for the remaining months up to 65 years of age.

The CEO may, in the event of change in ownership of the company, entailing 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 not more than six monthly gross salaries (including pension) provided that the employment has not been terminated within six months of the change in ownership, alternatively (ii) in the event of a significant change of the CEO's employment conditions, be entitled to terminate the employment with a right to severance payment in accordance with the above. In the event of a material change in the business, other senior executives may (i) be entitled to a retention bonus corresponding to not more than six monthly fixed salaries (excluding pension, or in specific cases, including pension), provided that the employment has not been terminated six months after such change, alternatively (ii) under certain circumstances, be entitled to terminate the employment with a right to severance payment, however, corresponding to not more than twelve monthly fixed salaries (excluding pension, or in specific cases, including pension), in addition to salary during the notice period.

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

In addition, other remuneration may be paid out in extraordinary circumstances, provided that such arrangements are designed to recruit or retain senior executives and that they are only agreed on an individual basis. Such extraordinary arrangements may include a one-time cash payment, or a benefit package in the form of relocation support, tax filing support, or similar.

Deviations from the guidelines

The Board is entitled to deviate from the guidelines above should the Board determine, in an individual case, that there are special reasons to justify such action.

Incentive programmes

Sobi currently has six active share programmes. To participate in the share programmes, employees must be permanently employed and invest in Sobi shares. The company also has a cash-based programme. All programmes have a vesting period of three years. The performance conditions are related to Sobi's share price trend. For more detailed information about all of the programmes, see Note 12.

Events after the balance-sheet date

Partnership agreement with Exelixis extended

In January, it was announced that the collaboration with Exelixis, Inc. regarding the commercialisation of Cometriq had been renegotiated and extended until 31 December 2019. The original agreement extended until 31 December 2015 and was concluded in February 2013 when the collaboration between the companies began.

Xiapex approved for the treatment of Peyronie's disease

In January 2015, the European Commission approved Xiapex (collagenase clostridium histolyticum) for the treatment of Peyronie's disease. Peyronie's disease is caused by an accumulation of collagen-rich scar tissue along the shaft of the penis under the skin. The scar tissue (plaque) develops along one side of the penis and as the disease progresses may harden and become less elastic causing the penis to bend during erection.

Positive results regarding efficacy and safety from the phase 3 study in children for the drug candidate Alprolix (rFIXFc)

In February 2015, Sobi and Biogen announced positive top-line results of the Kids B-LONG phase 3 clinical study that evaluated the safety, efficacy and pharmacokinetics of Alprolix in children under age twelve with severe haemophilia B. Alprolix was generally well tolerated and no inhibitors (neutralising antibodies that may interfere with the activity of the therapy) were detected during the study.

The results will enable an application for marketing authorisation in the EU, as well as future applications for indications for the treatment of children in other territories

Transactions with related parties

In February 2015 Sobi 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 2015 and is valid until 30 April 2016.

Fulfilment of outlook for 2014

In 2014, Sobi surpassed its revenue target, with expected revenues of between SEK 2,300 M and SEK 2,500 M.

The gross margin amounted to 59 per cent, which was in line with the expected gross margin of 58-60 per cent.

Outlook 20151

For 2015, Sobi expects total full-year revenues to be in the range of SEK 2,800 M to 3,000 M, and the gross margin to be in the range of 58-60 per cent.

Operating costs are projected to increase as the company continues to prepare for the planned launch of Elocta. Sobi expects EBITA to be in line with the adjusted 2014 level.

The outlook for 2015 is based on constant exchange rates and excludes revenue from the potential European launch of

Proposed appropriation of profit

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

SEK

Total	4,561,601,316
Profit/loss for the year	-120,725,307
Profit carried forward	549,398,381
Share premium reserve	4,132,928,241

The Board of Directors proposes that no dividend be distributed for the 2014 financial year.

The Board of Directors propose that the funds at their disposal, SEK 4,561,601,316, be carried forward.

¹ The outlook was first published in the 2014 Q4 and FY report on

Efficient risk management generates value

Sobi is aware of the various risks involved in the development and marketing of medicinal products for rare diseases. Prudent risktaking is necessary in order to generate long-term value.

Sobi's integrated risk management process aims to identify, assess and manage risks and uncertainties as early as possible.

Risk management is an integral part of Sobi's daily operations. Line and project managers are responsible for the continuous implementation of risk management within the framework of their function or projects. The procedure complies with the Committee of Sponsoring Organizations of the Treadway Commission – Enterprise Risk Management Integrated Framework (COSO - ERM). This also provides the foundation for Sobi's risk management policy, of which version 2.0 was launched in 2013. In 2014, implementation of this policy was intensified throughout the organisation, including in the country organisations. The policy demonstrates how proactive risk management and consistent identification, assessment and control create conditions for continued business growth. The Risk Management and Compliance Committee reports quarterly to the Executive Leadership Team and the Board.

Sobi's overall risk management consists of eight interrelated components that apply throughout the entire company, regardless of geography, activity or function:

- 1. Internal environment:
- 2. Objective setting:
- 3. Event identification;
- 4. Risk assessment;
- 5. Risk response;
- 6. Control activities;
- 7. Information and communication; and
- 8. Monitoring.

Most significant risks

Sobi's risks are divided into three main categories: operational risks, external risks and financial risks. The most significant risks are summarised below. The risks are not ranked in any particular order.

Operational risks

Bringing new medicines to the market

Bringing a new biopharmaceutical to the market is a capital-intensive, complicated and risky process. During the clinical development phase, it may emerge that the drug candidates are not sufficiently potent, or that they have undesirable or unintended side effects. This may disrupt, influence, delay or stop clinical development, and prevent or limit the commercial use of a candidate drug. Please read more regarding our innovation model on pages 38–41.

Marketing authorisation

Before any of Sobi's products can be launched, Sobi and its business partners must demonstrate that the products meet the rigorous demands on quality, safety and efficacy imposed by authorities in those countries or regions where they will be marketed. Although a medicinal product receives marketing authorisation, there is no guarantee that it will receive the expected price and status as a reimbursed medication in national or regional healthcare systems, nor market acceptance among physicians, patients, procurement organisations or the medical community.

Sobi collaborates and engages in dialogue with authorities from an early stage of the development process for a new medicinal product. Please read more on pages 18–20.

Collaboration and partnerships

Sobi's strategy to create a balanced project and product portfolio includes signing partnership agreements with academic institutions, as well as other pharmaceutical and biotechnology companies, for example, for joint development and/or authorisation and market launches

Intellectual property protection and patent risks

Sobi's success is largely dependent on the company's, or the licensor's, ability to obtain intellectual property rights for its products in the US, the EU and other countries or regions. The patent situation in the biotechnology and pharmaceutical field involves several complex legal and scientific issues.

Biopharmaceutical manufacturing and quality risks

The manufacture of Sobi's products requires precise and high-quality processes and verifications. Sobi must ensure that all manufacturing processes and methods, as well as all equipment, are consistent and compliant with current Good Manufacturing Practice (cGMP) regulations. Deviations at any stage of the manufacturing process may lead to loss of entire batches.

External risks

Competition

Sobi's competitors include other international pharmaceutical, biotech and speciality pharmaceutical companies. Some competitors have substantial financial, technical and human resources as well as major manufacturing, distribution, sales

and marketing capacity. Furthermore, Sobi's products under development risk being exposed to competition from similar products or entirely new product concepts that offer more value for the patient.

Sobi partners with external research groups, patient groups, government agencies and healthcare professionals to secure both medical quality during the development phase and the need for the product once it is launched. Sobi also operates in markets where there is no competition.

Prices

The growing cost of healthcare in many countries means that authorities and other payers are becoming more cost-conscious, which means that Sobi and the healthcare industry are operating under strong price pressure. In most markets where Sobi is active, governments exercise control over pharmaceutical prices. Sobi's success depends on whether the products developed by the company are covered by, and eligible for, reimbursement under private or government-owned reimbursement systems in the healthcare sector.

Product counterfeiting

The supply of traditional prescription drugs is increasingly challenged by illegally produced medicinal products and by the availability of counterfeit products in some distribution channels. None of Sobi's products have been exposed to counterfeiting to date. All of Sobi's distribution is handled in a quality system that is set up according to Good Distribution Practice to minimise the risk of counterfeiting.

Ethical and compliance risks

Issues concerning social responsibility and sustainable business play an increasingly significant role in the competitiveness and profitability of companies and, consequently, for their stakeholders and shareholders. Sobi's Code of Conduct & Ethics has been introduced across the company and signed by all employees. The aim of the Code is to help employees contribute to Sobi's sustainable development. Health Care Compliance within Sobi is defined as the ethical business standard for transparent promotional and non-promotional activities and interactions with healthcare professionals, providers, payers and patient organisations.

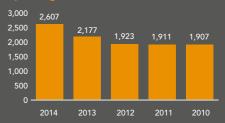
Financial risks

While most of Sobi's costs are incurred in SEK, a significant proportion of the company's revenues is generated in other currencies. Due to the company's international expansion, a lower exchange rate for significant foreign currencies in which revenues are generated, such as USD and EUR, could have a negative impact on Sobi's earnings and financial position. For more information about currency and other financial risks, refer to Note 3 on pages 75–77.

Consolidated statement of comprehensive income

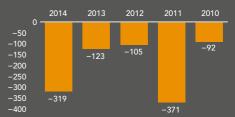
SEK 000s	Note	2014	2013
	1–4		
Operating revenues	5-6	2,606,976	2,176,694
Cost of goods and services sold		-1,059,176	-892,733
Gross profit		1,547,800	1,283,961
Sales and administration expenses	13	-1,031,489	-898,225
Research and development expenses		-500,486	-455,689
Other operating revenues	8	39,897	23,624
Other operating expenses	9	-380,697	-20,203
Operating profit/loss	7, 10, 12, 14, 17, 19, 20, 30	-324,975	-66,532
Financial income	15	69,832	14,303
Financial expenses	16	-63,422	-71,186
Financial items, net		6,410	-56,883
Profit/loss before tax		-318,565	-123,415
Income tax for the year	18	50,733	30,459
Profit/loss for the year		-267,832	-92,956
Other comprehensive income ¹			
Items that will not be reclassified to profit or loss			
Actuarial gains/losses on defined-benefit plan		812	2,010
Items that may be subsequently reclassified to profit or loss			
Translation differences		3,783	368
Cash flow hedges		528	1,862
Other comprehensive income		5,123	4,240
Comprehensive income for the year		-262,709	-88,716
Earnings/loss per share (SEK) ²		-1.01	-0.35
Earnings/loss per share after dilution (SEK) ²		-1.01	-0.35
		070 200 770	270 200 770
Number of shares (ordinary)		270,389,770	270,389,770
Average number of shares		266,158,798	265,266,117
Number of Class C shares held in treasury		396,180	4 (00 040
Number of ordinary shares held in treasury		3,674,140	4 688 948
Number of shares after dilution		270,389,770	270,389,770
Average number of shares after dilution		266,158,798	265,266,117





Operating revenues

Revenues for the full-year amounted to SEK 2,607 M currency effects, the increase was 15 per cent.



Profit/loss before tax

2014 includes impairment losses of SEK 325 M for the discontinuation of Kiobrina and SEK 25 M for the discontinuation of Multiferon.

Consolidated balance sheet

SEK 000s	Note	31 Dec. 2014	31 Dec. 2013
ASSETS	1–4		
Fixed assets			
Intangible fixed assets	19	4,247,488	4,637,028
Tangible fixed assets	20	115,229	125,779
Financial assets	22	2,862	2,010
Deferred tax assets	23	69,953	24,408
Total fixed assets		4,435,532	4,789,225
Current assets			
Inventories	24	763,935	725,950
Accounts receivable	25, 28	480,025	414,465
Other receivables	25	61,850	66,281
Prepaid expenses and accrued income	26	110,255	78,302
Cash and cash equivalents	27, 28	519,147	445,097
Total current assets		1,935,212	1,730,095
TOTAL ASSETS		6,370,744	6,519,320

SEK 000s	Note	31 Dec. 2014	31 Dec. 2013
EQUITY AND LIABILITIES			
Equity			
Share capital			148,362
Other contributed capital		4,883,930	4,867,595
Reserves			-55,908
Profit/loss carried forward		-191,023	-97,849
Profit/loss for the year		-267,832	-92,956
Equity attributable to owners of the Parent		4,522,870	4,769,244
.iabilities			
Non-current liabilities			
Deferred tax liability	23	272,164	297,802
Other liabilities	29	815,811	795,699
Provision for pension commitments	30, 31	12,915	9,141
Total non-current liabilities		1,100,890	1,102,642
Current liabilities			
Accounts payable	28		239,098
Tax liabilities			6,539
Other liabilities		48,611	82,479
Accrued expenses and prepaid income	32	451,488	319,318
Total current liabilities		746,984	647,434
TOTAL EQUITY AND LIABILITIES		6,370,744	6,519,320
Pledged assets and contingent liabilities - Group			
Pledged assets	33	200,000	200,000
Contingent liabilities			

Consolidated statement of changes in equity

SEK 000s	Share capital	Other contributed capital	Other reserves	Profit/loss carried forward	Total equity
Opening equity, 1 Jan. 2013	147,948	4,847,632	-60,148	-97,435	4,837,997
Comprehensive income					
Profit/loss for the year				-92,956	-92,956
Other comprehensive income					
Cash flow hedges			1,862		1,862
Actuarial loss/gain			2,010		2,010
Exchange-rate differences			368		368
Total comprehensive income	_	_	4,240	-92,956	-88,716
Transactions with shareholders					
Issue/repurchase of shares	414			-414	
Share-based remuneration		13,246			13,246
Sale of ordinary shares		6,717			6,717
Total transactions with shareholders	414	19,963	_	-414	19,963
Closing equity, 31 Dec. 2013	148,362	4,867,595	-55,908	-190,805	4,769,244
Closing equity, 31 Dec. 2013 Opening equity, 1 Jan. 2014	148,362 148,362	4,867,595 4,867,595	-55,908 -55,908	-190,805 -190,805	4,769,244
Opening equity, 1 Jan. 2014					
Opening equity, 1 Jan. 2014 Comprehensive income				-190,805	4,769,244
Opening equity, 1 Jan. 2014 Comprehensive income Profit/loss for the year				-190,805	4,769,244
Opening equity, 1 Jan. 2014 Comprehensive income Profit/loss for the year Other comprehensive income			-55,908 	-190,805	4,769,244 -267,832
Opening equity, 1 Jan. 2014 Comprehensive income Profit/loss for the year Other comprehensive income Cash flow hedges			-55,908 528	-190,805	4,769,244 -267,832 528
Opening equity, 1 Jan. 2014 Comprehensive income Profit/loss for the year Other comprehensive income Cash flow hedges Actuarial loss/gain			-55,908 528 812	-190,805	4,769,244 -267,832 528 812
Opening equity, 1 Jan. 2014 Comprehensive income Profit/loss for the year Other comprehensive income Cash flow hedges Actuarial loss/gain Exchange-rate differences			-55,908 528 812 3,783	-190,805 -267,832 	4,769,244 -267,832 528 812 3,783
Opening equity, 1 Jan. 2014 Comprehensive income Profit/loss for the year Other comprehensive income Cash flow hedges Actuarial loss/gain Exchange-rate differences Total comprehensive income			-55,908 528 812 3,783	-190,805 -267,832 	4,769,244 -267,832 528 812 3,783
Opening equity, 1 Jan. 2014 Comprehensive income Profit/loss for the year Other comprehensive income Cash flow hedges Actuarial loss/gain Exchange-rate differences Total comprehensive income Transactions with shareholders	148,362 — — — — — —		-55,908 528 812 3,783	-190,805 -267,832 -267,832	4,769,244 -267,832 528 812 3,783
Opening equity, 1 Jan. 2014 Comprehensive income Profit/loss for the year Other comprehensive income Cash flow hedges Actuarial loss/gain Exchange-rate differences Total comprehensive income Transactions with shareholders Issue/repurchase of shares	148,362 — — — — — —	4,867,595 — — — — —	-55,908 528 812 3,783	-190,805 -267,832 -267,832	-267,832 -267,832 528 812 3,783 -262,709

¹ At 31 December 2014, other reserves consisted of translation differences of SEK –23,559 K, revaluation of pensions under IAS 19 of SEK –24,744 K, cash flow hedges of SEK –4,104 K and actuarial gains/losses of SEK 1,622 K.

At year-end, Sobi's share capital was SEK 148,580,386 distributed between 270,785,950 shares with a par value of approximately SEK 0.55. Issued shares are distributed between 270,389,770 common shares and 396,180 Class C shares. Ordinary shares carry one vote per share, and Class C shares 1/10 votes per share. All Class C shares are held as treasury shares. Class C shares are intended for hedging commitments under the incentive programmes. On the balance-sheet date, the company held 3,674,140 ordinary shares in treasury. The treasury share item represents 1.4 per cent of the total number of shares in the company.

Earnings per share

Earnings per share before dilution are calculated by dividing the earnings/loss attributable to Parent Company shareholders by the weighted average number of ordinary shares outstanding during the period, excluding shares

	2014	2013
Earnings/loss attributable to Parent Company shareholders	-267,832	-92,956
Weighted average number of ordinary shares outstanding (thousands)	266,159	265,266
Earnings/loss per share before dilution (SEK per share)	-1.01	-0.35

Earnings/loss per share after dilution, is the same as above, since the result is negative both in 2013 as in 2014.

Consolidated cash flow statement

SEK 000s	2014	2013
Operating activities		
Profit/loss for the year	-267,832	-92,956
Adjustments for non-cash items	567,230	258,441
Cash flow from operating activities before changes in working capital	299,398	165,485
Cash flow from changes in working capital		
Decrease (+) / Increase (-) in inventories	-73,096	-25,582
Decrease (+) / Increase (-) in operating receivables	-92,081	-73,399
Increase (+) / Decrease (-) in operating liabilities	99,549	118,885
Cash flow from operating activities	233,770	185,389
Investing activities		
Acquisition of intangible fixed assets	-160,284	-384,175
Acquisition of tangible fixed assets	-22,858	-25,976
Acquisition of financial assets	-445	
Divestment of tangible fixed assets	84	143
Divestment of financial assets	_	2,489
Divestment of current assets	_	2,899
Cash flow from investing activities	-183,503	-404,620
Financing activities		
Issue of corporate bond	_	200,000
Sale of shares	_	6,717
Raising of loan ¹	20,000	
Cash flow from financing activities	20,000	206,717
Change in cash and cash equivalents	70,267	-12,514
Cash and cash equivalents at 1 Jan.	445,097	456,951
Exchange-rate differences in cash flow	3,783	660
Cash and cash equivalents at 31 Dec.	519,147	445,097

Supplemental disclosures to the consolidated cash flow statement

SEK 000s	2014	2013
Interest paid and received		
Interest received, see Note 15	4,228	4,489
Interest paid, see Note 16	56,621	60,412
Tax paid	15,067	13,536
Adjustments for non-cash items		
Depreciation and impairment of fixed assets, see Notes 19 and 20	581,548	307,621
Impairment of inventories	36,711	
Capital gain/loss from tangible fixed assets	_	2,952
Pensions, see Note 30	4,573	-20,080
Cost of share programmes ¹	16,335	13,246
Deferred tax, see Note 23	-71,183	-46,474
Other items	-754	1,176
Total	567,230	258,441

Parent Company income statement

SEK 000s	Note	2014	2013
	1–4		
Operating revenues	5–6	2,328,277	1,841,881
Cost of goods and services sold		-973,783	-889,838
Gross profit		1,354,494	952,043
Sales and administrative expenses	13	-623,686	-532,707
Research and development expenses		-469,908	-450,599
Other operating revenues	8	46,087	32,813
Other operating expenses	9	-110,144	-19,462
Operating profit/loss	7, 10, 12, 14, 17, 19–20	196,843	-17,912
Profit/loss from participations in Group companies	11	-174,663	2,288
Financial income	15	99,520	42,149
Financial expenses	16	-63,129	-70,229
Financial items, net		-138,272	-25,792
Tax allocation reserve			1,101
Group contributions		-158,844	241
Appropriations		-158,844	241
Profit/loss before tax		-100,273	-42,362
Income tax for the year	18	-20,452	34,714
Profit/loss for the year		-120,725	-7,648

Parent Company statement of comprehensive income

SEK 000s	2014	2013
Profit/loss for the year	-120,725	-7,648
Items that may be reclassified subsequently to profit or loss		
Cash flow hedges	679	555
Tax effect of cash flow hedges	–150	1,307
Other comprehensive income	529	1,862
Comprehensive income for the year	-120,196	-5,786

Parent Company balance sheet

SEK 000s	Note	31 Dec. 2014	31 Dec. 2013
ASSETS	1–4		
Fixed assets			
Intangible fixed assets	19		
Patent, licenses and product rights		933,023	934,747
Advance payments for intangible assets		73,503	
Tangible fixed assets	20		
Land and buildings		4,261	4,595
Machinery and technical equipment		42,537	37,988
Equipment, tools, fixtures and fittings		50,094	68,468
Construction in progress		7,130	4,585
Financial fixed assets			
Participations in Group companies	21	3,882,069	4,058,468
Receivables from Group companies		16,329	
Deferred tax assets	23	19,799	37,052
Other long-term financial receivables	22	621	621
Total fixed assets		5,029,366	5,146,523
Current assets			
Inventories	24		
Raw materials and consumables		10,745	16,982
Work-in-progress		401,587	360,060
Finished products and goods for resale		267,935	287,545
Current receivable			
Accounts receivable	25	194,003	193,297
Other receivables	25	46,714	52,266
Receivables from Group companies		697,482	728,061
Prepaid expenses and accrued income	26	100,042	68,546
Cash and bank			
Cash and cash equivalents	27	392,424	373,503
Total current assets		2,110,933	2,080,260
TOTAL ASSETS		7,140,299	7,226,783

SEK 000s Note	31 Dec. 2014	31 Dec. 2013
EQUITY AND LIABILITIES	_	
Equity	_	
Restricted equity	_	
Share capital	148,580	148,363
Statutory reserve	800,257	800,257
Total restricted equity	948,837	948,620
Non-restricted equity	_	
Share premium reserve	4,132,928	4,123,896
Loss carried forward	549,398	556,735
Profit/loss for the year	-120,725	-7,648
Total non-restricted equity	4,561,601	4,672,983
Total equity	5,510,438	5,621,603
Liabilities		
Non-current liabilities	_	
Other liabilities 29	811,775	790,775
Total non-current liabilities	811,775	790,775
	_	
Current liabilities	_	
Accounts payable	200,659	219,500
Liabilities to Group companies	309,596	299,422
Tax liabilities	3,424	828
Other liabilities	30,867	60,160
Accrued expenses and prepaid income 32	273,540	234,495
Total current liabilities	818,086	814,405
TOTAL EQUITY AND LIABILITIES	7,140,299	7,226,783
Pledged assets and contingent liabilities		
- Parent Company		
Pledged assets 33	206,000	203,000
Contingent liabilities		

Parent Company statement of changes in equity

	Restricted	d equity	Non-restri	cted equity	
SEK 000s	Share capital	Statutory reserve	Share premium reserve	Profit/loss brought forward and profit/loss for the year	Total equity
Opening equity, 1 Jan. 2013	147,948	800,257	4,110,650	548,571	5,607,426
Hedge accounting				1,862	1,862
Issue/repurchase of shares	415			-415	
Sale of ordinary shares				6,717	6,717
Share-based remuneration to employees			13,246		13,246
Profit/loss for the year	_		_	-7,648	-7,648
Closing equity, 31 Dec. 2013	148,363	800,257	4,123,896	549,087	5,621,603
Opening equity, 1 Jan. 2014	148,363	800,257	4,123,896	549,087	5,621,603
Hedge accounting				528	528
Issue/repurchase of shares	217				_
Share-based remuneration to employees			9,032		9,032
Profit/loss for the year		_	_	-120,725	-120,725
Closing equity, 31 Dec. 2014	148,580	800,257	4,132,928	428,673 ¹	5,510,438

At year-end, Sobi's share capital was SEK 148,580,386 distributed between 270,785,950 shares with a par value of approximately SEK 0.55. Issued shares are distributed between 270,389,770 common shares and 396,180 Class C shares. Ordinary shares carry one vote per share, and Class C shares 1/10 votes per share. All Class C shares are held as treasury shares. Class C shares are intended for hedging commitments under the incentive programmes. On the balance-sheet date, the company held 3,674,140 ordinary shares in treasury. The treasury shares item represents 1.4 per cent of the total number of shares in the company.

Parent Company cash flow statement

SEK 000s	2014	2013
Operating activities		
Profit/loss for the year	-120,725	-7,648
Adjustments for non-cash items	320,581	87,636
Cash flow from operating activities before changes in working capital	199,856	79,988
Cash flow from changes in working capital		
Decrease (+) / Increase (–) in inventories	-15,681	-46,645
Decrease (+) / Increase (-) in operating receivables	-11,400	228,202
Increase (+) / Decrease (–) in operating liabilities	3,681	26,703
Cash flow from operating activities	176,456	288,248
Investing activities		
Acquisition of subsidiaries	-1,036	–163
Divestment of financial assets	_	2,489
Acquisition of intangible fixed assets	-160,284	-384,133
Acquisition of tangible fixed assets	-16,215	-19,061
Divestment of tangible fixed assets	_	2,944
Cash flow from investing activities	-177,535	-397,924
Financing activities		
Raising of loan ¹	20,000	200,000
Sale of shares	_	6,717
Cash flow from financing activities	20,000	206,717
Change in cash and cash equivalents	18,921	97,041
Cash and cash equivalents at 1 January	373,503	276,462
Cash and cash equivalents at 31 December	392,424	373,503

Supplemental disclosures to cash flow statement – Parent Company

SEK 000s	2014	2013
Interest paid		
Interest received	3,436	4,489
Interest paid	56,268	59,455
Tax paid	3,348	1,032
Adjustments for non-cash items		
Depreciation/amortisation and impairment of assets	293,771	112,731
Capital gain/loss from tangible fixed assets	_	12
Deferred tax attributable to loss carry-forwards	17,253	-35,836
Cost of share programmes ¹	9,032	13,246
Other items	525	-2,517
	320,581	87,636

Note 1

General information

Swedish Orphan Biovitrum AB (publ), Corporate Registration Number 556038-9321, the Parent Company and its subsidiaries, collectively the Group, is a publicly listed international pharmaceutical company dedicated to rare diseases.

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

The Parent Company is a limited liability company headquartered in Stockholm, Sweden. The address of the head office is Tomtebodavägen 23A, Solna.

The Company has been listed on the Stockholm Stock Exchange (now Nasdaq Stockholm) since 15 September 2006, and as a Large Cap company since 2 January 2014.

Note 2

Significant accounting policies and basis for preparation of the Parent Company and consolidated financial statements

Summary of significant accounting policies for Groups
The primary accounting policies applied in the preparation of
these consolidated financial statements are set out below.
These policies have been consistently applied to all years
presented, unless otherwise stated.

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, International Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the EU. The consolidated financial statements have been prepared under the historical cost convention, except in the case of certain financial assets and liabilities (including derivative instruments) which are measured at fair value.

New and amended standards applied by the Group

The accounting policies applied are consistent with those applied the preceding year with the exceptions stated below. During the year, the Group introduced the following new and amended IFRS from 1 January 2014, although with limited or no impact on the financial statements.

IFRS 12 Disclosure of Interests in other Entities outlines the expanded disclosure requirements for interests in subsidiaries, associates and joint arrangements aimed at increasing understanding of the holdings' effects and risks. No expanded disclosure requirements are deemed to exist for the Group's wholly owned subsidiaries.

The amendment to IAS 32 Financial Instruments includes a clarification regarding offsetting financial assets and liabilities.

The amendment to IAS 36 Impairment of Assets means that the requirement to disclose the recoverable amount of all cash-generating units to which goodwill has been allocated, has been removed. Additional disclosure requirements for fair value were introduced when the recoverable amount of an impaired asset is based on fair value less selling expenses.

New standards, amendments to, and interpretations of, existing standards not yet applied by the Group

IFRS 9 Financial Instruments will be effective for financial years commencing on or after 1 January 2018 and will replace IAS 39 Financial Instruments: Recognition and Measurement.

The new standard has been revised in various sections; one section pertains to the recognition and measurement of financial assets and liabilities. The standard is divided into three sections: classification and measurement, hedge accounting and impairment.

IFRS 9 contains three principal classification categories for financial assets: measured at amortised cost, fair value through other comprehensive income or fair value in profit or loss. Classification is determined at initial recognition, based on the asset's characteristics and the company's business model. For financial liabilities, there are no major changes compared with IAS 39. The greatest change relates to liabilities measured at fair value. For these, the amount of change in fair value attributable to changes in own credit risk is to be presented in other comprehensive income rather than profit or loss, unless this causes inconsistencies in the accounts.

The second section relates to hedge accounting and requires additional disclosures on risk management and the impact of hedge accounting. Finally, new principles were introduced for impaired financial assets, based on the premise of providing for expected losses.

IFRS 15 Revenue from Contracts with Customers. The standard will be effective for financial years commencing on or after 1 January 2017. The standard will replace all standards and interpretations previously used for revenue. IFRS 15 provides a single model for revenue recognition to be applied to all contracts with customers.

The idea is that everything begins with a contract between two parties for the sale of a product or a service. Initially, a contract with a customer is to be identified, which generates performance obligations for an entity (rights, an entitlement to consideration) and a liability (an undertaking, a promise to transfer goods or services).

The entity then recognises revenue according to the model to show that it has satisfied the performance obligation of transferring the promised goods or services to the customer.

CONSOLIDATED ACCOUNTS

General information

The consolidated financial statements include the Parent Company and the subsidiaries.

Subsidiaries

Subsidiaries are all entities (including special purpose entities) over which Sobi has the power to govern the financial and operating strategies in a manner generally accompanying a shareholding of more than one half of the voting rights. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The Group has applied the acquisition method for business combinations. The cost of acquisition is comprised of the total of the fair value of the assets transferred as reimbursement, equity instruments issued and liabilities incurred or assumed from the previous owner of the acquired company on the transfer date. Each conditional payment is recognised at fair value on the acquisition date. Subsequent changes to the fair value of any conditional purchase price classified as a provision are recognised in profit or loss. 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 measured at fair value on the acquisition date.

The difference between the cost and the fair value of the Group's share of the acquired assets, liabilities and contingent liabilities is recognised as goodwill. Goodwill in a step acquisition is determined on the acquisition date when the controlling influence is obtained and not in conjunction with previous acquisitions. The determination of goodwill in step acquisitions is to include the previously held equity interest in the acquiree, adjusted to fair value, with any gains or losses arising due to remeasurement recognised in profit or loss. 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 net fair value of the assets, liabilities and contingent liabilities of the acquired operations exceeds the cost, the surplus (negative goodwill) is recognised directly in profit or loss.

Intra-group transactions, balance-sheet items and unrealised gains or losses on transactions between Group companies are eliminated. Any unrealised losses are considered an impairment indicator of the asset transferred.

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 executive decision maker. The Group has identified the highest executive decision maker as the CEO. In internal reporting to the CEO, only one segment is used. For more information, see Note 6.

Functional and reporting currency

Items included in the financial statements 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 kronor (SEK) which is the Company's functional and reporting currency.

Transactions and balance-sheet items

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 profit or loss. Items relating to operations are recognised in 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 closing day rate into the Group's presentation currency (SEK) and exchange rate differences arising from this are recognised 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 closing day rate.

Revenues

Operating revenues

Revenue from the sale of pharmaceuticals is recognised when risks and benefits have been transferred to the buyer, which normally occurs when the goods have been delivered from the company's consignment stock to the end customer.

Contract manufacturing revenues (ReFacto) are recognised 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 also include revenue from licensing agreements, such as out-licensing revenue, royalties from third parties and milestone payments. Milestone payments are part payments received from partners triggered by the fulfilment of a specific part of a partnership contract, for example, the regulatory approval a jointly developed product.

Depending on the contract, the initial licensing fee is either recognised up front when the fee is received or distributed over the expected life of the contract.

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 are recognised as revenue in the period in which the cost to which the grant pertains is recognised.

Sobi receives government grants mainly in the form of lower employer's contributions for research for commercial purposes, which is utilised in full, and 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 operating receivables and liabilities and impairment of the development and product portfolio. For more information, see Notes 8 and 9.

Classifications

Within the Group, assets and liabilities are classified as either current or non-current. Non-current 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. For more information, see Note 7.

Goodwill

Goodwill consists of the amount by which the cost exceeds the fair value of the Group's share of the acquired subsidiary/associated company's net identifiable assets at the date of acquisition. Goodwill on acquisition of a subsidiary is recognised as an intangible fixed asset. 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 recognised at cost less any accumulated impairment losses. Gains or losses upon disposal of a unit includes residual carrying amount of the goodwill pertaining to the disposed unit.

Acquired development projects

Expenditures for acquired research and development projects are recognised as intangible fixed 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.

Product rights

Product rights are recognised at cost less accumulated amortisation. Product rights have a limited useful life and are amortised to allocate the cost over this period (5 to 20 years). Amortisation is adapted to the expected earnings for each product right. The product rights and licensing rights are not related to any inventory cycle or production, nor is it necessary to otherwise bring the inventories to their present location and condition. Amortisations is classified as selling expenses. For more information see Note 4.

Research and development costs

Expenditure for development projects is recognised as an intangible fixed 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 FDA or European Commission (EC) approval is obtained. Acquired research projects are activated at the acqusition date. Amortisation is carried out to allocate the cost of development projects over their estimated useful lives, and is implemented once the development project starts to generate revenues. Other research and development expenditures that do not meet the accounting requirements according to IAS 38 are recognised as incurred.

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 overheads.

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 software that has been recognised as fixed assets is done using the straight-line method over the software 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 fixed 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 recognised 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 recognised as expenses in profit or loss in the period in which they are incurred.

Depreciation of tangible fixed assets

Laboratory equipment and other investments

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 and with consideration for residual value. The following depreciation/ amortisation periods are applied:

Plant and machinery

Other major investments,	
for example redevelopment of property	5–20 years
Equipment, tools, fixtures and fittings	
Computers, servers and other major	
computer hardware items	3–5 years

3-7 years

5-10 years

Land and buildings

Furniture, fixtures and fittings

Buildings	20 years
Land	Indeterminate useful life

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

An asset's carrying amount is immediately impaired 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 recognised 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 recognised as a fixed asset in the balance sheet. Corresponding commitments of future leasing fees are recognised as current or non-current liabilities. The leased assets are depreciated according to plan, while lease payments are recognised as interest and repayment of debt. Leased assets where the lessor essentially retains ownership of the assets are classified as operating leases and leasing fees are expensed on a straight-line basis over the term of the lease. For more information, see Note 10.

Impairment of tangible and intangible fixed assets Goodwill, with an indeterminable useful life, and intangible fixed 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 carrying amount 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. An asset is impaired if its carrying amount exceeds the recoverable amount. Impairment thus comprises 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 Sobi'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. Sobi has made the assessment that the Group's operations as a whole comprise a cash-generating unit. Any impairment of goodwill is not reversed. Impairment loss for an asset other than goodwill is reversed if there has been any change in the conditions used to determine the recoverable amount. Reversal amounts do not exceed the carrying amount that would have been recognised, less depreciation, if no impairment had been performed. Impairment testing of goodwill, product rights and research projects is described in Note 19.

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. See also Note 3.

The Group classifies its financial instruments in the following categories:

- 1) Loan receivables and accounts receivable
- 2) Financial instruments measured at fair value in profit or loss (including derivatives not classified as hedging instruments)
- 3) Other financial liabilities
- 4) Financial instruments held for sale (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 instruments not recognised at fair value in profit or loss. Financial instruments measured at fair value in profit or loss are initially recognised at fair value, while related transaction costs are recognised in 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 carrying amount of the asset is reduced and the amount of the loss is recognised in the consolidated income statement.

Financial instruments recognised in the balance sheet include, on the assets side, cash and cash equivalents and accounts receivable. Financial liabilities include accounts payable, equity instruments and borrowings.

1) Loan receivables and accounts receivable

Loan receivables and accounts receivable are non-derivative financial instruments 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 loan receivables 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 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 instruments measured at fair value in profit or loss (including derivatives not classified as hedging instruments) Financial assets measured at fair value in profit or loss are financial assets that do not constitute hedging instruments. 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 twelve 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 handle transaction risk in operational activities are recognised in operating profit and derivatives that are held to handle 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. If there are liabilities in this category, they are recognised in a manner corresponding to the assets.

3) Other financial liabilities

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 transaction costs. Borrowing is subsequently recognised at amortised cost and any difference between the amount received and the repayment amount is recognised in profit or loss over the duration of the loan, using the effective interest method.

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

4) Financial instruments held for sale (including derivatives classified as hedging instruments)

Financial instruments held for sale 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 income statement 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

The Group uses derivative instruments to manage risks of exchange-rate fluctuations and interest-rate risk in financing. All derivatives are assigned a market value and the market values are recognised in the balance sheet, both initially and at subsequent remeasurement. 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 non-current liability when the hedged item's remaining maturity is longer than twelve months, and as a current asset or current liability if the hedged item's remaining maturity is less than twelve months. Derivative instruments that do not constitute hedging instruments 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 in 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 in profit or loss. Accumulated gains or losses in equity are 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 when a hedge no longer meets the criteria for hedge accounting and accumulated gains or losses from the hedge are in recognised equity, the gains or losses on the hedge remain as a separate component of equity and are recognised when the forecast transaction is finally recognised in profit or loss.

c) Net investment hedaes

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 in profit or loss. Accumulated gains and losses in equity are recognised in 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 measured 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 are 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.

Equity

Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new shares or options are recognised 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 recognised in 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 current 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 profit or loss 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 since the Parent Company can govern the time for reversal of the temporary differences and it is probable that such a transfer will not take place 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 loss carry-forwards are recognised 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 deemed likely that they can be used. Tax is recognised under the Income tax item in the statement of comprehensive income except for those items recognised under other comprehensive income or shareholders' equity. See also Notes 18 and 23.

Employee benefits

Pensions

Sobi has both defined-contribution and defined-benefit pension plans. However, Sobi strives to implement defined-contribution pension plans. The CEO and senior executives are mainly covered by defined-contribution plans. A defined-contribution pension plan provides a contribution to a pension plan determined as a percentage of the pensionable salary. The level of the pension benefit on retirement is determined by the premiums paid and the return on the investments, less management expenses.

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 such plans fall due within a twelve month period.

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.

The net amount of the estimated present value of the commitments and fair value of the plan assets is recognised in the balance sheet as either a provision or a non-current financial receivable.

Regarding defined-benefit plans, pension costs and pension commitments are calculated according to the applicable principles of IAS 19. This calculation is performed annually by independent actuaries.

The company's commitments have been measured at the present value of expected future payments. For discounting commitments in Sweden, a discount rate is applied 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 30.

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 policy 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 2005-2014 financial years, the Group did not have access to the information necessary to be able to recognise this plan as a defined-benefit plan. The ITP pension plan insured through Alecta is therefore recognised as a defined-contribution plan.

A special employer's contribution is calculated on deductible pension premiums.

Long-term incentive programmes

Sobi currently has six active share programmes. The fair value of the allotted share programme is calculated on the issue date by applying a generally accepted valuation model, the Monte Carlo simulation model, also taking into account conditions that are related to the market. The total amount to be expensed is based on the fair value of the allocated shares.

The total amount is recognised as a personnel cost in profit or loss, distributed over the vesting period, and corresponding adjustments are made in equity.

At the end of every quarter, the Group reviews its assessments of how many shares are expected to be vested based on the service requirement.

The shares are delivered to the employee when vested under the framework of the programmes.

The Group has also had a long-term incentive programme since 2014 that does not comprise share-based remuneration. Since remuneration under this programme is conditional on continued employment at the company, the costs are recognised continuously over the vesting period. A liability is calculated at the end of every accounting period taking into account the time value, new assessments of target fulfilment and the amount earned. The net of these effects is recognised as a personnel cost in consolidated profit or loss.

Costs for social security contributions are handled as cash-settled share-based remuneration that is remeasured at each account closing until settlement occurs and allocated in accordance with the same policies for expenses as for shares.

A more detailed description of the long-term incentive programmes can be found in Note 12.

Remuneration in connection with terminated employment A provision is recognised 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 prepared 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 recognised 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 recognised 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 policies

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 policies as the Group with the following exceptions:

Employee benefits/defined-benefit plans

In the calculation of defined-benefit pension plans, the Parent Company complies with the Swedish Pension Obligations Vesting Act and the Swedish Financial Supervisory Authority's instructions, which is a prerequisite for tax deductibility. 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 for future increases, and recognition of all actuarial gains and losses in profit or loss as they occur. For more information, see Note 12 regarding the incentive

Leased assets

All of the Parent Company's leases are recognised according to the rules for operating leases.

Taxes

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

Subsidiaries

Participations in subsidiaries are recognised 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 associated with the acquisition of companies are recognised as part of the cost. Contingent considerations are recognised as part of the cost if it is likely that they will produce results. If, in subsequent periods, it turns out that the initial assessment needs to be revised, the cost should be adjusted.

Group contributions

Sobi applies the alternative rule and, consequently, recognises Group contributions received/paid as appropriations.

Basis for preparation of the Parent Company's and the consolidated financial statements

The Parent Company's functional currency is Swedish kronor (SEK), which is also the presentation currency for the Parent Company and the Group. The financial statements are consequently presented in SEK.

All amounts are stated in thousands of SEK (KSEK) unless otherwise indicated. Assets and liabilities are recognised at historical cost, except for certain financial assets and liabilities, which are measured at fair value.

In order to prepare the financial statements 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 reqularly reviewed.

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

The stated amounts and figures in parenthesis are comparative figures from 2013. See also Note 4.

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 risks are also described in a separate section in the Directors' 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.

Financial risk factors

Currency risk - Transaction risk

Transaction risk 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.

The currencies with the largest net exposures are shown in the graph below. The amounts shown in the graph represent the net amount that has to be revaluated. Transaction exposure at 31 December 2014 amounted to SEK 442 M (291) and has been calculated as exposed net flow. A deviation of one percentage point, either way, would impact profit or loss before tax by SEK 4 M (3).

SEK M



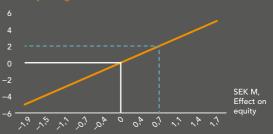
Transaction

exposure, 31 December 2013,



Currency risk - Translation risk

Translation risk 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 SEK. This risk is considered low and therefore not managed. The following graph shows the company's sensitivity to this risk. The graph shows that the translation effect on the Group's equity would be positive if the SEK weakened, and vice versa. If the SEK weakened 2 per cent against other currencies, the translation effect on the Group's equity would amount to SEK 0.7 M.



Positive translation effect if the SEK weakens, and vice versa. If, for example, the SEK weakened 2 per cent against other currencies, the translation effect on the Group's equity would amount to SEK 0.7 M.

Interest-rate risk

Interest-rate 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 acceptable as Sobi's general principle is to minimise the volatility of earnings.

Sobi's financing sources primarily consist of equity, cash flow from operating activities and borrowings. In the case of interest-bearing borrowings, the Group is exposed to interestrate risk. Sobi's long-term financing consists of a bond loan of SEK 800 M with variable interest, which will mature on 26 June 2017. In 2014, a loan of SEK 20 M with variable interest was also raised with AB Svensk Exportkredit (SEK), which will mature on 19 March 2016. Sobi has managed the interest-rate risk related to the bond loan by locking the interest with interest-rate swaps maturing 26 June 2015, where the flows from these swaps 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. At 31 December 2014, such a change would have had an annual impact of SEK 4 M (0) on net financial items. At 31 December 2014, Sobi's interest-bearing liabilities amounted to SEK 818 M (798).

Credit risk

Credit risk refers to the risk of loss if a counterparty does not meet its obligations. Credit risk can be divided up into credit risk in accounts receivable and financial credit risk.

Sobi's credit risk is mainly associated with accounts receivable. On the balance sheet date, these amounted to SEK 480 M, of which SEK 148 M represents overdue receivables. See Note 25 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, and at 31 December 2014, such provisions amounted to SEK 12.4 M. Normally there is no collateral for the credit risk in accounts receivable.

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. How the liquidity risk should be managed is described in the finance policy. 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 the operating activities. 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 instruments issued by the Swedish Government and banks, financial institutes and enterprises with a minimum credit rating of A- from Standard & Poor's or an equivalent rating from another rating agency. A high level of liquidity means that the investments can be converted into liquid funds at any given time. According to the

policy, there must also be a liquidity reserve the size of which should be based on a proportion of annual sales. The liquidity reserve consists of bank balances, short-term investments and the unutilised portion of granted credit facilities. The company has unutilised, confirmed credit facilities totalling SEK 315 M.

Long-term financing consists of a loan of SEK 20 M maturing on 19 March 2016 and 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 for the bond also contains restrictions regarding any significant change in the company's ownership structure, 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.

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.

Maturity analysis

	Less than 1 year	Between 1–2 years	Between 2-5 years	than 5 years
At 31 December 2014				
Bond ¹	42,096	42,096	820,414	
Derivatives	8,120			
Borrowings				
Accounts payable	235,972			
Other liabilities	1,704	4,036	_	_
Total	288,145	66,187	820,414	
At 31 December 2013				
$Bond^2$	52,735	52,735	879,103	
Derivatives				
Borrowings				
Accounts payable				
Other liabilities	22,897	4,924	_	_
Total	314,730	63,598	879,103	_

The interest rate has been calculated using an interest rate of 5.3 per cent,

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 structure is assessed based on the Group's equity ratio. Sobi's goal is an equity ratio of at least 40 per cent. At 31 December 2014, the equity ratio was as follows:

	2014	2013
Equity	4,522,870	4,769,244
Total assets	6,370,744	6,519,320
Equity ratio, %		73.2

Financial instruments measured at fair value

The following table shows financial instruments measured at fair value, based on their classification in the fair value hierarchy. The different levels are defined as follows:

- Level 1: Quoted prices in active markets for identical assets
- Level 2: Observable data for the asset or liability other than guoted prices included in Level 1
- Level 3: Data for the asset or liability that is not based on observable market data

At 31 December 2014	Level 1	Level 2	Level 3	Total
Financial liabilities measured at fair value in profit or loss				
Derivative instruments held for trade				
Financial liabilities held for sale				
Derivative instruments used for hedging purposes				
Total		7,876		7,876

² The interest rate has been calculated using an interest rate of 6.6 per cent,

At 31 December 2013	Level 1	Level 2	Level 3	Total
Financial liabilities held for sale				
Derivative instruments used for hedging purposes		5,939		5,939
Total	_	5,939	_	5,939

All derivatives are measured at fair value based on market data in accordance with IFRS. At 31 December 2014, the recognised value of derivatives in the balance sheet was SEK -8 M (-6). See also Note 28.

Note 4

Important estimates and assumptions, and judgement for accounting purposes

The Group makes estimates and assumptions concerning the future and judgments for accounting purposes. Key judgments for accounting purposes, estimates and assumptions that have a significant risk of material adjustment in reported values of assets and liabilities within the next fiscal year are discussed below.

Judgement for accounting purposes 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 fees and milestone revenues.

Inventories

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.

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 proiect has reached the commercialisation phase and fulfills the criteria according to IAS 38. Evaluation of the project's progress and impairment testing are carried out regularly, at least

Expenses for internal development and payments for projects and substances under agreements with third parties are expensed continuously if they do not fulfil the requirements of IAS 38 Intangible fixed assets. Standards and uncertainty usually mean that the criteria are not fulfilled. However, in cases where the criteria are met, intangible fixed assets are capitalised and amortised according to plan from when the company can show that it is technically possible and profitable to commercialise the results.

For a sensitivity analysis, see Note 19.

Estimates and assumptions Intangible fixed assets

The Group's intangible fixed assets are essentially attributable to goodwill, research projects and product rights. The goodwill stems from the acquisition of Swedish Orphan. Annual impairment testing of goodwill, research projects and product rights is based on their recoverable amounts, including important assumptions such as sales growth, margins and discount rates, see below as well as Note 19.

Goodwill

The Group periodically conducts assessments 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 19. At 31 December 2014, Sobi's goodwill amounted to SEK 1,554 M (1,648). Goodwill linked to Kiobrina was impaired in the amount of SEK 94 M, see Note 19. The other impairment tests carried out did not indicate any impairment requirement.

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 19.

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 of 5-20 years and is adapted to the expected earnings of each product right. The Company has determined that most of these depreciation attributable to the sales costs as intangible assets that are classified as product rights relate primarily to marketing rights These rights enable Sobi to market and sell certain products. Usefulness of rights is not consumed in a manufacturing process but rather over a period of use that relates to how long the related product is relevant to the market. Where the carrying amount of these product rights is 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 medicinal product. 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 included in impairment testing of product rights are presented in Note 19.

Taxes

Deferred tax is calculated using the balance sheet method based on temporary differences between the carrying amounts of assets and liabilities and their tax bases. The amounts are calculated using the tax rates and tax regulations that apply or have been announced as of the balance sheet date. Tax loss carry-forwards never mature, under current tax legislation.

Assumptions for the calculation of pension benefits

The actuarial calculation of pension commitments and pension costs is based on actuarial assumptions as specified in Notes 2 and 30.

Inventory

Obsolescence

Stock consist of raw materials for manufacturing, manufactured semi-finished and finished products for Kepivance, Orfadin, Ammonaps and Kineret, and finished stock for other products. For this stock, 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 shelf life results in an impairment. Products not approved at quality inspection are 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 inventory is not approved by Sobi's and/or Pfizer's quality department, the material is immediately expensed. Obsolescence assessments are regularly updated 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. All finished inventories are measured continuously with respect to the shelf life limitations of pharmaceuticals.

Note 5

Distribution of operating revenues

GROUP	2014	2013
Operating revenues by major revenue type		
Product sales	1,932,501	1,557,661
Manufacturing and contract development	465,927	491,943
Royalty revenues	172,515	127,090
Licensing and milestone revenues	15,433	
Service fee	20,600	_
Total	2,606,976	2,176,694
Revenues by geographic market ¹		
Europe ²	1,814,447	1,544,261
MENAR ³	180,689	55,126
North America	578,881	550,176
RoW ⁴	32,959	27,131
Total	2,606,976	2,176,694

PARENT COMPANY	2014	2013
Operating revenues by major revenue type		
Product sales	1,653,802	1,222,848
Manufacturing and contract development	465,927	491,943
Royalty revenues	172,515	127,090
Licensing and milestone revenues	15,433	
Service fee	20,600	_
Total	2,328,277	1,841,881
Revenues by geographic market ¹		
Europe⁵	1,711,325	1,426,528
MENAR ³		38,425
North America	497,507	363,391
RoW⁴	35,166	13,537
Total	2,328,277	1,841,881

 $^{^{\}rm I}$ The geographic distribution is based on where customers are located. $^{\rm 2}$ Sales in Sweden amounted to SEK 112 M (107).

Revenues by product category

GROUP	2014	2013
Inflammation: Kineret	609,302	561,689
Genetics & Metabolism: Orfadin	547,900	365,901
Genetics & Metabolism: Other		84,364
Haemophilia	30,922	_
Key Therapeutic Areas	1,306,592	1,011,954
Partner Products	682,222	545,707
Manufacturing revenues	465,927	491,943
Royalty revenues	152,235	127,090
ReFacto	618,162	619,033
Total	2,606,976	2,176,694

³ Middle East, North Africa <u>& Russia.</u>

⁴ Rest of world. ⁵ Sales in Sweden amounted to SEK 112 M (107).

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 revenues by geographic areas. See Note 5 for more information regarding the distribution of major revenue types and geographic areas.

Sobi's single largest customer is Pfizer, which accounted for sales of SEK 618 M (619), corresponding to 24 per cent (29) of the company's total revenues. Sobi has not had any other customer for which revenues exceed 10 per cent of the company's total revenues in 2014 and 2013. Most of the company's fixed assets are in Sweden. There are no fixed assets of any significant value outside Sweden.

Note 7

Depreciation/amortisation and impairment of intangible and tangible fixed assets

GROUP	2014	2013
Depreciation/amortisation according to plan by type of asset		
Capitalised software expenses	-3,634	-3,869
Patents and licenses	-54,149	-52,850
Product rights	-223,816	–218,177
Land and buildings	-334	-334
Plant and machinery	-8,791	–11,361
Equipment, tools, fixtures and fittings	-20,569	-17,044
Cars	-1,975	-1,319
Total	-313,268	-304,954
Depreciation/amortisation according to plan by function		
Cost of goods and services sold	-18,181	-19,248
Sales and administrative expenses	-293,259	-284,861
Research and development expenses	–1,828	–845
Total	-313,268	-304,954
Impairment losses by asset	-94 <i>.</i> 149	
Research and development	-94,149 -174,131	_
Patents and licenses	-1/4,131	— -2,667
Total	-268,280	-2,667
		2,007
Impairment losses by function		
Sales and administrative expenses		–2,667
Other operating expenses	-268,280	-
Total	-268,280	-2,667

PARENT COMPANY	2014	2013
Depreciation/amortisation according to plan by type of asset		
Capitalised software expenses		-3,869
Patents and licenses	-2,406	-1,585
Product rights	-82,503	-76,864
Land and buildings	-334	-334
Plant and machinery		-10,864
Equipment, tools, fixtures and fittings		–16,547
Total	-116,336	-110,063
Depreciation/amortisation according to plan by function		
Cost of goods and services sold		-19,248
Sales and administrative expenses	-96,504	-90,030
Research and development expenses	–1,651	–785
Total	-116,336	-110,063
Impairment losses by asset		
Patents and licenses		-2,667
Total		-2,667
Impairment by function		
Sales and administrative expenses		-2,667
Total	_	-2,667

Other operating revenues

GROUP	2014	2013
Exchange-rate gains		20,895
Other	781	2,729
Total	39,897	23,624
PARENT COMPANY	2014	2013
Exchange-rate gains		19,150
Further invoiced costs to		
subsidiaries	10,009	10,934
Other	505	2,729
Total	46,087	32,813

Note 9

Other operating expenses

GROUP	2014	2013
Exchange-rate losses on operating receivables/liabilities	-31,966	–17,419
Divestment of fixed assets	_	1,271
Impairment of Multiferon ¹	-25,246	_
Impairment of Kiobrina ²	-324,898	_
Other	1,413	-4,055
Total	-380,697	-20,203

PARENT COMPANY	2014	2013
Exchange-rate losses on operating receivables/liabilities		-16,678
Divestment of fixed assets		1,271
Write-down of Multiferon ¹		_
Write-down of Kiobrina ²		_
Other		-4,055
Total	-110,144	-19,462

and melanoma. This also entails that the company's facility in Umeå will be closed down. Sobi will supply Multiferon to patients until the end of 2015. The discontinuation entails a write-down of SEK 25.2 M, with a slight impact on

Note 10

Leasing fees for operational leasing

Contractual future rental payments for premises with noncancellable contracts, due for payment as follows:

	Group		Parent Company	
	2014	2013	2014	2013
Within one year		58,509		56,305
Between one and five years	215,970	268,722	209,850	267,832
Later than five years	119,221	121,490	119,221	121,490
Total	398,080	448,721	388,689	445,627
Leasing costs for the year	63,472	57,889	58,552	54,364

Contracted future minimum lease payments for noncancellable contracts, due for payment as follows:

	Group		Parent Company	
	2014	2013	2014	2013
Within one year	6,126	4,342		689
Between one and five years		5,238		502
Total	17,414	9,580	508	1,191
Leasing costs for the year	8,052	6,080		832

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 payments does not constitute a substantial amount of the fair value of the property and that, moreover, there is no convincing evidence that a financial lease exists.

² The Kiobrina research project was written off in the first quarter of 2014, since the phase 3 study did not meet its primary endpoints, refer to Note 19.

Profit/loss from participations in Group companies

PARENT COMPANY	2014	2013
Dividends from subsidiaries	2,772	2,288
Impairment of participations in Group companies	-177,435	
Total	-174,663	2,288

Wright-down for the year is attributable to the Arexis AB subsidiary, since parts of the Kiobrina research project were recognised as an asset in this company, see also Note 19.

Note 12

Personnel, personnel costs and remuneration to Board members and senior executives

Average number of employees

GROUP	2014	% of whom women	% of whom men	2013	% of whom women	% of whom men
Sweden				394	62	38
Denmark		83		10	90	10
Finland/ Baltics				8	56	44
Norway				9	70	30
United Kingdom				20	44	56
France				20	63	37
Germany				19	61	39
Italy				13	63	37
Spain				12	54	46
Belgium ¹				0	71	29
Russia				5	60	40
${\sf Switzerland}^2$				0	0	0
Austria³				0	0	0
Central and Eastern						
Europe				14	67	33
USA				19	35	65
Middle East			83	3	25	75
Total	589	57	43	546	58	42

¹ Employees as of December 2013. ² Employed as of April 2014. ³ Employees as of June 2014.

Salaries, other remuneration and social security costs

	201	14	20′	13
GROUP AND PARENT COMPANY	Salaries and remu- neration	Social security costs	and remu-	Social security costs
Parent Company	297,406		278,384	149,090
(of which pension cost)		(52,639)		(31,499)
Subsidiaries	225,432	53,023	129,150	32,580
(of which pension cost)		(15,872)		(9,599)
Group, total	522,838		407,534	181,670
(of which pension cost)		(68,511)		(41,098)

Salaries and other remuneration by Board members and CEO, and other employees

	20	14	2013		
	Board and CEO	Other employ- ees	Board and CEO	Other employ- ees	
Parent Company					
Salaries and other					
remuneration		280,376	14,085	264,299	
(of which bonuses)	(1,803)	(32,101)	(1,102)	(23,093)	
Subsidiaries					
Salaries and other					
remuneration		203,813	16,052	113,098	
(of which bonuses)	(4,481)	(39,094)	(3,811)	(13,544)	
Group, total	38,649	484,189	30,137	377,397	
(of which bonuses)			(4,913)	(36,637)	

Senior executives' terms and remuneration

Sobi aims to offer competitive terms to help the company recruit and retain skilled personnel. (For complete guidelines, see the Directors' Report).

Fees are paid to the elected Board members in accordance with resolutions by the Annual General Meetings, with exception for the Chairman of the Board, who is not eligible for any remuneration for Board duties or Committee work. No pension is paid to Board members.

Remuneration of the CEO is reviewed and proposed by the Board Chairman together with the Remuneration Committee and is approved by the Board. Remuneration of other members of Group management is proposed by the CEO in close consultation with the Remuneration Committee and is approved by the Board. Remuneration of the CEO and other senior executives comprises fixed salary, short and long-term variable salary, benefits and pension. "Other senior executives" refers to the individuals who, together with the CEO, comprise the Executive Leadership Team. During 2014, there was a total of 11 other senior executives.

Fixed salary

The specific senior executive's areas of responsibility, experience and performance are taken into account in determining fixed salary. Fixed salary is reviewed every year.

Short-term variable remuneration

Short-term variable remuneration for the CEO in 2014 was maximised at 50 per cent of fixed salary. Variable remuneration is based on targets at Group level as well as individual targets established by the Board. For other senior executives, short-term variable remuneration is maximised at 40 per cent of fixed salary and is based on targets at Group and division level as well as individual targets. 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.

Pension terms and conditions

The CEO has a defined-contribution-based pension agreement under which Sobi pays a contribution of 25 per cent of annual gross salary. In 2014, gross salary including pension provisions amounted to SEK 4,810 K. The age of retirement is 65.

Other senior executives employed in Sweden are encompassed by the ITP plan with a retirement age of 65. These executives are also encompassed by a supplementary defined-contribution pension commitment of 27 per cent of pensionable salary including ITP. The pensionable salary is limited to 50 income base amounts. In conjunction with the transition from defined-benefit to defined-contribution plans, separate agreements were reached with individuals with contribution percentages exceeding 27 per cent. Members of Group Management employed in other countries receive pension conditions according to market practice in their country of employment.

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

	Basic	Variable			Financial instruments,	
	salary/fees	remuneration	Pension cost	Other benefits	etc.	Total
2014²						
Chairman of the Board						
Bo Jesper Hansen³	2,268					2,268
Other Board members ⁴						
Helena Saxon	392					392
Hans Schikan	403					403
Adine Grate Axén ⁵	363					363
Lennart Johansson	403					403
Hans Wigzell	363					363
Matthew Gantz	387					387
Annette Clancy ⁶	237					237
Chief Executive Officer						
Geoffrey McDonough ⁷	3,614				3,247	12,213
Other senior executives ^{1, 7}	18,217	5,912	5,726	1,069	3,732	34,655
Total	26,647	7,715	6,922	3,422	6,979	51,685

Other senior executives refers to Sobi's Executive Leadership Team, consisting of 11 persons other than the CEO at 31 December 2014.

³ Bo Jesper Hansen's employment and monthly salary are not linked to his position as Chairman of the Board.

compensation for social security contributions

⁶ Annette Clancy has been a member of the Board since the 2014 AGM. Remuneration pertains to work carried out during this period.

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

Total	24,377	5,180	4,985	1,538	6,815	200	43,095
Other senior executives ¹	16,601	4,078	3,905	442	3,784	200	29,010
Geoffrey McDonough	3,240	1,102	1,080	1,096	3,031		9,549
Chief Executive Officer							
Matthew Gantz	381						381
Hans Wigzell	333						333
Lennart Johansson	373						373
Adine Grate Axén ⁵	333						333
Hans Schikan	372						372
Helena Saxon	358						358
Other Board members ⁴							
Bo Jesper Hansen³	2,386						2,386
Chairman of the Board							
2013 ²							
	Basic salary/ fees	Variable remuneration	Pension cost	Other benefits	instruments, etc.	Other remuneration	Total
					Financial		

1 Other senior executives refers to Sobi's Executive Leadership Team, consisting of 11 persons other than the CEO at 31 December 2013.

Other sellior executives refers to solic Executive Leadership learn, consisting of 11 persons other than the CEO at 31 December 2013.

3 Possible Shows the company's costs (excluding social security costs).

4 For more information regarding Board fees, see the Corporate Governance Report.

5 The fee includes director's fee excluding social security contributions. The gross payment to the Board members company amounted to 438 TSEK, which includes compensation for social security contributions.

Remuneration and other benefits to the Board, CEO¹ and other senior executives

	2014	2013
Parent Company and Subsidiaries		
Parent Company		
Salaries and other remuneration	36,085	32,631
(of which bonuses)	(5,596)	(4,768)
Pensions	6,258	4,617
Number of persons (excl. employee representatives)	17	16
Subsidiaries		
Salaries and other remuneration	30,397	21,531
(of which bonuses)	(6,600)	(4,423)
Pensions	2,136	1,928
Number of persons	15	12
Group		
Salaries and other remuneration	66,482	54,162
(of which bonuses)	(12,195)	(9,191)
Pensions	8,394	6,545
Number of persons (excl. employee representatives)	32	28
employee representatives)	32	20

¹ Includes remuneration to the Managing Directors of subsisidiaries.

Long-term incentive programmes

Annual General Meetings in 2011–2014 resolved in accordance with the Board's proposal to establish long-term incentive programmes. The aim has been 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 senior executives and key employees. Below is a description of the longterm share-based remuneration programmes in the company.

The performance share programmes for 2011–2014 are structured according to similar principles.

- The programmes have a three-year vesting period.
- The programmes also require investment in Sobi shares.
- Employees receive matching shares free of charge and potential performance shares if the conditions in the programme are met. The number of potential performance shares that the employee has the possibility of receiving differs between the organisational levels.
- The employee must be permanently employed during the entire vesting period and keep the investment shares during this period to receive matching and potential performance shares.
- The performance targets are that the share price increases by a certain percentage over a three-year period.
- Who the eligible employees are differs between the programmes, as well as how exactly the performance target has been formulated.

Share programme 2011 (vested 2014)

The Board meeting in December 2014 resolved that the following performance conditions and other terms for remuneration were fully met when the 2011 share programme was redeemed on 15 December 2014. Managers and key employees were therefore allotted 514,808 shares at a market value of SEK 39.3 M, of which the CEO's portion comprised 178.396 shares at a market value of SEK 13.6 M.

The Board decided in December 2011 that the following performance conditions had been complied with in full.

Performance Condition 1: The total return of the Sobi share must amount to at least 15 per cent during each performance period in order for performance shares to be allotted.

Performance Condition 2: Upon fulfilment of Performance Condition 1, an evaluation is carried out of the total return of the Sobi share in relation to the total return for an established group of comparable companies. Full allotment is attained if the total return for the Sobi share corresponds to the upper quartile for the comparable group (the maximum level) or exceeds this level. If the minimum level is reached (the median for the comparable group), an allotment of 35 per cent of the maximum number of performance shares will be take place. Straight-line allotment takes place between the minimum and maximum levels.

Long-term share programme for CEO Geoffrey McDonough (vested 2014)

The Board meeting in August 2014 resolved that the following performance conditions and other terms for remuneration were fully met when the share programme for the CEO was redeemed on 15 August 2014. The CEO was therefore allotted 500,000 shares at a market value of SEK 41.5 M.

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 measurement period.
- b) For the maximum allotment of 400,000 performance shares, the volume-weighted average share price during the last ten trading days of the measurement period shall amount to at least SEK 45. If the volume weighted-average share price for the ten last trading days of the measurement period is between the thresholds set out here and in item a, the portion of the 400,000 performance shares is to be allotted on a straight-line basis.

Threshold allotment 1 of 30,000 performance shares

c) The participant is to be allotted an additional 30,000 performance shares if the volume-weighted average share price for the last ten trading days of the measurement period amounts to at least SEK 30.

Threshold allotment 2 of 70,000 performance shares

d) The participant is also to be allotted 70,000 performance shares if the volume-weighted average share price for the last ten trading days of the measurement period amounts to at least SEK 35.

Share programme 2012

The 2012 AGM approved a long-term share programme that encompasses the CEO, senior executives and managers, and a programme for other employees. The performance target is that the share price is to increase between 25 and 75 per cent from the volume-weighted share price ten days prior to the roll-out of the programme. The performance outcome is 0 if the share price is below 25 per cent and straight-line allotment takes place between 25 and 75 per cent.

Share programme 2012

	Number of performance shares	Number of matching shares	Value in SEK
CEO and other senior executives in the Group, 9	376,130	91,197	5,398,115
Total	376,130	91,197	5,398,115

Share programme 2013

The 2013 AGM approved a long-term share programme that encompasses the CEO, senior executives and managers, and a programme for other employees. The performance target is that the share price is to increase between 15 and 75 per cent from the volume-weighted share price ten days prior to the roll-out of the programme. The performance outcome is 0 if the share price is below 15 per cent and straight-line allotment takes place between 15 and 75 per cent.

Share programme 2013

	Number of performance shares	Number of matching shares	Value in SEK
CEO and other senior executives in the Group, 11	318,509	79,867	9,745,523
Total	318,909	79,867	9,745,323

Share programme 2014

The 2014 AGM approved a long-term share programme that encompasses the CEO, senior executives and managers, and a programme for other employees. The performance target is that the share price is to increase between 15 and 75 per cent from the volume-weighted share price ten days prior to the roll-out of the programme. The performance outcome is 0 if the share price is below 15 per cent and straight-line allotment takes place between 15 and 75 per cent.

Share programme 2014				
	Number of performance shares	Number of matching shares	Value in SEK	
CEO and other senior executives in the Group, 11		40,627	9,106,516	
Total	163,951	40,627	9,106,516	

Cash-based programme 2014

The 2014 AGM approved a long-term cash-based programme comprising all employees in the US. The performance target is that the share price rises between 15 and 75 per cent from the volume weighted average share price ten days prior to the program's rollout. A development of under 15 per cent will results in a performance outcome of 0, and an outcome between 15 per cent and 75 per cent will result in a linear assignment. The turnover should also be at 95 to 105 per cent relative to the average budget over three years. Compensation under this program is subject to continued employment during the vesting period, which is three years.

Expensing of the Share Programmes 2012, 2013 and 2014 are calculated using the following parameters:

	Start date	End date	No. of matching shares	No. of per- formance shares	Vesting period (months)	Fair value of matching share	Fair value of per- formance share	Expected employee turnover, %	Max. allotment of shares
Share Programme 2012, Leadership Programme	2012-05-14	2015-05-14	155,800	488,310	36	21.99	9.02	5	644,110
Share Programme 2012, Employee Programme	2012-05-14	2015-05-14		21,900	36		12.24	5	21,900
Share Programme 2013:1	2013-05-16	2016-05-15	293,179	662,785	36	42.62	19.69	5	955,964
Share Programme 2013:2	2013-11-15	2016-11-14	15,299	26,921	36	65.00	29.70	5	42,150
Share Programme 2014:1	2014-05-09	2017-05-09	133,760	249,852	36	81.78	37.41	5	383,612
Share Programme 2014:2	2014-11-17	2017-11-17	39,093	139,962	36	83.34	34.03	5	179,055

Volatility is measured as the standard deviation of the expected return on the share price, based on a static analysis of daily share prices for Sobi's ordinary share over the past three years. The valuation model also includes the corresponding historical volatility for comparative companies' share prices over the same period, as well as the correlation between all share prices.

Gender distribution of the Board and management

The data in the table does not include employee representatives. The data refers to conditions on the balance-sheet date.

Group	2014	2013
Board		
Men		5
Women		2
Total	8	7
CEO and other senior executives		
Men		8
Women	4	4
Total	12	12

Fees and remuneration to auditors

GROUP	2014	2013
PwC		
Auditing assignments ¹	-455	-3,371
of which audit activities in addition to the auditing		
assignment	_	(–697)
Tax consultancy	-48	-3,675
Other services	-214	-1,542
Total PwC	–717	-8,588
EY		
Auditing assignments ¹	-2,577	_
of which audit activities in addition to the auditing		
assignment	_	_
Tax consultancy	-100	_
Other services	–756	_
Total EY	-3,433	_
Total	-4,150	-8,588

PARENT COMPANY	2014	2013
PwC		
Auditing assignments ¹		-2,302
of which audit activities in addi-		
tion to the auditing assignment		(–697)
Tax consultancy		-3,392
Other services	-124	-1,274
Total PwC	-124	-6,968
EY		
EY Auditing assignments	-1,305	_
	-1,305	_
Auditing assignments ¹	–1,305 —	_ _
Auditing assignments ¹ of which audit activities in addi-	–1,305 — –100	
Auditing assignments ¹ of which audit activities in addition to the auditing assignment		- - - -
Auditing assignments ¹ of which audit activities in addition to the auditing assignment Tax consultancy	 	- - - -

¹ Auditing assignment refers to the statutory audit in order to submit the audit report and audit consultancy. The "Audit activities in addition to the auditing assignment" category includes reviews of interim reports.

Costs according to type of cost

GROUP	2014	2013
Raw materials and consumables	-817,535	-645,909
Other external costs	-673,196	-668,998
Costs for remuneration to employees	-787 , 152	-624,119
Depreciation/amortisation	-313,268	-307,621
Other operating expenses ¹	-380,697	-20,203
Total	-2,971,848	-2,266,850

PARENT COMPANY	2014	2013
Raw materials and consumables	- 732,156	-637,051
Other external costs	-732,286	-655,636
Personnel costs		-467,726
Depreciation/amortisation	-116,336	-112,731
Other operating expenses ²	-110,144	-19,462
Total	-2,177,521	-1,892,606

¹ Other operating expenses includes write-downs relating to Kiobrina and Multiferon of SEK 350.1 M.

Financial income

GROUP	2014	2013
Interest income, other	4,228	4,489
Profit from current investments	_	1,333
Exchange-rate gains	65,604	5,284
Revaluation of financial receivable	_	3,085
Other	_	112
Total	69,832	14,303

PARENT COMPANY	2014	2013
Interest income, Group companies	30,954	29,291
Interest income, other	3,436	4,489
Exchange-rate gains		5,284
Revaluation of financial receivable	_	3,085
Total	99,520	42,149

Exchange-rate gains are mainly derived from the revaluation of internal loan receivables in the Parent Company.

Financial expenses

GROUP	2014	2013
Interest expenses, borrowings	-54,415	-51,787
Interest expenses, other	-2,206	-8,625
Exchange-rate losses		-7,399
Management expenses		-3,375
Other	-254	
Total	-63,422	<i>–</i> 71,186

PARENT COMPANY	2014	2013
Interest expenses, Group companies	-500	_
Interest expenses, borrowings	-54,415	-51,787
Interest expenses, other		-7,668
Exchange-rate losses		-7,399
Management expenses		-3,375
Other	-254	_
Total	-63,129	-70,229

² Other operating expenses includes write-downs relating to Kiobrina and Multiferon of SEK 81.1 M.

Exchange-rate differences affecting operating profit/loss

GROUP	2014	2013
Exchange-rate differences affecting operating profit/loss		3,476
Total	7,150	3,476
PARENT COMPANY	2014	2013
Exchange-rate differences affecting operating profit/loss	3,607	2,472
Total	3,607	2,472

Income tax

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

GROUP	2014	2013
Tax expense/income for the period	-16,093	-14,983
Adjustment of tax attributable to previous years	-3,348	–1,032
Total current tax for the Group	-19,441	-16,015
Deferred tax relating to:		
Provision for pensions	1,107	-4,367
Change in tax allocation reserve and excess depreciation	-8,800	-21,375
Internal gains in stock	40,073	-16,122
Amortisation of intangible fixed	40,073	-10,122
assets	38,148	34,253
Loss carry-forwards	-35,514	35,552
Revaluation of deferred tax	31,772	17,060
Other	3,388	1,473
Total deferred tax for the Group	70,174	46,474
Total tax for the Group	50,733	30,459
PARENT COMPANY	2014	2013
Tax expense/income for the period	_	
Adjustment of tax attributable		
to previous years	-3,348	<u>–1 032</u>
Total current tax for the Parent Company	-3,348	-1,032
Deferred tax relating to:		
Loss carry-forwards	-10,976	11,235
Revaluation of deferred tax	-6,128	24,511
Total deferred tax for the Group	-17,104	35,746
Total tax for the Parent Company	-20,452	34.714

Reconciliation of effective tax

GROUP	2014	2013
Profit/loss before tax	-318,565	-123,415
Tax according to the applicable tax rate for the Parent Company		27,151
Effect of foreign tax rates		-9,038
Unrecognised taxable income	270	_
Non-deductible expenses	-1,521	-5,357
Non-taxable income	878	629
Interest on tax allocation reserve		-386
Adjustment of tax attributable to previous years		-1,032
Impairment of goodwill		_
Deferred tax assets previously unrecognised		18,492
Recognised effective tax	50,733	30,459

PARENT COMPANY	2014	2013
Profit/loss before tax	-100,273	-42,362
Tax according to the applicable tax rate for the Parent Company	22,060	9,320
Unrecognised taxable income	270	-3
Non-deductible expenses	-1,502	-5,344
Adjustment of tax attributable to previous years	-3,348	-1,032
Non-taxable income	1,362	1,132
Impairment of participations in subsidiaries	-39,036 ¹	_
Revaluation of deferred tax	-258	30,641
Recognised effective tax	-20,452	34,714

 $^{^{\}rm 1}$ Pertains to impairment of participations in the Arexis subsidiary, linked to the Kiobrina research project.

The applicable tax rate for the Parent Company is 22 per cent

Intangible fixed assets and impa	airment testing							
GROUP	Goodwill	Research & development	Licenses & patents	Product rights	Advanced payment	Capitalised soft- ware expenditure	IT software in progress	Total
1 January-31 December 2013								
Opening carrying amount	1,605,307	172,274	481,647	2,251,174		7,697	15,267	4,533,366
Acquisitions			12,447²	366,515²			5,171²	384,133
Reclassification of cost	43,000¹		-122,507 ¹			10,146	-14,940	-84,301
Write-downs			-2,667³					-2,667
Amortisation			-52,850	-218,177		-3,869		-274,896
Reclassification of accumulated amortisation			84,190	221		-3,018		81,393
Closing carrying amount	1,648,307	172,274	400,260	2,399,733	_	10,956	5,498	4,637,028
At 31 December 2013								
Cost	1,648,307	281,420	599,427	3,381,273		67,531	5,498	5,983,456
Accumulated depreciation and		100111	4004/7	004 540		E / E3E		4 24 / 400
impairment losses		-109,146	_199,167	_981,540	<u> </u>	-56,575		-1,346,428
Carrying amount	1,648,307	172,274	400,260	2,399,733		10,956	5,498	4,637,028
1 January–31 December 2014								
Opening carrying amount			400,260					4,637,028
Acquisitions			11,907⁴	51,160⁴		4,807⁴	18,907⁴	
Reclassification of cost								
Write-downs		−174,131 ⁵						
Amortisation	_	_	-54,149	-223,816	_	-3,634		–281,599
Closing carrying amount	1,554,158		356,161	2,227,077	73,503	12,184	24,405	4,247,488
At 31 December 2014								
Cost		283,277	609,477	3,432,433		72,393	24,405	6,143,795
Accumulated depreciation and	04.149							
write-downs	-94,149 4 FF4.4F3	-283,277	<u>-253,316</u>	_1,205,356		-60,209		_1,896,307
Carrying amount	1,554,158		356,161	2,227,077	73,503	12,184	24,405	4,247,488

¹ Reclassification linked to the acquisition of Arexis
² Acquisitions in 2013 pertain 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 others (SEK 0.8 M).
³ The write-down in 2013 pertains to impairment of the O4CP project. Management has deemed that these assets are of no value.
⁴ Acquisitions in 2014 pertain to Elocta, recognised as an advance payment (SEK 73.5 M), XTEN (SEK 51.2 M), IFS (SEK 18.6 M), Affibody (SEK 11.0 M) and others (SEK 6.0 M).
⁵ The write-down in 2014 pertains to the Kiobrina research project. Management has deemed that these assets are of no value.

PARENT COMPANY	Licenses & patents	Product rights	Advanced payment	Capitalised software expenditure	IT software in progress	Total
1 January–31 December 2013						
Opening carrying amount	82,377	535,896		5,003	15,267	638,543
Acquisitions	12,447¹	366,515¹			5,171¹	384,133
Reclassification of cost	– 79,507			10,110	-14,940	-84,337
Write-downs	-2,667²					-2,667
Amortisation	-1,585	-76,864		-3,869		-82,318
Reclassification of accumulated amortisation	84,190	221	_	-3,018	_	81,393
Closing carrying amount	95,255	825,768	_	8,226	5,498	934,747
At 31 December 2013						
Cost	101,258	1,096,573		61,312	5,498	1,264,641
Accumulated depreciation and impairment losses	-6,003	-270,805	_	-53,086	_	-329,894
Carrying amount	95,255	825,768	_	8,226	5,498	934,747
1 January–31 December 2014						
Opening carrying amount	95,255	825,768		8,226		934,747
Acquisitions	11,907³	51,160³	73,503	4,807³	18,907³	
Reclassification of cost	_					
Write-downs	_					
Amortisation	-2,406	-82,503				-88,470
Reclassification of accumulated amortisation						
Closing carrying amount	104,756	794,425	73,503	9,437	24,405	1,006,526
At 31 December 2014						
Cost	113,165	1,147,733			24,405	1,424,890
Accumulated depreciation and write-downs	-8,409	-353,308		-56,647		-418,364
Carrying amount	104,756	794,425	73,503	9,437	24,405	1,006,526

¹ Acquisitions in 2013 pertains 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 others (SEK 0.8 M).

² The write-down in 2013 pertains to the O4CP project. Management has deemed that these assets are of no value.

³ Acquisitions in 2014 pertain to Elocta, recognised as an advance payment (SEK 73.5 M), XTEN (SEK 51.2 M), IFS (SEK 18.6 M), Affibody (SEK 11.0 M) and others (SEK 6.0 M).

Testing for impairment of intangible fixed assets Goodwill

Assessment of the value of the Group's goodwill is based on the value in use of the smallest cash-generating unit, which for Sobi is defined as the Group.

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, sales and expenses. Cash flows beyond the five-year period have been extrapolated using an estimated growth rate of 2 per cent. At 31 December 2014, Sobi's goodwill amounted to SEK 1,554 M (1,648), after the write-down of Kiobrina. Goodwill linked to Kiobrina was written down in the amount of SEK 94 M, see also impairment losses in 2014. There is no other indication of goodwill impairment on the group level.

The following table shows the growth rate and discount rate used before and after tax:

PARAMETER, %	2014	2013
Growth rate beyond the initial five-		
year period		2
Discount rate before tax		11.5
Discount rate after tax	8.7	9.0

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

Risk-free interest rate: ten-year treasury bills or comparable financial investment with the lowest possible risk.

Market risk premium: 6.1 per cent (6.5)

Beta coefficient: Sobi's beta coefficient has been calculated at 0.9 (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 volume and eternal growth rate. The sensitivity analysis indicates that there are good margins in the calculation.

Development projects and product rights

Development projects and product rights are tested annually for impairment. Impairment testing has been carried out for each product or project separately. The assessment of the value of research projects and product rights is based on the value in use of each asset. The value in use is based on cash flows that are expected to be generated over the remaining life of the asset. When discounting of future cash flows, the discount rate is used as described above.

For impairment testing of research projects, key parameters are future cash flows from the individual asset, the probability to achieve positive outcomes in clinical trials, and assumptions of 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. A best-case assumption is made on the basis of the parameters that affect whether the project will develop a drug with the highest commercial potential, and is 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.

In the impairment testing of product rights, a number of assumptions are made. 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 exceed five years, the contract or the patent term is used as the remaining lifetime. Implemented impairment testing of product rights does not indicate any impairment.

Impairment losses in 2014

In 2014, Sobi evaluated the future potential of the Kiobrina research project and deemed the value of the intangible fixed assets needed to be impaired. The valuation was based on the phase 3 study of Kiobrina not achieving its primary endpoint. The entire carrying amount was impaired at a total of SEK 325 M, of which intangible fixed assets accounted for SEK 268 M (whereof goodwill amounted to SEK 94 M), stock for SEK 32 M, and other costs for SEK 25 M. The impairment loss was charged to earnings under other operating expenses.

Contractual commitments for acquisitions of intangible fixed assets

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

Biogen

According to the agreement between Sobi and Biogen regarding the development and commercialisation of rFVIIIFc (Eloctate/ Elocta) and rFIXFc (Alprolix), Biogen takes full responsibility for the development and production, and the costs for this until Sobi exercises its opt-in right to the programmes.

Sobi has opt-in rights to take over final development and commercialisation in Europe, North Africa, Russia and certain countries in the Middle East (Sobi's territory). Biogen has commercialisation rights for North America (Biogen's North American territory) and for the rest of the world excluding Sobi's territory (Biogen's direct territories and Biogen's distribution territory). Sobi and Biogen receive a royalty on each other's sales in the respective company's territories, according to the royalty rates in the table below.

Under the terms of the opt-in right and following Biogen's submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for each programme, Sobi may opt to take over final regulatory approval and other commercialisation activities in Sobi's territory by making a deposit of USD 10.0 M for each programme. In November 2014, Sobi decided to exercise its opt-in right for Eloctate/ Elocta (see below).

Following the EU regulatory approval of Elocta, Sobi will be liable to reimburse Biogen for 50 per cent of the total production costs for clinical manufacture of the product, development costs for the product from 1 October 2009 until the date on which Sobi is registered as the Marketing Authorisation Holder, or 90 days after the approval, and certain shared expenses related to regulatory approval, costs for final development and commercialisation, and 100 per cent of some development costs that only benefitted Sobi's territory.

Sobi's reimbursement to Biogen for each programme will be effected by adjusting the royalty rates between the companies until full reimbursement is achieved, see the table. Assuming that Sobi exercises its opt-in right, reimbursement will take place as follows:

> Percentage after first commercial sales in Sobi's territory if Sobi exercvises its opt-in

PERCENTAGES FOR ROYALTIES AND REMUNERATION BETWEEN THE COMPANIES	Method	Percentage before first com- mercial sales in Sobi's territory, %	Base rate, %	Percentage during the repayment period ⁶	Net royalty pay- ment during repayment period, % ⁷
From Sobi to Biogen based on net sales in Sobi's territory	Royalty on sale	N/A	124	Base rate plus 5%	17
Biogen to Sobi based on net sales in North American territory	Royalty on sale	2	124	Base rate minus 5%	7
Biogen to Sobi based on net sales in Biogen's direct territory outside North America	Royalty on sale	2	175	Base rate minus 5%	12
Biogen to Sobi based on net partner revenue ¹ from Biogen's distribution territory ²	Royalty on net profit	10	50	Base rate minus 15%	35

¹ Net partner revenue pertain to Biogen's revenues before tax from distributors (third-party), less expenses incurred by Biogen for supporting these sales.

If full reimbursement has not been achieved within six years of Biogen's first commercial sale for each programme, Biogen is entitled to request that Sobi pay the remaining amount within 90 days from the sixth anniversary of the date of the first commercial sale.

Elocta

In October 2014, Sobi's partner Biogen submitted an MAA for Elocta (rFVIIIFc) to the EMA. This application for marketing approval to the EMA, together with the delivery of data from Biogen to Sobi, triggered Sobi's exclusive opt-in right to assume final development and commercialisation of Elocta in Europe, North Africa, Russia and most countries in the Middle East. On November 21, Sobi exercised its opt-in right and paid, in accordance with the agreement, a deposit of USD 10 M. The deposit has been recognised in the balance sheet as an advance payment under intangible fixed assets. Total payment is estimated to be about USD 245 M.

XTEN

On 19 September, Sobi decided to include the preclinical development programme for a potentially longer-lasting haemophila A treatment, XTEN (rFVIIIFc VWF-XTEN Heterodimer) in the agreement with Biogen. In accordance with the agreement between Sobi and Biogen, Sobi will thus have an opt-in right to the programme and receive the commercial rights for Sobi's territory according to the principles described above.

² Biogen's distribution territory pertains to the territory in which sales are conducted through a third party.
³ Sobi will receive credit from Biogen against the payment made by Sobi according to its opt-in right in an amount equal to the difference between the royalty payments that Biogen made to Sobi for sales in Biogen's territories during certain periods before first sales in Sobi's territory, and the percentage that would

 ^{4 10%} if Sobi only exercises its opt-in right for one of the programmes.
 5 15% if Sobi only exercises its opt-in right for one of the programmes.

⁶ The adjusted royalty goes towards repayment of the liability.

⁷ Actual payments that impact cash flow

Tangible	e fixed	assets	

		61	Equipment,		a:	
GROUP	Land and buildings	Plant and machinery	tools, fixtures and fittings	Cars	Construction in progress	Total
1 January–31 December 2013						
Opening carrying amount	4,930	34,241	81,181	3,550	1,683	125,585
Acquisitions		11,754	4,399	5,238	4,585	25,976
Reclassification of cost	-672		3,052		-1,683	697
Disposals			–13			–13
Depreciation	-334	-8,812	–19,593	-1,319		-30,058
Reclassified depreciation	671	-471	3,392			3,592
Closing carrying amount	4,595	36,712	72,418	7,469	4,585	125,779
At 31 December 2013						
Cost	6,728	392,146	201,957	10,448	4,585	615,864
	-2,133				4,303	
Accumulated depreciation and write-downs Carrying amount	-2,133 4,595	-355,434 36,712	_129,538 72,418			<u>-490,084</u> 125,779
Carrying amount	4,373	30,712	72,410	7,409	4,303	125,779
1 January–31 December 2014						
Opening carrying amount			72,418			125,779
Initiation of construction in progress						_
Acquisitions					7,092	22,858
Reclassification of cost						-1,646
Disposals				-1,128		-1,128
Depreciation	-334					-31,669
Reclassified depreciation			_	1,035		1,035
Closing carrying amount	4,261	41,261	56,598	5,979	7,130	115,229
At 31 December 2014						
Cost	6,728	405,487	206,705	8,859		634,909
Accumulated depreciation and write-downs		-364,225				-519,679
Carrying amount	4,261	41,261	56,598	5,979	7,130	115,229

PARENT COMPANY	Land and buildings	Plant and machinery	Equipment, tools, fixtures and fittings	Construction in progress	Total
1 January–31 December 2013					
Opening carrying amount	4,931	35,362	77,977	1,683	119,952
Initiation of construction in progress					
Acquisitions		10,915	3,561	4,585	19,061
Reclassification of cost	-2		2,647	-1,683	962
Disposals			-13		–13
Depreciation	-334	-8,315	-19,096		-27,745
Reclassified depreciation		26	3,392		3,418
Impairment losses	_	_	_	_	
Closing carrying amount	4,595	37,988	68,468	4,585	115,635
At 31 December 2013					
Cost	6,726	387,170	190,964	4,585	589,445
Accumulated depreciation and write-downs	-2,131	-349,182	-122,496		-473,809
Carrying amount	4,595	37,988	68,468	4,585	115,635
1 January–31 December 2014					
Opening carrying amount		37,988			115,635
Initiation of construction in progress					_
Acquisitions			367		16,217
Reclassification of cost					40
Disposals					_
Depreciation	-334				-27,866
Reclassified depreciation					-2
Impairment losses	_	_	_	_	_
Closing carrying amount	4,261	42,537	50,094	7,130	104,022
At 31 December 2014					
Cost	6,728	400,510	191,331		605,853
Accumulated depreciation and write-downs			-141,237		-501,830
Carrying amount	4,261	42,537	50,094	7,130	104,022

Participations	in Group	companies

PARENT COMPANY	2014	2013
Accumulated cost		
At 1 January		4,058,305
Purchasing		163
Total	4,059,504	4,058,468
Accumulated impairment losses		
At 1 January		_
Impairment losses for the year	-177,435	_
Total	-177,435	_
Carrying amount at end of period	3,882,069	4,058,468

The write-down for the year is attributable to the Arexis AB subsidiary, since parts of the Kiobrina research project were recognised as an asset in this company. The Kiobrina research project was fully impaired during the year, for more information see Note 19. Purchasing for the year pertains to new subsidiaries in Switzerland and Austria.

Specification of Parent Company and Group holdings of participations in Group companies

SUBSIDIARY/CORP. REG. NO./REG. OFFICE	No. of par- ticipations	Participa- tions in %¹	Carrying amount
Swedish Orphan Biovitrum International AB, 556329-5624, Stockholm, Sweden - Swedish Orphan Biovitrum A/S, 19179079, Copenhagen, Denmark - Swedish Orphan Biovitrum SARL, 490259405, Paris, France - Swedish Orphan Biovitrum s.r.o, 28171276, Prague, Czech Republic - Oy Swedish Orphan Biovitrum AB, 1024811, Abo, Finland - Swedish Orphan Biovitrum s.r.l, 5288990962, Parma, Italy - OOO Swedish Orphan Biovitrum, 5087746194520, Moscow, Russia - Swedish Orphan Biovitrum AS, 976313682, Trollasen, Norway - Swedish Orphan Biovitrum S.L, B84710623, Madrid, Spain - Swedish Orphan Biovitrum Ltd, 4369760, Cambridgeshire, Great Britain - Swedish Orphan Biovitrum GmbH, HRB 42329, Langen, Germany	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	225,137
Sobi, Inc EIN 68-0682244, Delaware, USA	1,000	100.0	7
Swedish Orphan Biovitrum S:R:O, 28171276, Prague, Czech Republic ²		1.0	8
BVBA Swedish Orphan Biovitrum, 0536.217.087, Brussels, Belgium	100	100.0	162
Swedish Orphan Biovitrum AG, 284.917.678, Luzern, Switzerland	100	100.0	723
Swedish Orphan Biovitrum GmbH, 416986, Vienna, Austria	100	100.0	313
Total			3,882,069

¹ Refers to the ownership of capital, which also corresponds to the percentage of voting rights.

Note 22

Financial assets

GROUP	2014	2013
Accumulated cost		
At 1 January		4,381
Impairment of loans and share- holdings		-2,000
Financial receivables	810	-371
Other	42	_
Accumulated cost	2,862	2,010
Carrying amount at end of period	2,862	2,010

PARENT COMPANY	2014	2013
Accumulated cost		
At 1 January		3,110
Financial receivables		-489
Impairment of loans and share- holdings		-2,000
Accumulated cost	621	621
Carrying amount at end of period	621	621

Note 23

Deferred tax assets and deferred tax liabilities Recognised deferred tax assets and liabilities

GROUP 2014	Deferred tax assets	Deferred tax liabilities	Net
Stock	58,442		58,442
Acquired product rights	18,383	-366,350	-347,967
Pensions			3,251
Excess depreciation		-143,352	-143,352
Other			10,457
Other intangible fixed assets	216,700		216,700
Loss carry-forward			258
Total	307,491	-509,702	-202,211
Offsetting	-237,538	237,538	_
Tax assets/liabilities, net	69,953	-272,164	-202,211

GROUP 2013	Deferred tax assets	Deferred tax liabilities	Net
Stock	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
Excess depreciation		-134,552	-134,552
Other	5,842		5,842
Other intangible fixed			
assets	216,700		216,700
Loss carry-forward	35,772		35,772
Total	303,556	-576,950	-273,394
Offsetting	-279,148	279,148	_
Tax assets/liabilities, net	24,408	-297,802	-273,394

For the Parent Company, a deferred tax asset of SEK 1.2 M (1.3) remains, pertaining to deferred tax on derivatives. Deferred tax on deficits amounted to SEK 18.6 M (35.8), entailing a deferred tax asset totalling SEK 19.8 M (37.1) in the Parent Company.

The closing balance for tax loss carry-forwards pertains to Swedish companies. Deficits never mature, under current tax legislation. Deficits are capitalised since the Group assesses it likely that the remaining deficit will be offset against future taxable profits. The value of deferred tax after year-end is calculated using a tax rate of 22.0 per cent (22.0).

² The remaining portion is owned by Swedish Orphan Biovitrum International AB.

Change in deferred tax on temporary differences and loss carry-forwards

GROUP 2014	Amount at 1 January	Recognised in profit or loss	Recorded in other comprehensive income	Translation difference	Amount at 31 December
Stock	18,406			-37	58,442
Acquired R&D	-37,900	37,900			
Acquired product rights	-379,987	32,020			-347,967
Pensions	2,325				
Tax allocation reserves/Excess depreciation	-134,552	-8,800			-143,352
Other	5,842		1,227		
Other intangible fixed assets	216,700				216,700
Capitalised loss carry-forwards	35,772	-35,514			258
Total	-273,394	70,174	1,046	-37	-202,211

GROUP 2013	Amount at 1 January	Recognised in profit or loss	Recorded in other comprehensive income	Translation difference	Amount at 31 December
Stock	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 fixed assets	216,700				216,700
Capitalised loss carry-forwards	196	35,552		24	35,772
Total	-318,281	46,474	-1,611	24	-273,394

Inventories

GROUP	2014	2013
Raw materials and consumables	10,745	16,982
Work-in-progress	401,587	360,060
Finished goods and goods for		
resale	351,602	348,908
Total	763,935	725,950

The cost of inventories that was expensed is included in cost of goods sold and amounted to SEK 370,373 K (292,254). Obsolescence cost for the year amounted to SEK 4,744 K (58,923).

PARENT COMPANY	2014	2013
Raw materials and consumables	10,745	16,982
Work-in-progress	401,587	360,060
Finished goods and goods for		
resale	267,935	287,545
Total	680,268	664,587

The cost of inventories that was expensed is included in cost of goods sold and amounted to SEK 369,824 K (289,605). Obsolescence cost for the year amounted to SEK 4,744 K (58,923).

Accounts receivable and other receivables

GROUP	2014	2013
Accounts receivable	492,449	424,907
Minus:		
Provision for doubtful receivables	-12,424	-10,442
Accounts receivable, net	480,025	414,465
Tax assets	19,567	18,048
Other receivables	42,283	48,233
Total other receivables	61,850	66,281
Total accounts receivable and		
other receivables	541,875	480,746
PARENT COMPANY	2014	2013
Accounts receivable	202,804	203,667
Minus:		
Provision for doubtful receivables	-8,801	_10,370
Accounts receivable, net	194,003	193,297
Tax assets		17,010
Other receivables	29,605	35,256
Total other receivables	46,714	52,266
Total accounts receivable and other receivables	240,717	245,563

No established bad debt losses were charged against the Company's profit for the year.

At 31 December 2014, accounts receivable amounting to SEK 148 M (145) had fallen due. Provisions in the amount of SEK 12.4 M (10.4) have been made for overdue accounts receivable, which are considered doubtful.

Changes in the provision for doubtful receivables are as

Doubtful receivables

GROUP	2014	2013
At 1 January	-10,442	-5,136
Provision for doubtful accounts receivable		-5,306
Reversed provisions		_
At 31 December	-12,424	-10,442
PARENT COMPANY	2014	2013
At 1 January	2014 -10,370	2013 –5,068
At 1 January Provision for doubtful accounts		-5,068

Past due accounts receivable

GROUP	2014	2013
Undue		269,821
Past due 1–30 days		46,184
Past due 31–90 days	34,327	21,747
Past due 91–120 days	7,879	8,488
Past due > 121 days	36,624	68,225
Total	480,025	414,465
PARENT COMPANY	2014	2013
PARENT COMPANY Undue	2014 181,697	2013 155,468
Undue	181,697	155,468
Undue Past due 1–30 days	181,697 5,974	155,468 16,187
Undue Past due 1–30 days Past due 31–90 days	181,697 5,974 3,760	155,468 16,187 5,598

Recognised amount per currency for accounts receivable and other receivables

GROUP	2014	2013
AUD		3,700
CHF	1,817	1,891
CZK		6,271
DKK	16,524	21,642
EUR		219,333
GBP	43,293	37,491
NOK		9,887
PLN	4,832	4,075
RON		4,461
SEK	100,392	89,877
USD		81,313
Other currencies	3,407	805
Total	541,875	480,746

2014	2013
	3,700
1,722	1,891
	3,970
	21,642
69,973	70,151
2,878	6,601
	9,689
4,832	4,075
	4,461
100,392	89,877
	28,706
	800
240,717	245,563
	1,722 3,365 16,346 69,973 2,878 15,897 4,832 10,685 100,392 4,985 3,407

Prepaid expenses and accrued income

GROUP	2014	2013
Accrued royalty revenues	43,277	23,728
Accrued co-promotion revenues		6,372
Prepaid leasing fees		125
Prepaid rents		16,344
Prepaid insurance expenses		12,666
Accrued interest income		2,562
Other accrued revenues		1,378
Other prepaid expenses	30,004	15,127
Total	110,255	78,302

PARENT COMPANY	2014	2013
Accrued royalty revenues	43,277	23,728
Accrued co-promotion revenues		5,545
Prepaid leasing fees		_
Prepaid rents		15,270
Prepaid insurance expenses	9,443	11,195
Accrued interest income		2,562
Other accrued revenues		1,034
Other prepaid expenses	23,111	9,212
Total	100,042	68,546

Current investments and cash equivalents

	2014		20	13
GROUP	Fair value	Carrying amount	Fair value	Carrying amount
Cash and bank balances	519,147	519,147	445,097	445,097
Total	519,147	519,147	445,097	445,097
	2014		2013	
	20	14	20	13
PARENT COMPANY	20 Fair value	Carrying amount	20 Fair value	Carrying amount
	Fair	Carrying	Fair	Carrying

Financial assets and liabilities per category (Group)

	Loans and receivables	Assets measured at fair value in profit or loss	Assets held for sale	Total
31 December 2014				
Assets in the balance sheet				
Accounts receivable	480,025			480,025
Cash and cash equivalents	519,147			519,147
Total	999,172			999,172
31 December 2013				
Assets in the balance sheet				
Accounts receivable	414,465			414,465
Cash and cash equivalents	445,097	_	_	445,097
Total	859,562	_	_	859,562

	Liabilities measured at fair value in profit or loss	Other financial liabilities	Liabilities held for sale	Total
31 December 2014				
Liabilities in the balance sheet				
Borrowings	_	811,775		811,775
Financial leasing	_			5,740
Derivatives	2,616			7,876
Accounts payable	_	235,972	_	235,972
Total	2,616	1,053,487	5,260	1,061,363
31 December 2013				
Liabilities in the balance sheet				
Borrowings		790,775		790,775
Financial leasing		6,821		6,821
Derivatives			5,939	5,939
Accounts payable		239,098		239,098
Other current liabilities	_	20,750	_	20,750
Total	_	1,057,444	5,939	1,063,383

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

Other liabilities, non-current

GROUP	2014	2013
Bond Ioan	791,775	790,775
Other	24,036	4,924
Total	815,811	795,699
PARENT COMPANY	2014	2013
PARENT COMPANY Bond loan	2014 791,775	2013 790,775

Bond loans are presented net after transaction costs. At 31 December 2014, the recognised value of the bond loan in the balance sheet amounted to SEK 792 M (791). The estimated fair value is SEK 838 M (848), based on the average of the bid and ask price at the balance sheet date. Other pertains to a newly raised loan of SEK 20 M from AB Svensk Exportkredit. See Note 28 for more information.

Note 30

Post-employment benefits

Pension commitments are calculated annually, on the balance sheet date, based on actuarial principles. Sobi has a definedbenefit pension plan for the subsidiary in Norway, and for two individuals in Sweden.

The present value of the commitment includes special payroll tax, in accordance with IAS 19, for the Swedish and Norwegian pension plans.

Pension costs are recognised under the items: selling expenses, administrative expenses and research and develop-

In 2013, Sobi dissolved its defined-benefit pension commitments comprising some 50 individuals and replaced the now terminated plan with a defined-contribution plan.

Through its defined-benefit pension plans after concluded employment, the Group is exposed to a number of risks. The most significant risks are:

Life expectancy assumptions: Most of the pension commitments entail that employees covered by the plan will receive life-long benefits and, accordingly, longer life expectancy assumptions will result in higher pension liabilities. This is most significant in the Swedish plan, in which inflation increases result in higher sensitivity to changes in life expectancy assumptions.

Inflation risk: Some of the plan's pension commitments are linked to inflation; higher inflation leads to higher liabilities (even though, in most cases, a ceiling has been set for the level of inflation to protect the plan against exceptional increases in inflation). Most of the plans assets are either unaffected by (fixed-rate bonds) or weakly correlated with (shares) inflation, meaning that an increase in inflation will also increase the deficit.

Discount rate: A decrease in corporate bond interest rates will increase the liabilities of the plan, although this will partially be offset by an increase in the value of the bond holdings.

Pension benefits

For white-collar employees in Sweden, the ITP 2 plan's defined-benefit pension commitments for retirement pensions and family pensions are insured through Alecta. According to statement UFR10 Accounting for pension plans in ITP2 financed through insurance with Alecta, this is a defined-benefit plan covering multiple employers. For the 2014 financial year, the company did not have access to information enabling a presentation of its proportionate share of the plans commitments, plan assets or expenses, which meant it has not been possible to report the plan as a defined-benefit plan. The ITP 2 pension plan insured through Alecta is therefore recognised as a defined-contribution plan. The premium for the defined-benefit retirement and family pension is calculated on an individual basis, depending on such factors as salary, previously vested pension and expected remaining period of employment. Expected contributions in the next reporting period for the ITP 2 pension plan insured through Alecta amount to SEK 18 M (20.9 MSEK). The Group's share of total plan contributions and the Group's share of the total number of active members in the plan are insignificant.

The collective consolidation level consists of the market value of Alecta's assets as a percentage of insurance commitments calculated according to Alecta's actuarial methods and assumptions, which do not correspond to IAS 19. The collective consolidation level should normally be allowed to vary between 125 and 155 per cent. If Alecta's collective consolidation level falls below 125 per cent, or rises above 155 per cent, measures are to be taken to create the conditions for returning the consolidation level to the normal range. 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 2014, Alecta's surplus in the form of the collective consolidation level amounted to 143 per cent (2013: 148 per cent).

The Norwegian pension plan is subject to the Norwegian corporate pension act (Foretakspenjonsloven) and the Swedish plan to the Pension Obligations Vesting Act and the consortium agreement. Under the consortium agreement, Sobi is required to allocate the funds necessary for ensuring that the pension assets correspond to the Sobi's share of the pension liability.

Both Swedish and Norwegian plans are based on final salary.

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

1 January– 31 December 2014	Present value of commit- ments	Fair value of plan assets	Total
At 1 January	-36,255	27,114	-9,141
Current service cost	-1,900		-1,900
Interest expense	-1,441		-1,441
Gains/losses on settlements			
Revaluations:			
– Return on plan assets, excl. amounts included in interest expenses		787	787
 Gain/loss from change in demo- graphic assump- tions 			
– Changed financial assumptions	-5,299		
– Experience-based assumptions			2,008
Contributions			
– employer		752	2,337
– settlements			
Exchange-rate differences	65	-140	-75
At 31 December	-41,285	28,371	-12,915

1 January– 31 December 2013	Present value of commit- ments	Fair value of plan assets	Total
At 1 January	-144,111	112,878	-31,233
Current service cost	-1,896	-249	-2,145
Interest expense	-1,361		-1,361
Gains/losses on settlements ¹	102,945	-84,654	18,291
Revaluations:			
 Return on plan assets, excl. amounts included in interest expenses 		1,393	1,393
 Gain/loss from change in demo- graphic assump- tions 	1,853	-11	1,842
– Changed financial assumptions	-416		-416
Experience-based assumptions	– 570	363	-207
Contributions			
– employer	5,967	258	6,225
– settlements		-2,185	-2,185
Exchange-rate differences	1,334	-679	655
At 31 December	-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.

BREAKDOWN OF NET PENSION COMMITMENT PER COUNTRY	2014	2013
Sweden	-4,725	-3,903
Norway	-8,190	-5,238
Total	-12,915	-9,141

Actuarial assumptions on the balance sheet date

SWEDISH PENSION PLAN	2014	2013
Discount rate, %		3.6
Expected annual inflation, %		2.0
Remaining life expectancy after retirement age, men, years		19.6
Remaining life expectancy after retirement age, women, years	22.8	22.8

NORWEGIAN PENSION PLAN	2014	2013
Discount rate, %	3.00	3.70
Expected annual inflation, %	1.50	2.00
Remaining life expectancy after retirement age, men, years	21.3	20.4
Remaining life expectancy after retirement age, women, years	24.4	23.2

Demographic assumptions

Mortality assumptions are the same as those proposed by the Swedish Financial Supervisory Authority in force from 31 December 2007 for the Swedish pension plan, while the K2013 BE mortality table has been used for the Norwegian plan. At the balance sheet date, Norway had eight active employees and Sweden had one active employee and one retiree. Retirement ages are set at 65 years.

Breakdown of asset class

	2014	Of which quoted, %	2013	Of which quoted, %
Shares/equity funds	8,710	100	7,295	100
Interest-bearing securities	12,350		14,023	100
Properties	905		796	
Other funds	6,279		4,740	
Other	127		260	_
Total	28,371		27,114	

>> Note 30, cont.

Sensitivity analysis

	2014	2013
Pension commitment		2/ 255
under current assumptions	41,285	36,255
Discount rate –0.5%		39,827
Discount rate +0.5%	37,604	33,087
Inflation +0.5%	44,374	37,536
Inflation –0.5%	39,228	35,139
Life expectancy after retirement –1 year	39,039	34,466
Life expectancy after retirement +1 year	42,910	37,491

The above sensitivity analyses are based on a change in one assumption, while all other assumptions remain constant. In practice, this is highly unlikely and some changes in the assumptions may be correlated. When calculating the sensitivity of the defined-benefit commitments to significant actuarial assumptions, the same method (present value of the defined-benefit commitment by applying the projected unit credit method at the end of the reporting period) has been applied as when calculating the pension liability recognised in the statement of financial position.

Other information

For the 2015 financial year, contributions to plans for remuneration after terminated employment are expected to amount to SEK 1,371 K (1,661). The weighted average maturity of the commitment is estimated to be 32 years.

Note 31

Provision for pension commitments

	Group		Parent Co	ompany
	2014	2013	2014	2013
Provision at 1 January		31,233	_	
Redemption of defined-benefit pension plan		-18,927	_	
Payments		-3,404	_	
Provisions for the year	3,964	239	_	
Provisions at 31 December	12,915	9,141		

See also the Consolidated statement of changes in equity, and Note 30.

	Group		Parent Company	
	2014	2013	2014	2013
Non-current	12,915	9,141	_	
Current	_		_	
Total provisions	12,915	9,141	_	_

Note 32

Accrued expenses and deferred income

GROUP	2014	2013
Provision for vacation pay and bonuses,		
incl. social security contributions	147,492	91,026
Accrued social security contributions	48,523	54,830
Accrued royalty expense	13,783	18,212
Restructuring expenses		6,587
Discontinuation of Multiferon	17,100	_
Accrued manufacturing expenses		12,994
Accrued R&D expenses		31,825
Accrued interest expenses		3,213
Accrued consulting and travel		
expenses	7,640	_
Accrued discounts		34,001
Accrued expenses for audit and		
annual report		5,254
Co-promotion		7,259
Other accrued expenses	47,982	54,117
Total	451,488	319,318

PARENT COMPANY	2014	2013
Provision for vacation pay and bonuses, incl. social security contri-		
butions		72,751
Accrued social security contributions	45,428	51,367
Accrued royalty		16,138
Restructuring expenses		6,587
Discontinuation of Multiferon	17,100	_
Accrued manufacturing expenses		10,088
Accrued R&D expenses		31,825
Accrued interest expenses		3,213
Accrued expenses for audit and annual report	4,200	4,188
Accrued consulting and travel expenses	3,935	_
Co-promotion		7,259
Other accrued expenses		31,079
Total	273,540	234,495

Pledged assets

GROUP	2014	2013
Contingent liabilities	200,000	200,000
Total	200,000	200,000
PARENT COMPANY	2014	2013
Contingent liabilities	200,000	200,000
Guarantee commitment	6,000	3,000
Total	206,000	203,000

In a credit agreement that includes an operating credit of SEK 135 M, there are pledged assets in the form of a floating charge of SEK 200 M. Swedish Orphan Biovitrum AB (publ.) has issued limited general guarantees for local credit requirements on behalf of four (one) subsidiaries.

Note 34

Tax and legal disputes

Sobi has had an ongoing dispute with the Swedish Tax Agency regarding a sale of the Paradiset 14 property. The decision from the Tax Agency entailed that the company has made a final payment of SEK 0.8 M in 2014. A provision for this amount was made in the 2013 accounts.

On 29 March 2012, Sobi signed a supplementary agreement regarding acquisition of the pharmaceutical company Arexis AB in 2005. The agreement entails that Sobi is to pay a total of SEK 77 M. Sobi paid the remaining amount of SEK 21 M in

Note 35

Transactions with related parties

Orfacare, a company associated with the Chairman of the Board, provides consulting services regarding procuring, marketing and distributing products from Sobi in Switzerland and Austria among others. In 2014, consultancy expenses amounted to SEK 3.0 M (3.3).

Note 36

Events after the balance-sheet date

The partnership agreement with Exelixis, Inc. pertaining to the commercialisation of Cometriq was renegotiated and extended until 31 December 2019.

The European Commission approved Xiapex for the treatment of Peyronie's disease.

Positive efficacy and safety results from Sobi and Biogen's phase 3 study, Kids B-LONG, in children for the drug candidate Alprolix (rFIXFc) for haemophilia B.

The company extended the employment contract with Bo Jesper Hansen.

Refer also to the Directors' Report.

The Board of Directors and the CEO 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 annual accounts 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.

The Directors' Report for the Group and Parent Company provides a fair overview of the Group's and the Parent Company'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 presented to the Annual General Meeting on 6 May 2015 for adoption.

Stockholm, 27 March 2015

Bo Jesper Hansen	Matthew Gantz	Adine Grate Axén	Hans GCP Schikan
Chairman of the Board	Board member	Board member	Board member
Helena Saxon	Lennart Johansson	Hans Wigzell	Annette Clancy
Board member	Board member	Board member	Board member
	Catarina Larsson Employee representative	Bo-Gunnar Rosenbrand Employee representative	

Geoffrey McDonough Chief Executive Officer

Our auditors' report was submitted on 27 March 2015 Ernst & Young AB

> Björn Ohlsson Authorised Public Accountant

Sobi's Corporate Governance

Swedish Orphan Biovitrum AB (publ) "Sobi" is a Swedish public limited liability company with its registered office in Stockholm, Sweden. Sobi is listed on Nasdag Stockholm. In addition to the rules stipulated by law or other statutes, Sobi applies the Swedish Corporate Governance Code complete. This report pertains to the 2014 financial year and is a part of Sobi's Directors' Report and has been reviewed by the company's auditors.

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 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 the appropriation of profits. The AGM also elects the company's auditor.

2. Nomination Committee

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

3. Board of Directors/Chairman of the Board

The Board of Directors is responsible for the Group's organisation and management. The Board also decides on overall objectives, strategies, the financial structure, policies, appointment of the Chief Executive Officer (CEO), remuneration to the management, acquisitions, divestments and major investments. The Board approves and

adopts the annual report and interim reports, and proposes dividends, if any, to 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 various committees established by the Board. The Board's working procedures and instructions for the CEO are revised and updated once a year. The Chairman of the Board leads the Board's work, monitors the company's performance, ensures that important issues are addressed as needed and that all important decisions are preceded by active and constructive discussion. Sobi's Chairman is employed by the company as Executive Chairman.

4. Audit Committee

The Audit Committee's main duties are to handle the company's accounting, financial, reporting and audit matters, as well as issues relating to Sobi's internal control. The responsibilities of the Committee include an annual discussion of proposals from the auditors regarding the scope and methods of the audit, examining in advance proposed changes to accounting policies and adjustments to accounting documents that affect financial reporting. The responsibilities also include 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 Sobi's remuneration programmes. This includes an overview, and proposals for remuneration to senior executives and for long-term incentive programmes, pension plans and other issues relating to remuneration to the company's employees.

6. Scientific Committee

The Scientific Committee's tasks include advising on scientific matters, evaluating the Company's research strategies, and monitoring and reporting to the Board on scientific trends and new fields of research.

7. CEO/Executive Leadership Team

Sobi 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 research and development and in producing and selling pharmaceuticals. In addition, the Executive Leadership Team's members possess the requisite skills in finance, law, human resources and communication. The operative management is based on the decision-making procedure established by the Board, as reflected in the organisational and governance model according to 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

Sobi's auditors', elected at the AGM, reviews the consolidated financial statements, as well as the annual accounts of the Parent Company and subsidiaries, and also prepares an audit report.

Major internal regulations

- Articles of Association
- Board of Directors' working procedures
- CEO instructions
- Policy documents

Major external regulations

- Swedish Companies Act
- Swedish and international accounting laws
- Nasdaq Stockholm's rules and regulations
- Swedish Corporate Governance Code



Shareholders, share capital, the share and voting rights

At year-end, Sobi had a total of 12,955 (10,153) shareholders. Investor AB was the largest shareholder, with 39.7 per cent (39.8) of the share capital and 39.8 per cent (39.8) of the voting rights. The 15 largest shareholders accounted for 71.6 per cent (75.5) of the share capital and 71.6 per cent (75.5) 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 contain any specific provisions regarding the appointment and dismissal of Board members 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.

Significant events in the Board's work in 2014

- Decision to exercise the option on Elocta, potential drug for haemophilia A.
- Elected to include new potentially longer-acting haemophilia A candidate, XTEN, in collaboration agreement with Biogen.
- Decision to discontinue the development of Kiobrina.
- Decision to cease manufacturing of Multiferon.
- Election of Annette Clancy as a new Board member at the 2014 AGM.
- Election of Ernst & Young as new auditor.

Annual General Meeting (AGM)

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 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.

2014 AGM

The AGM on 8 May 2014 re-elected Board members 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. Annette Clancy was elected as new Board member.

The AGM resolved on remuneration for the Chairman of the Board and the Board members elected by the AGM. Ernst & Young was elected as Sobi's new auditor until the end of the 2015 AGM.

The AGM also voted in favour of a long-term incentive programme and the hedging measures associated with this, encompassing a decision to issue Class C shares and authorising the Board to repurchase the issued Class C shares. The AGM also resolved to approve the Board's proposal on transfer of treasury shares.

The minutes of the 2014 AGM are available at www.sobi.com.

2015 Annual General Meeting

The Annual General Meeting will be held on Wednesday, 6 May 2015, at Näringslivets Hus, Stockholm, Sweden.

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 2014, 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 prior to the AGM.

The Nomination Committee for the 2015 AGM consists of:

- Petra Hedengran, Investor AB (Nomination Committee's Chairman)
- Lennart Francke, Swedbank Robur Fonder AB
- Anders Oscarsson, AMF Pension AB
- Bo Jesper Hansen, Chairman of the Board, Swedish Orphan Biovitrum AB (publ)

The Nomination Committee has held four meetings.

Board of Directors

Sobi is a speciality pharmaceutical company with a focus on marketing, developing and producing pharmaceutical products to treat rare diseases. The product portfolio contains products that are both marketed, and in all phases of clinical research. 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 solid financial expertise.

Composition of the Board

During the 2014 financial year, the Board consisted of eight members elected at the AGM on 8 May 2014, as well as two employee representatives and two deputies appointed by the trade unions. Four members, including the employee representatives, were women. For more information about the Board, see pages 112-113.

Chairman of the Board

The duties of the Chairman of the Board, apart from leading the Board in its work, include monitoring the performance 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 in strategic matters, participate in important external relationships and represent the company in ownership issues. The Chairman is also responsible for ensuring that the performance of the Board is regularly evaluated and that new Board members receive adequate instruction.

The Chairman of the Board is employed by the company as Executive Chairman. As such, his duties also 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 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 106 shows the independence of the Board members on the date that this report was published.

Number of meetings

The Board is to meet at least five times a year, usually in conjunction with the publication of 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 the operations during at least one Board meeting each year. The Board has scheduled a total of eight meetings in 2015.

The Board's work in 2014

The Board held 26 meetings in 2014, of which nine were ordinary and 17 were extra Board meetings. At seven of the 17 extra Board meetings, decisions were made per capsulam. Sobi's General Counsel served as secretary at the meetings. Other Sobi employees presented reports. The number of extra Board meetings was partly motivated by the resolution regarding the results of the phase 3 study for Kiobrina, a decision to discontinue the production of Multiferon and to close the company's production facility in Umeå, proposals for possible collaborations and several cases involving commercial agreements.

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. Sobi's elected auditors attended five of the meetings. Topics discussed at the meetings included the change of auditors, the auditors' planning of the audit, their observations and review of the company, auditors' fees and the Company's interim reports. For information regarding fees for the company's auditors, see Note 13.

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 of management. Sobi's HR Director is the Committee's secretary, but is not a member.

The Compensation & Benefits Committee met five times during the year. At these meetings, the Committee discussed and monitored annual salary revision and bonus outcomes for the CEO and senior executives, and proposed guidelines, nominations and allocations for the long-term incentive programme. The proposals for guidelines for remuneration of the CEO and senior executives will be presented at the AGM in May 2015 for the approval of shareholders.

For information about salaries and remuneration of the CEO and senior executives, see Note 12.

Scientific Committee

The Scientific Committee consists of four members, three of whom are independent in relation to management, Hans Wigzell (Chairman), Hans GCP Schikan and Annette Clancy. The fourth member, Bo Jesper Hansen, does not qualify as independent to management. The Committee's work in 2014 entailed a strategic overhaul of the company's IL-1 portfolio of projects and activities.

The Committee met once in 2014, with all members in attendance.

Board fees

The AGM on 8 May 2014 resolved that Board fees for the period until the next AGM would amount to a total of SEK 2,630,000, of which an amount of SEK 310,000 would be paid to Board members elected by the AGM, with the exception of the Chairman, who is not entitled to any remuneration for his work on the Board or in the Board's committees. For Audit Committee work, the Chairman would receive SEK 100.000 and other members SEK 60.000 each. For Compensation & Benefits Committee work, the Chairman would receive SEK 60,000, and other members SEK 30.000 each. For Scientific Committee work, the Chairman would receive SEK 60,000 and the other members SEK 30,000 each. However, Board fees in 2014 totalled SEK 2,548,000 due to the Chairman of the Board not receiving any remuneration for his work in the committees. It was further resolved that for each Board meeting, an amount of SEK 10,000 would be paid to Board members residing in Europe but outside the Nordic region, and SEK 20,000 to Board members residing outside Europe.

At the 2014 AGM, the Nomination Committee recommended that the Board adopt a policy under which Board members, who do not already have such holdings, over a five-year period, would be expected to build up their own holding of shares in Sobi with a market value that is expected to account for at least one year's fees before tax, excluding fees for committee work.

For more information about the remuneration of Board members, see Note 12.

Changes to the Board

The Board was re-elected in its entirety at the AGM in May. Annette Clancy was also elected to the Board as a new member.

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 2014, the Executive Leadership Team met once a month and, at year-end, consisted of twelve mem-

For more information about the Executive Leadership Team, refer to pages 112-113.

Remuneration to senior executives

To attract and retain competent 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 12.

			Remuneration, (SEK K)					Attendance ⁶		
	Independence	Basic pay/fees	Audit Committee	Compensation & Benefits Committee	Scientific Committee	Other	Total	Board of Directors	Audit Committee	Compensation & Benefits Committee
Bo Jesper Hansen								25/26		5/5
Hans Wigzell	•	307			56		363	22/26		
Lennart Johansson		307	97				403	25/26	9/9	
Helena Saxon		307	57	28			392	25/26	8/9	5/5
Adine Grate Axén³	•	307	57				363	23/26	9/9	
Hans GCP Schikan	•	307		28	28	40	403	24/26		5/5
Matthew Gantz	•	307				80	387	25/26		
Annette Clancy⁴	•	207			20	10	237	12/17		
Catarina Larsson								22/26		
Bo-Gunnar Rosenbrand			<u> </u>	<u> </u>			<u> </u>	24/26	<u> </u>	<u> </u>

 $^{^\}dagger$ Board member does not qualify as independent of the company and its management. 2 Board member does not qualify as independent of major shareholders.

³ Fee include Board fees excluding social security contributions. Gross payment to the Board member's company amounted to SEK 477 K, which included remuneration for social security contributions.

⁴ Annette Clancy has been a member of the Board since the 2014 AGM. Remuneration pertains to work carried out during this period

Employee representative.
The figures in the table show total attendance/meetings. In 2014, the Board held a total of 26 meetings, of which nine were scheduled and 17 were extra meetings. At seven of the 17 extra meetings, decisions were made per capsulam.

Internal control and risk management systems for 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 Sobi's internal control and risk management systems for financial reporting. In 2014, efforts to streamline and develop the processes in the accounting department continued.

The internal control environment at Sobi follows the established COSO framework (Internal Control – Integrated Framework of the Committee of Sponsoring Organisations), comprising 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 Sobi'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 other 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 intranet and include the following:

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

2. Risk Assessment

Effective risk assessment brings together Sobi's business opportunities and results with the requirements of shareholders and other interested parties for stable, long-term value growth and control. A 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 set goals, and, as such, is the basis for risk management.

Structured risk assessment and risk management make it

- Identify and mitigate risks that could affect set goals with respect to financial reporting; and
- Identify and manage the specific risks associated with changes.

Risk management is intended to minimise the number of risk factors in financial reporting, and to ensure that the opportunities that exist within the company are used in the best possible way.

The operating units conduct risk analyses together with the controllers responsible for financial reporting. Within the framework of this process, the units are to identify and evaluate risks in the various accounting and reporting processes. Work in 2014 included monitoring the units' work with process-based control, and reporting internal governance and control. Risk work is reported quarterly to the Executive Leadership Team, Risk Committee, Audit Committee and Board.

3. Control Activities

Control activities are the manuals, processes and policies that ensure that directives and decisions are implemented. The purpose of the control activities is to prevent and detect errors and irregularities, and to propose subsequent corrective actions. Activities include analytical monitoring and comparison of financial performance or items, account reconciliation, monitoring, checking Board decisions and Board-approved policies and procedures, approval and reporting of business transactions and partnership agreements, mandate and authorisation instructions, as well as accounting and valuation principles.

The Controllers are responsible for maintaining internal controls in each area and ensuring that this is developed as necessary. They monitor the operations through a variety of control measures, such as forecasts and budgets, earnings and balance sheet analyses, 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 management and the Board.

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

4. Information and Communication

Sobi has (internal) information and communication channels aimed at ensuring efficient and accurate disclosure of its financial reporting. Effective communication is important for all of the company's employees. Guidelines for financial reporting are set out in policies, communicated to employees and available on 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 external disclosure aim to provide the market with relevant, reliable and correct information about Sobi's development and financial position. Sobi has a communication policy that meets the requirements of a listed company.

To assess the relevance of information and ensure timely Disclosure Committee has been formed that includes the CEO, COO, CFO, General Counsel, SVP Patient Access Officer and Head of Communications.

Financial information is presented regularly in the form of:

- Interim and full-year reports;
- Annual reports;
- Press releases on important news and events that could significantly affect the valuation of the company and the
- Presentations and teleconferences for financial analysts. investors and the media on the same date that interim and full-year reports are published and in conjunction with the release of other important information; and
- Meetings with investors and financial analysts.

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

5. Surveillance, monitoring and evaluation

The Board and the Audit Committee decide on the forms of surveillance, monitoring and evaluation of internal controls. Sobi's CFO is responsible for ensuring that internal controls are maintained in accordance with the Board's decisions. Monitoring is carried out at various levels of the Group.

The Board deals with all quarterly financial statements and annual reports before publication, and monitors the audit 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 conduct monitoring and the annual evaluation of compliance with the internal control and risk management related to financial reporting through the existing organisation. The Board and Audit Committee continuously examine the issue of whether an internal audit function should be established.

Breaches

The company has not breached any regulations on the stock exchange on which the company's shares are traded, or any generally accepted practices on the stock market.

Auditors' report on the Corporate Governance Statement

To the annual meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-9321.

Engagement and responsibility

We have audited the corporate governance statement for the year 2014 on pages 103–108. It is the Board of Directors who is responsible for the corporate governance statement and that it has been prepared in accordance with the Annual Accounts Act. Our responsibility is to express an opinion on the corporate governance statement based on our audit.

The scope of the audit

We conducted our audit in accordance with Fars auditing standard RevU 16. The auditors' examination of the corporate governance statement. That standard requires that we have planned and performed the audit to obtain reasonable assurance that the corporate governance statement is free of material misstatements. An audit includes examining, on a random sample basis, evidence supporting the information included in the corporate governance statement. We believe that our audit procedures provide a reasonable basis for our opinion set out below.

Opinion

In our opinion, the corporate governance statement has been prepared and is consistent with the annual accounts and the consolidated accounts.

Stockholm, 27 March 2015 Ernst & Young AB

Björn Ohlsson Authorised Public Accountant

Sobi has what it takes Interview with Annette Clancy

addition to the Board.

Why did you choose Sobi, and what can you bring to the company?

There are three main reasons why I agreed to join the Board of Directors. Firstly, Sobi is a robust company with a prominent position in both the development and commercialisation of important medications. Secondly, I admire Sobi's growth ambitions as a company. But probably the strongest reason for my decision was all the people at Sobi. The company's culture, mission and vision are firmly in place and embraced by employees, the CEO and the entire Board. That facilitates dialogue and collaboration at Board level.

With more than 30 years' experience in various functions in a major, global pharmaceutical company, mainly in global teams for business development and commercialisation, I think I can participate in, and contribute to, Sobi's continued success. In recent years, I have worked with Boards, and served as Chair, for a number of smaller biotechnology companies, and I believe this experience may also benefit Sobi.

What is your view of the pharmaceutical indus-

Pharmaceutical companies have a two-fold objective – to be profitable, and to develop drugs that create social value. The profits can be reinvested in research and development, which leads to the production of new and innovative medications, and so the cycle can continue. But there is virtually

no low-hanging fruit left in the traditional pharmaceutical industry - new areas must

At the same time, as luck would have it, the scientific understanding of genetic and metabolic diseases is increasing, which is reflected in the growing number of approved medications for these dis-

eases in recent years. The development of medications for rare diseases can also be carried out in a focussed manner, which saves time and reduces costs. But the most important factor is these new therapies are often the first and only option for a limited group of patients with a significant medical need. We can offer them a medicinal product that may be transformational.

in 2014 and what are you looking forward to in 2015?

Biogen's launch of Eloctate in the US was one of most important events for Sobi in 2014. This, combined with Sobi's preparations for launching factor VIII in Europe, is obviously highly significant for Sobi's future. I am now looking forward to a successful launch of Elocta – something that is needed by both patients and the European pharmaceutical market. Sobi is doing a fantastic job as it prepares for the launch and seeing the dedication and profiles of the company's new employees is inspiring. Sobi is once again joining the haemophilia community and I am confident that the company has both the expertise and the products to



"I am looking forward

to a successful

launch of Elocta."

Board of Directors



BO JESPER HANSEN

Born 1958.

Chairman and Board member since 2010, M.D. with a Ph.D. from Copenhagen University.

Other assignments: Board member of Hyperion Therapeutics Inc., GenSpera Inc., Newron Pharmaceuticals SpA, Orphazyme ApS, Karolinska Development AB and Ablynx NV.

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

Shares: 8.893.846



MATTHEW GANTZ

Born 1965.

Board member since 2012. BA Princeton University and MBA from Harvard Business School.

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

Previous assignments: Founder and former CEO of Acureon Pharmaceuticals, CEO of Hydrabiosciences Inc., Vice President Europe for Chirons Biopharmaceutical Division and General Manager of PathoGenesis Europe as well as numerous positions in sales and marketing in the US at Abbott Laboratories Diagnosis Division.

Shares: 0



ADINE GRATE AXÉN

Born 1961.

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

Other assignments: Board member of BSkyB Ltd, Sampo OY, HI3GS Holding AB, 3GIS Infrastructure Services AB, HI3G Denmark ApS, Madrague AB and Swedavia AB. Chairman of Nasdaq OMX Stockholm's Listing Committee and Vice Chairman of the Seventh AP Fund.

Previous assignments: Member of the Advisory Committee for the Sale of State-owned Companies. Board member of Gambro AB, OMX AB, several senior positions and Board assignments at Investor AB and member of the management team. Board member of Acne Studios Holding AB, Evry AS and Carnegie Investment Bank AB.

Shares: 32,000



LENNART JOHANSSON

Born 1955.

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

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

Previous assignments: CEO of 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



Born 1970.

Board member since 2011. M.Sc. from Stockholm School of Economics.

Other assignments: CFO at Investor AB, Board member of Aleris and Mölnlycke Health Care.

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

Shares: 15,500





Born 1958.

Board member since 2011. Pharm.D. Utrecht University.

Other assignments: CEO of Prosensa, Netherlands. Board member of Core Team Dutch Top Sector Life Sciences & Health. Member of Biotechnology Industry Organization's Emerging Companies Section Governing Board. Member of the Advisory Board of BioScience Park Leiden.

Previous assignments: Chairman of the Dutch Association of the Innovative Pharmaceutical Industry, Nefarma. Several leading positions in former companies Organon and Genzyme. Board member of Top Institute Pharma.

Shares: 0





Born 1938.

Board member since 2005. M.D. D.Sc., Professor emeritus of immunology.

Other assignments: Chairman of Rhenman & Partners Asset Management AB. Board member of Karolinska Development AB, RaySearch Laboratories AB, Valneva SE, Sarepta Therapeutics Inc. and AB Wigzellproduktion. Member of the Royal Swedish Academy of Sciences and the Royal Swedish Academy of Engineering Sciences.

Previous assignments: Vice Chancellor of Karolinska Institutet. Board member of NeoDynamics AB, PROBI AB and Diamyd Medical AB.

Shares: 200,000



ANNETTE CLANCY

Born 1954.

Board member since 2014. B.Sc. in Pharmacology from Bath University, UK.

Other assignments: Chair and Board member of Genable Technologies, Board member of Lysogene. Senior European Advisor to the Biopharmaceutical Team in Frazier Healthcare Ventures.

Previous assignments: Head of Transaction and Alliance Management at GlaxoSmithKline (GSK). Board member of Silence Therapeutics plc. and Clavis Pharma in Norway.

More than 30 years' experience from the pharmaceutical/biotechnology industry in a variety of functions (R&D, Marketing, Global Business Development) in both the US and the UK.

Shares: 0



CATARINA LARSSON

Born 1952.

Employee Representative. Laboratory engineer. Board member since 2001.

Representative of Federation of Salaried Employees in Industry and Services (PTK).

Shares: 1.461



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 (PTK).

Shares: 4.5581

BJÖRN OHLSSON Authorised Public Accountant Ernst & Young AB

¹Includes holdings of related natural persons or legal entities.

Executive Leadership Team



GEOFFREY MCDONOUGH

Born 1970.

Chief Executive Officer. Employed since 2011.

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

Previous positions: Various senior positions at 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). Has also served as an internist and paediatrician in the US.

Shares: 578.838



MATS-OLOF WALLIN

Born 1951.

Senior Vice President Chief Financial Officer.

Employed since 2013.

B.Sc. from Uppsala University.

Previous positions: More than 30 years' experience in the life science industry in various executive positions at such companies as Pharmacia, Ortivus,

and, most recently, Biotage AB (publ) where he served as CFO between 2003 and 2011.

Shares: 20,012



ALAN RAFFENSPERGER

Born 1960.

Senior Vice President.

Chief Operating Officer.

Employed since 2012.

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

Other assignments: Chairman of the Board. Pharmanest AB.

Previous positions: CEO of Benechill Inc., Executive Director, Head of the Global Nephrology Business at Amgen International (2008– 2010), General Manager of the Nordic and Baltic Region at Amgen (2005–2008). Sales and Marketing Director at Roche Pharmaceuticals, Sweden (1999–2004), Vice President, Global Marketing Diabetes Care at Roche Diagnostics (1996–1998). Business Director Europe, Diabetes Care at Boehringer Mannheim (1994 –1996). Senior positions at Pharmacia in Sweden and the US. Shares: 43,590



WILLS HUGHES-WILSON

Born 1971.

Senior Vice President, Chief Patient Access Officer.

Employed since 2012. LLV 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 in the European veterinary medicine industry, and Ernst & Young Consulting. Shares: 31,880¹



BIRGITTE VOLCK

Born 1962.

Senior Vice President, Chief Medical Officer.

Employed since 2012.

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

Previous positions: Various senior positions at Amgen since 2007, most recently as Executive Development

Director of Bone, Neuroscience & Inflammation, International R&D at Amgen Limited in Uxbridge, UK. Nordic Medical Director and Project Director at Genzyme A/S in Denmark (2004–2007) as well as Vice President, Clinical Development & Medical Affairs at Pharmexa A/S in Denmark (2001–2004) and various clinical and scientific positions at Copenhagen University Hospital (1991-2000).

Shares: 54.748



DENNIS PEDERSEN

Born 1970.

Senior Vice President, Human Resources.

Employed since 2013.

Trained officer from the Royal Danish Officers Academy, specialised in leadership development, analytical studies and tactics.

Previous positions: HR Director

for Northern Europe at Takeda. Prior to this, extensive experience in the transformation of local HR models to more integrated international practices, and he has held several senior positions in a number of international companies including, Genzyme, Ferring Pharmaceuticals and A.P. Moller-Mærsk.

Shares: 7,124



STEFAN FRAENKEL

Born 1972.

Senior Vice President, Head Corporate Development Employed since 2009.

Ph.D. in International Accounting and Management, MBA from the Copenhagen Business School and an engineering degree from Chalmers University of Technology.

Previous positions: A number of senior positions in business development at Wyeth (2001–2009). Prior to this, he worked as a management consultant.

Shares: 26,7891



FREDRIK BERG

Born 1955.

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

LLM from Stockholm University 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). Legal Counsel and various management positions in the legal departments of KabiVitrum, Procordia, Kabi Pharmacia and Pharmacia & Upjohn (1988–1996). Law firm Tisell & Co (1984–1988).



STEPHEN JAMES

Born 1966.

Vice President, Head of Drug Design & Development. Employed since 2001.

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

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

Shares: 19,410



KIRSTI GJELLAN

Born 1963.

Senior Vice President, Head of Manufacturing Operations.

Employed since 2014.

Pharmacist and Doctor of Pharmaceutical Technology from the University of Oslo, Norway.

Previous positions: Factory Director, Biologics Manufactur-

ing, MD at Pfizer Health AB (2010–2014) and Board member of Pfizer Health AB (2011–2014). Director of Quality Operations, Pfizer (2005–2010). 17 years' experience from senior positions in research and manufacturing medicines at Astra Zeneca.

Shares: 359



ANDERS EDVELL

Born 1969.

Vice President, Head Specialty Care and Partner Products.

Employed since 2006.

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

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

Shares: 38,623

Shares: 72,447



CECILIA FÖRBERG

Born 1956.

Vice President, Head of Project & 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: Various

positions as project manager and manager, mainly in biopharmaceutical process development at Kabi Pharmacia, Pharmacia and Pharmacia & Upjohn since 1989.

Shares: 21 698

¹ Includes holdings of related natural persons or legal entities.

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 2014. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 50-113.

Responsibilities of the Board of Directors and the Chief Executive Officer (CEO) for the annual accounts and consolidated accounts

The Board of Directors and the CEO 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 CEO 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.

Auditors' 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. These 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 CEO, 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 2014 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 2014 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 general 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.

Other matters

The audit of the annual accounts for 2013 was performed by another auditor who submitted an auditors' report dated 1 April 2014, with unmodified opinions in the Report on the annual accounts.

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 adminis-

tration of the Board of Directors and the CEO of Swedish Orphan Biovitrum AB (publ) for the year 2014.

Responsibilities of the Board of Directors and the CEO

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 CEO are responsible for administration under the Companies Act.

Auditors' 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 CEO is liable to the company. We also examined whether any member of the Board of Directors or the CEO 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 CEO be discharged from liability for the financial year.

> Stockholm 27 March 2015 Ernst & Young AB

Björn Ohlsson Authorised Public Accountant

Global Reporting Initiative Index 2014

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
Anti-corruption	G4-SO4, G4-SO5, G4-SO8,

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 42-43 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 2014 or www.sobi.com.

Standa	ard disclosure	Cross- reference	Reported	Comment
Strate	gy and analysis			
G4-1	CEO's statement	6–7 www.sobi.com	•	
G4-2	Description of key impacts, risks and opportunities	42–45, 57–58	•	
Organ	isational profile			
G4-3	Name of the organisation	69	•	
G4-4	Primary brands, products and services	2, 22, 36	•	
G4-5	Location of organisa- tion's headquarters	69		
G4-6	Countries where the organisation operates	3, 16–17, 81, 94	•	

Standa	rd disclosure	Cross- reference	Reported	Comment
G4-7	Nature of ownership and legal form	46–47, 69	•	
G4-8	Markets served	3, 16–17, 8–9	•	
G4-9	Scale of the organisation	55, 59–60, 81	•	
G4-10	Total workforce by employment type, contract, region and gender	81	•	
G4-11	Percentage of employees covered by collective bargaining agreements		•	All employees in the Swedish operations (representing approximately 66 per cent of Sobi's employees) are covered by collective bargaining agreements.
G4-12	Describe the organi- sations' supply chain	45	•	
G4-13	Significant changes during the report period	4–7	•	
G4-14	Explanation of how the precautionary principle is applied	57–58	•	Risk management is integrated with all strategic and operational work. There is a specific procedure for handling of hasardous 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	42–45, 57	•	In clinical programmes and studies, 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	•	
	ied material aspects undaries			
G4-17	Operational structure of the organisation	103, 110–113	•	
G4-18	Process for defining report content	42-43	•	

Standa	rd disclosure	Cross- reference	Reported	Comment
G4-19	Material aspects identified in the process for defining report content	42–45	•	
G4-20	Aspect boundaries within organisation		•	Indicators cover all of Sobi's operations.
G4-21	Aspect boundaries outside organisation	42–45	•	
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 have been no changes regarding scope, boundaries etc. since previous reports.
Stakeh	older engagement			
G4-24	List of stakeholder groups	42	•	
G4-25	Basis for identifica- tion and selection of stakeholders with whom to engage	18–20, 42	•	
G4-26	Approaches to stake- holder engagement	18–20, 42–45	•	
G4-27	Key topics and concerns raised by stakeholders	21, 25, 31, 42–45	•	
Report	t profile			
G4-28	Reporting period		•	Calendar year 2014
G4-29	Date of most recent previous report		•	April 2014
G4-30	Reporting cycle		•	Annual
G4-31	Contact point for questions regarding the report		•	Oskar Bosson, Head of Communications oskar.bosson@sobi.com

Standa	rd disclosure	Cross- reference	Reported	Comment
G4-32	Table identifying the location of the Standard Disclosures in the report	115–118	•	
G4-33	Policy and current practice with regard to seeking external assurance for the report		•	Sobi's sustainability report has not been subject to external assurance.
Gover	nance			
G4-34	Governance structure of the organisation	103	•	
Ethics	and integrity			
G4-56	Values, principles and norms of behaviour such as codes of conduct and codes of ethics	10, 44–45, 54 www.sobi.com	•	Sobi's Code of Conduct and Ethics is available on www.sobi.com.

Indicator material		Cross- reference	Reported	Comment
ECONO	MIC			
Indirect	economic impacts			
Manage	ment approach	42–43, www.sobi.com	0	Sobi's Charter on Patient Access Bridging Programmes is available on www.sobi.com
G4-EC8	Significant indirect economic impacts	42, 57–58, 75–77	•	
SOCIAL				
	R PRACTICES CENT WORK			
Employ	ment			
Manage	ment approach	44–45, 54–56	•	
G4-LA1	Rate of employee turnover by age group, gender and region	81	•	

Indicators for material aspects		Cross- reference	Reported	Comment
Occupati	onal health and safety	-1		
Managen	nent approach	44-45, 54-55	•	
G4-LA6	Rates of injury, occu- pational diseases, lost days, work related fatalities, by region and by gender	44–45		During 2014 there were ten incidents, none of which led to lost time in terms of sick-leave.
Training	and education			
Managen	nent approach	44–45	•	
G4-LA11	Employees receiving regular performance and career develop- ment reviews, by region and by gender	44–45	•	
Diversity	and equal opportunity			
Managen	nent approach	44–45	0	
G4-LA12	Composition of gov- ernance bodies and employees according to diversity indicators	45, 81, 110–113	•	
SOCIETY	,			
Anti-corr	uption			
Managen	nent approach	44 www.sobi.com	•	

Indicator material		Cross- reference	Reported	Comment
G4-SO4	Communication and training on anti-corruption policies and procedures	44, 107–108	•	All questions relating to anticorruption 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.
G4-SO5	Confirmed incidents of corruption and actions taken		•	During 2014 no case of corruption involving Sobi or Sobi's employees have been brought to the attention of the company management.
Complia	nce			
Management approach		42–45 www.sobi.com	•	
G4-SO8	Significant fines and non-monetary sanctions for non compliance with laws and regula- tions		•	During 2014 Sobi has not identified any non-compliance with laws and regulations, which possibly could have led to fines or non-monetary sanctions.

Indicator material		Cross- reference	Reported	Comment
PRODU	CT RESPONSIBILITY			
Custom	er health and safety			
Manage	ment approach	19–20, 42–45, www.sobi.com	•	
G4-PR1	Percentage of significant product and service catego- ries for which health and safety impacts are assessed for improvement	20, 39, 42–45	•	
G4-PR2	Incidents of non- compliance with regulations concern- ing health and safety impacts of products		•	During 2014 Sobi has not identified any non-compliance with laws, regulations or voluntary codes concerning the health and safety impacts of its products.
Product	s and services labeling			
Manage	ment approach	42–45, www.sobi.com	•	
G4-PR4	Incidents of non- compliance with regulations and voluntary codes concerning product and service informa- tion and labeling		•	During 2014 Sobi has not identified any non-compliance with laws, regulations or voluntary codes concerning product and service information and labeling.
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.

Indicators for material aspects		Cross- reference	Reported	Comment
Marketi	ng communications			
Manage	ment approach	42–45, www.sobi.com	•	
G4-PR7	Incidents of non- compliance with regu- lations concerning marketing communi- cations		•	Sobi has identified one incident of non-compliance with regulations concerning marketing communications in connection with our products during 2014, in Sweden. The incidence was considered to be of formal character and less severe. A fine of SEK 40,000 was issued.
Efterlev	nad			
Management approach		42–45, www.sobi.com	•	
G4-PR9	Significant fines for non-compliance with laws and regulations concerning the provi- sion and use of prod- ucts and services		•	During 2014 Sobi has not identified any non-compliance with laws, regulations or voluntary codes concerning the provision and use of its products.

2015 Annual General Meeting

2015 Annual General Meeting

Swedish Orphan Biovitrum AB (publ) will hold its Annual General Meeting on Wednesday, 6 May 2015 in the Wallenberg Auditorium at Näringslivets hus, Storgatan 19, Stockholm, Sweden.

To participate

Shareholders who wish to attend the meeting must be recorded in the share register maintained by Euroclean Sweden AB (the Swedish Central Securities Depository) on Wednesday, 29 April 2015. Shareholders must notify the company of their intention to participate no later than Wednesday, 29 April 2015 in one of the following ways:

- via Sobi's website: www.sobi.com
- by phone: +46 (0)8-697 34 27
- by post: Swedish Orphan Biovitrum AB (publ), Annual General Meeting, SE-112 76 Stockholm, Sweden

The notification should include the shareholder's:

- name
- personal identity number/corporate registration number
- address and telephone number (daytime)
- number of shares held
- where applicable, information about any representatives/ advisors

Nominee shares

Shareholders who have registered their shares with a bank or another nominee must, to be entitled to participate in the General Meeting, register their shares in their own name, so that the person concerned is recorded in the share register maintained by Euroclear Sweden AB on Wednesday, 29 April 2015. Shareholders wishing to register their shares in their own name should inform the nominee in good time before this date. Such registration may be temporary.

Shareholders who intend to be represented by proxy must issue a written and dated power of attorney for the proxy. If the power of attorney is issued by a legal entity, a certified copy of the registration certificate or equivalent for the legal entity must be attached. The power of attorney is valid for one year from the date of issuance, or until the date of expiration shown on the power of attorney, but not later than five years. The registration certificate shall evidence the circumstances prevailing at the date of the Meeting and should not be older than one year on the date of the Meeting. The original power of attorney and any registration certificate should be sent to the company by mail at the address indicated above well in advance of the Meeting. A proxy form is available on the company's website, www.sobi.com, and can also be sent to shareholders upon request.

Financial calendar 2015

January-March Interim Report and Annual General Meeting 6 May 2015 January-June Interim Report 17 July 2015 January-September Interim Report 29 October 2015

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

Contact details

Swedish Orphan Biovitrum AB (publ) SE-112 76 Stockholm, Sweden Street address: Tomtebodavägen 23A Phone: +46 (0)8-697 20 00

Fax: +46 (0)8-697 23 30 Website: www.sobi.com

Definitions

Capital employed

Total assets less non-interest-bearing responsibilities.

Cash flow per share

Changes in cash and cash equivalents divided by the weighted average number of outstanding shares.

Debt/Equity ratio

Relative proportion of shareholders equity and debt used to finance the company's assets.

EBIT

Earnings Before Interest and Taxes (Operating profit/loss).

EBITA

Operating profit/loss before amortisation.

EBITDA

Operating profit/loss before depreciation and amortisation.

Earnings per share

The portion of a company's profit allocated to each outstanding share of common stock.

Equity per share

The value of the company's common stock adjusted for any outflow (dividends and stock buy backs) and inflow (retained earnings) related to amount of shares outstanding.

Equity ratio

Shareholders' equity as a proportion of total assets.

Full-time equivalents

Unit that indicates the workload of an employed person in a way that makes workloads comparable across various contexts.

Gross margin

Gross profit as a percentage of sales.

Gross profit

Net sales less cost of goods and services sold.

Net debt

Interest bearing long term and short term debt less cash at bank.

Non-recurring items

Non-recurring items are defined as transactions of a nonrecurring nature.

Profit/loss

Profit/loss for the period.

Return on shareholders' equity

Profit/loss after tax as a percentage of average shareholders' equity.

Return on capital employed

Earnings Before Interest and Tax (EBIT)/Capital Employed.

Return on equity

Profit/loss after tax as a percentage of average shareholders' equity.

Return on total capital

Profit/loss after financial items plus financial expenses as a percentage of average total assets.

Shareholders' equity per share

Shareholders' equity divided by the number of shares.

Glossary

Alprolix (rFIXFc)

rFIXFc is a long-acting recombinant factor IX Fc fusion protein product candidate for people with haemophilia B. rFIXFc is also known as Alprolix [Coagulation Factor IX (Recombinant), Fc Fusion Protein], in the US, Canada, Australia and Japan, where it is approved for the treatment of haemophilia B.

Biologic

A protein based drug derived from living cells cultured in a laboratory.

CAPS

Cryopyrin-associated periodic syndromes, 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.

CHMP

The Committee for Medicinal Products for Human use at the European Medicines Agency, responsible for preparing opinions on questions concerning medicines for human

ChondroCelect

A cell-based medicinal product for the repair of cartilage defects of the knee.

Cometriq

Cometriq (cabozantinib) is a therapy for the treatment of adult patients with progressive, unresectable, locally advanced or metastatic medullary thyroid carcinoma

Dupuytren's contracture

Dupuytren's contracture is a condition where one or more fingers are bent forwards toward the palm and cannot be fully straightened. It is caused by a thickening of the tissues under the skin of the palm that form 'cords' pulling down on the fingers.

Elocta (rFVIIIFc)

Elocta is a long-acting recombinant factor VIII Fc fusion protein product candidate in the EU for people with haemophilia A. Elocta is the trade name in Europe for rFVIIIFc, also known as Eloctate [Antihemophilic Factor VIII (Recombinant), Fc Fusion Protein] in the US, Canada, Australia and Japan, where it is approved for the treatment of haemophilia A. A MAA for Elocta is currently under review by the EMA.

EMA

European Medicines Agency.

EMENAR

A business region including Europe, Middle East, North Africa and Russia.

FDA

US Food and Drug Administration.

Haemophilia

Haemophilia is a group of hereditary genetic disorders that impair the body's ability to control blood clotting or coagulation. Haemophilia A (clotting factor VIII deficiency) is the most common form of the disorder, present in about 1 in 5,000 male births. Haemophilia B (clotting factor IX deficiency) occurs in around 1 in about 25,000 male births.

Kepivance

A therapy indicated to decrease the incidence and duration of severe oral mucositis in patients with haematologic malignancies receiving myelotoxic therapy requiring haematopoietic stem cell support.

Kineret

Kineret (anakinra) is a recombinant protein drug which blocks the biological activity of IL-1 by binding to the interleukin-1 (IL-1) type 1 receptor, which is expressed in a wide variety of tissues and organs. IL-1 is a key mediator of inflammation and driver of autoinflammatory diseases in both adults and children.

MAA

Marketing Authorisation Application.

MENAR

A business region including Middle East, North Africa and

NOMID

Neonatal Onset Multisystem Inflammatory Disease, the most severe form of CAPS, also associated with chronic meningitis, hearing loss, craniofacial abnormalities, bone lesions and increased mortality.

NPU

Named patient use. When an unsoliced request in placed regarding treatment intended for patients with at lifethreateing, chronic or serious debilitating disease where there is no other satisfactory alternative treatment options with medicinal products authorised in their country.

Orfadin

Orfadin (nitisinone) is a pharmaceutical used for the treatment of Hereditary Tyrosinaemia type 1 (HT-1), a rare genetic disorder which can cause liver failure, kidney dysfunction and neurological problems.

PC3

Patient and Customer-Centric approach to Commercialisation, Sobi's commitment to support and understand the patient needs at all stages of the patient journey, and engaging with all the stakeholders surrounding the rare disease patient to ensure that our products are developed and continuously supported in a way that give the patients the best chance of timely access and benefit of treatments.

Peyronie's disease

Peyronie's disease is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis. The scar tissue, known as a Peyronie's plaque, may harden and reduce flexibility, which may cause bending or arching of the penis during erection. Peyronie's disease can result in varying degrees of penile curvature deformity and disease "bother" (encompassing concern about erection appearance, erection pain and the impact of Peyronie's disease on intercourse and on frequency of intercourse).

PTP

Previously treated patients.

SOBI002

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.

UCD

Urea Cycle Disorders is a group of serious conditions in which patients suffer from deficiencies in the enzymes required to remove ammonia from the blood stream.

Xiapex

Xiapex (collagenase clostridium histolyticum), is a pharmacological treatment for Dupuytren's contracture and Peyronie's disease and may be an alternative to invasive and often complicated surgery for patients.

XTEN

XTEN is a DNA-based hydrophilic polymer that increases the hydrodynamic radius of target proteins with the goal of extending the half-life of those proteins.

Solberg
Print: Göteborgstryckeriet
Photo: Autoinflammatory Alliance,
Christina Redmann, David Leach, EHC, EMA,
FDA, Gregg Shupe, Krytian Winszewski, Martin
Botvidsson, NORD, Ralph Skorge and Sobi.



contact us!

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