sobi

Pioneer in Rare Diseases

A new chapter of our story

Annual Report

2015

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*The audited annual report includes pages 64-116.

Elocta® approved in EU

In November 2015, Elocta was approved by the European Commission for the treatment of haemophilia A.

Sobi in haemophilia
page 38

Our innovation model
page 32

Investing in our pipeline

In 2015, Sobi presented three new programmes in preclinical development aimed at finding treatments for rare diseases.

Sobi is growing
page 20

We reach more patients than ever before

Disclaimer In order to utilise the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, Swedish Orphan Biovitrum AB (publ) is providing the following cautionary statement. This Annual Report contains forward-looking statements with respect to the financial condition, results of operations and businesses of Swedish Orphan Biovitrum AB. By their nature, forward-looking statements and forecasts involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. There are a number of factors that could cause actual results and developments to differ materially from that expressed or implied by these forward-looking statements. These factors include, among other things, the loss or expiration of patents, marketing exclusivity or trademarks; exchange rate fluctuations; the risk that research and development will not yield new products that achieve commercial success; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any failure by third parties to supply materials or services; the risk of delay to new product launches; the difficulties of obtaining and maintaining governmental approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect; and the risk of environmental liabilities.

The financial year in brief

- Total revenues increased to SEK 3,228 M (2,607), an increase of 24 per cent.
- Total product revenues increased to SEK 2,568 M (1,989), an increase of 29 per cent.
- Gross margin increased to 62 per cent (59).
- EBITA amounted to SEK 433 M (–43)*.
- Ended the year with a cash position of SEK 904 M (519).

REVENUES, %

+24

GROSS MARGIN, %

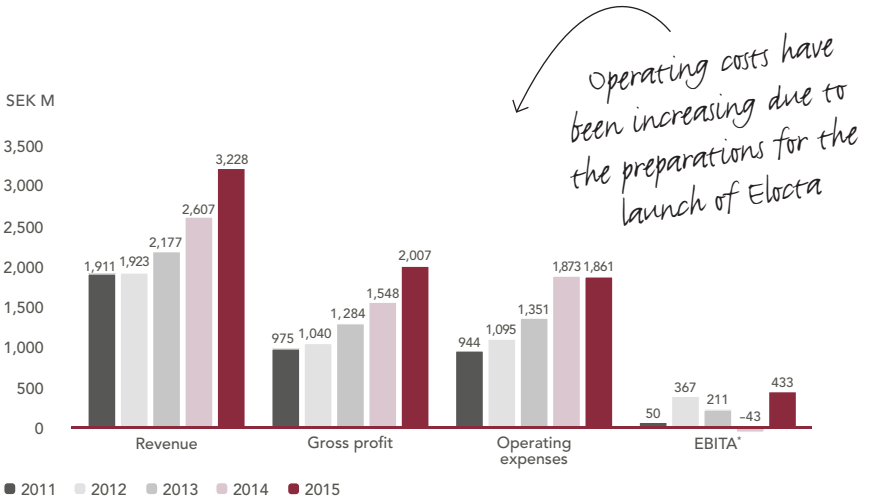
62

EBITA, SEK M

433

KEY FIGURES

SEK M	2011	2012	2013	2014	2015
Total revenues	1,911	1,923	2,177	2,607	3,228
Gross profit	975	1,040	1,284	1,548	2,007
Gross margin, %	51	54	59	59	62
Operating expenses	944	1,095	1,351	1,873	1,861
EBITA*	50	367	211	–43	433
EBIT	–319	–55	–67	–325	146
Profit/loss for the year	18	–101	–93	–268	68
Earnings per share, SEK	0,07	–0,38	–0.35	–1	0,26
Cash flow from operations	103	406	185	234	507
Equity per share, SEK	19	18	18	17	17
Equity assets ratio, %	74	77	73	71	56
Dividend	0	0	0	0	0
No. of employees	517	514	546	589	702

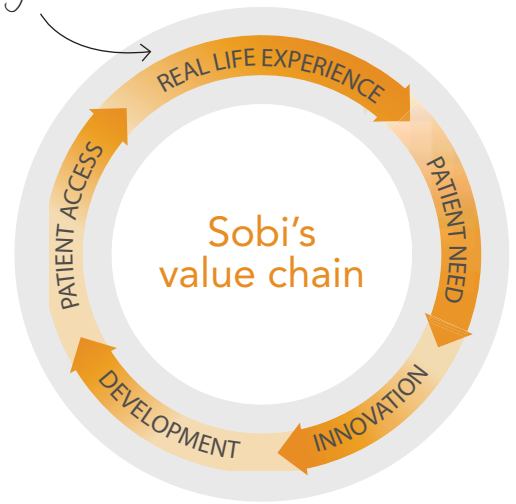


* The figures for 2014 include write-downs of SEK 325 M for Kiobrina® and SEK 25 M for Multiferon®.
The figures for 2012 include revenues of SEK 308 M from the sale of co-promotion rights of ReFacto AF® to Pfizer.

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 patient journey guides us



Who

Pioneers in rare disease

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.

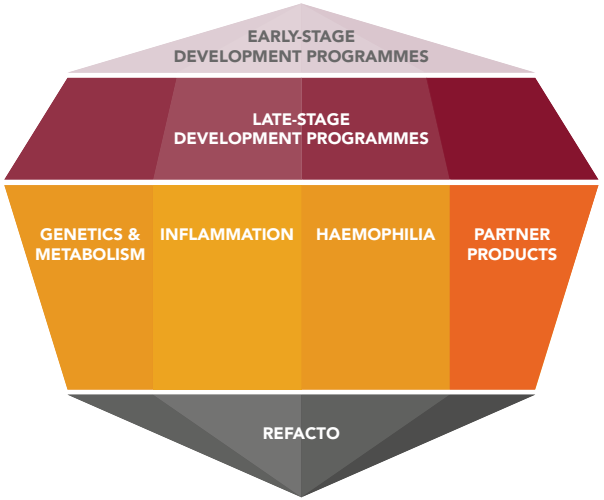
Read more on page 18

What

A strong and growing portfolio

We are an integrated biotechnology company dedicated to rare diseases. Our research and product portfolio is primarily focused on haemophilia, inflammation and genetic and metabolic diseases. We also market and make available across Europe, the Middle East, North Africa and Russia a portfolio of specialty and rare disease products for partner companies. In addition, we manufacture the drug substance for the haemophilia treatment ReFacto AF/Xyntha® for the global market.

Read more on page 30



Where

Growing international presence

Today, our organisation spans 24 countries, delivering therapies to patients in 67 countries across the globe. Europe accounts for 54 per cent of sales. The North American business has developed significantly and will support growth in the coming years.

In 2015, we continued to expand our presence by establishing a new affiliate in Canada, and grew our offices in Germany, the UK and Belgium. We also restructured our distribution, assuming more direct responsibility in Latin America.

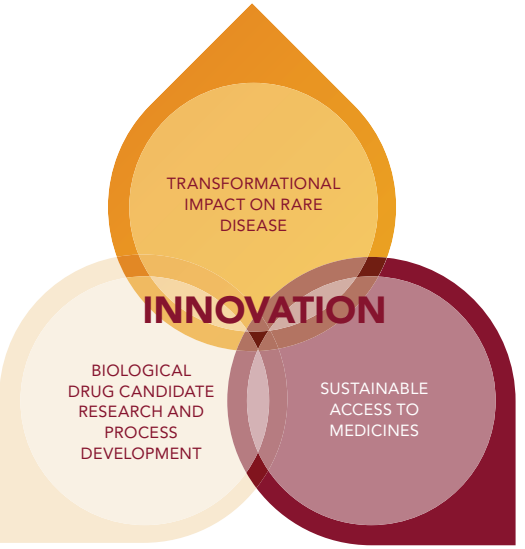
Read more on page 20

How

A collaborative approach

We consider real access by patients to treatments a far more relevant measure than market access alone. This means putting the needs of patients first, in the belief that this will create long-term, sustainable value for everyone. We have developed a patient and customer-centric approach to commercialisation model (PC3) to ensure that patient needs guide us. Our research and development is collaborative and patient-centred and ranges from the early phases of research to the development of biopharmaceuticals. By working in a collaborative way, we believe it is possible to create a win-win environment for all parties – patients, healthcare systems, budget holders, our employees, investors and the pharmaceutical industry.

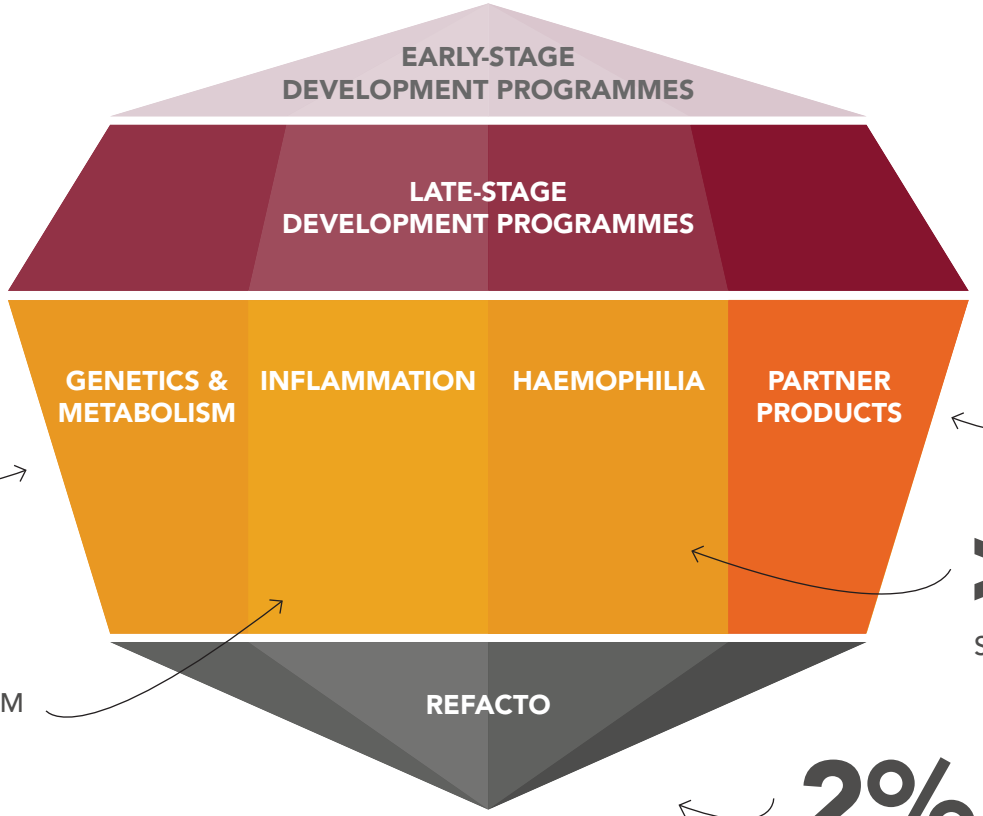
Read more on page 12



Our revenues

Revenues and growth percentage, by business area

Growth at constant exchange rates compared with 2014.



28%
SEK 940 M / USD 111 M

17%
SEK 805 M / USD 95 M

1%
SEK 727 M / USD 86 M

>100%
SEK 96 M / USD 11 M

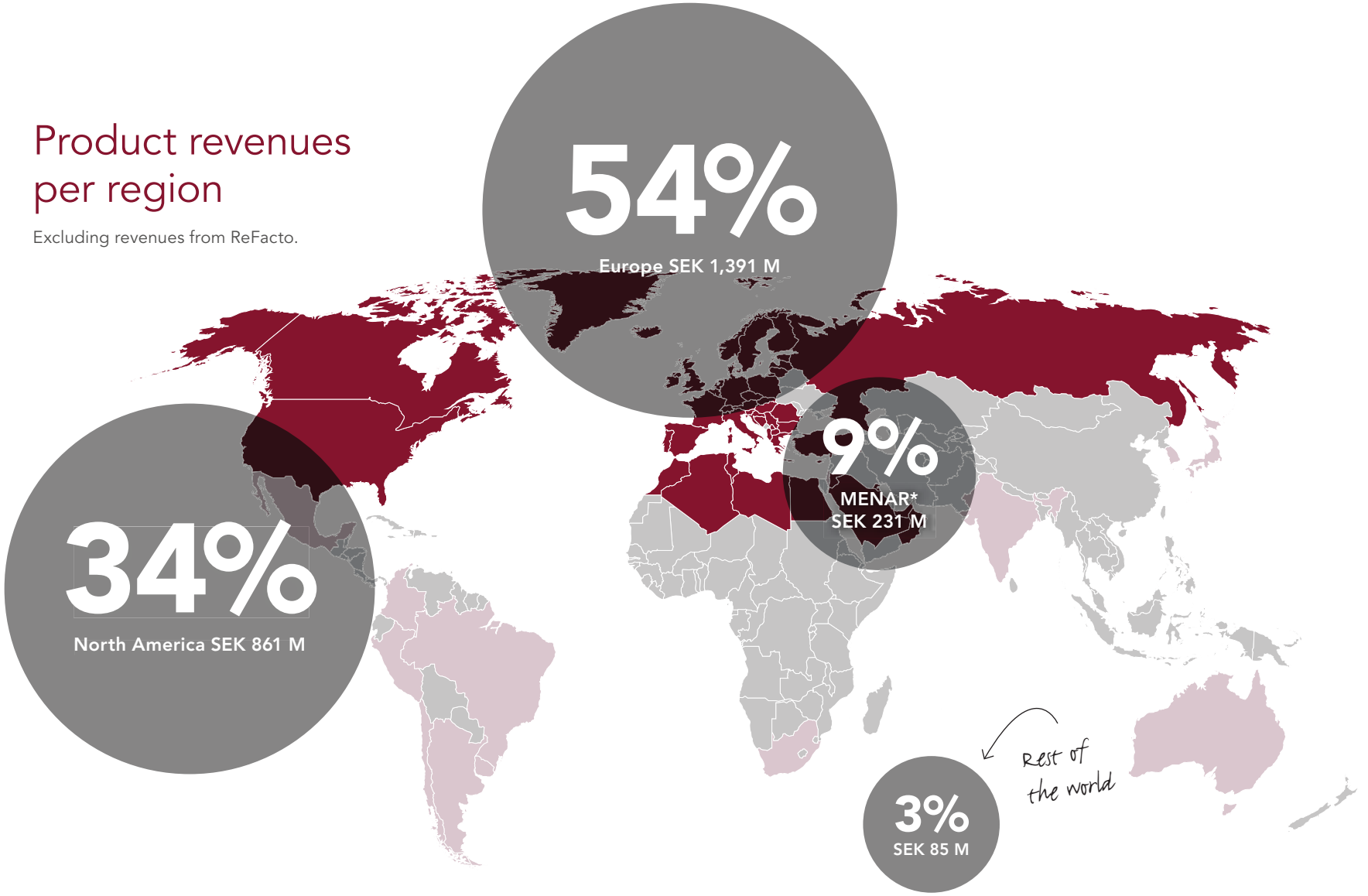
2%
SEK 660 M / USD 78 M

Total revenues	2011	2012	2013	2014	2015
SEK M	1,911	1,923	2,177	2,607	3,228
USD M	227	228	258	309	383

Exchange rate USD 1 = SEK 8.435 (average rate for 2015).

Product revenues per region

Excluding revenues from ReFacto.



* Middle East, North Africa and Russia

Milestones 2015

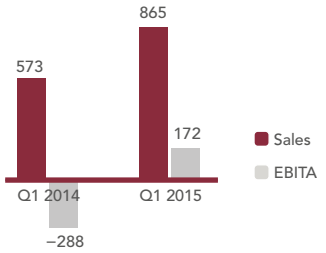
Q1

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

KIDS B-LONG STUDY
Positive top-line results announced for the phase 3 Alprolix® paediatric study, Kids B-LONG.

KINERET® APPROVAL IN AUSTRALIA
Kineret received regulatory approval in Australia for use in systemic juvenile idiopathic arthritis (SJIA).

SALES AND EBITA



Total revenues were SEK 865 M, an increase of 51 per cent, reflecting our strong underlying business.

Q2

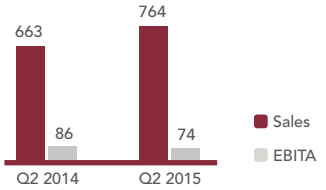
ORFADIN® ORAL SUSPENSION
The liquid formulation, Orfadin oral suspension, and the Orfadin 20 mg capsule approved by the European Commission.

ALPROLIX SUBMISSION
Marketing authorisation application for Alprolix submitted in the EU.

HAEMOPHILIA DATA AT ISTH
23 abstracts with new haemophilia data presented at the International Society on Thrombosis and Haemostasis (ISTH) 2015 Congress.

ALPROLIX VALIDATION
Marketing authorisation application for Alprolix validated by the European Medicines Agency, EMA.

SALES AND EBITA



Base business showed solid growth across the portfolio.

ALPROLIX OPT-IN

Opt-in right to take over final development and commercialisation of Alprolix in Sobi territory exercised.

ASPIRE STUDY DATA

Results from the extension study ASPIRE supporting long-term safety and efficacy of Elocta published in the scientific journal *Haemophilia*.

B-YOND STUDY DATA

Results from the extension study B-YOND reinforced the long-term clinical profile of Alprolix for the treatment of haemophilia B.

Q3

ELOCTA POSITIVE OPINION

The Committee for Medicinal Products for Human Use (CHMP) in the EU adopted a positive opinion on Elocta for the treatment of haemophilia A.

US ORPHAN DESIGNATION FOR STILL'S

Kineret granted orphan drug designation (ODD) by the US Food and Drug Administration (FDA) for Still´s disease.

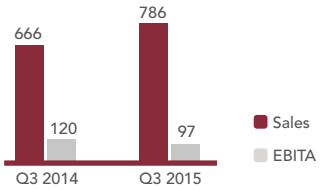
OPENED OFFICE IN BELGIUM

New EMENAR and Benelux regional office opened in Brussels, Belgium.

ORFADIN ORAL SUSPENSION VALIDATED

Orfadin oral suspension file validated by the FDA.

SALES AND EBITA



Revenues for Orfadin increased by 22 per cent, supported by growth in all markets.

ELOCTA APPROVED

Elocta approved in the EU for the treatment of haemophilia A.

HAEMOPHILIA DATA PRESENTED

New data showed that Elocta and Alprolix may reduce target joint bleeds in people with haemophilia A and B.

HUMANITARIAN AID DONATION

Sobi and Biogen initiated deliveries of largest ever donation of haemophilia therapy to World Federation of Hemophilia for patients in the developing world.

ORPHAN DESIGNATION IN SWITZERLAND

Received orphan drug designation for Alprolix in Switzerland.

29 GAUGE NEEDLE

Thinner 29-gauge needle for Kineret approved for markets where Kineret is currently approved.

EXPANDED XIAPEX INDICATION

Xiapex approved by EMA for the treatment of two Dupuytren's contracture cords concurrently.

OPENED CANADIAN AFFILIATE

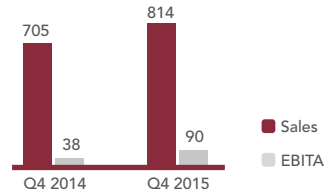
Opened Canadian affiliate in Toronto, Canada.

EXPANSION OF LONDON OFFICE

Expanded Haemophilia office in London, UK.

Q4

SALES AND EBITA



Sales of Kineret increased by 36 per cent in both new and old markets.

Sobi – a community dedicated to transforming lives

Sobi's vision is real. We are not just participating, but contributing to creating a world in which rare disease patients can look forward to a full and healthy life within the boundaries of their disease.

Our CFO comments on our 2015 financial results on page 63

	Actual 2015	Outlook 2016*
Revenues, SEK M	3,228	4,800–5,000
Gross margin, %	62	68–70
EBITA, SEK M	433	1,200–1,300

*The outlook was published on 29 February 2016.

Thank you for taking time to review our annual report. You will find the usual elements here: financial results, programme summaries, technical notes, and a review of our business segments. While we are proud of all we have accomplished in these areas over the past year, I hope you will also take the time to step back from the details and gain an impression of the Sobi community that emerges from these pages.

Realising our vision

We are 700 people working together across 50 countries because each of us in our own way knows what it looks and feels like to make a major transformational impact on the life of a family dealing with a severe rare disease. When a newborn or young child is diagnosed with a rare disease, we are working to be there with a specific, highly effective, and sustainably delivered therapy that permanently changes their outlook for the better. Our history and current portfolio allow us to refer to actual experiences that substantiate this purpose. Orfadin has made it possible for children with hereditary tyrosinaemia to live into adulthood and to have children of their own. Kineret has allowed children with NOMID, a severe inflammatory disorder, to achieve days in which they forget why they are taking the medicine. Finally, the emergency treatments in our partner portfolio save lives every day for patients with severe intoxications.

Pioneering starts with a vision, begins its journey with partners, forges its path with persistence, and solves problems through collaboration and innovation.

Pioneer in rare diseases

This shared purpose and experience informs our commitment at Sobi to be pioneers in rare diseases. Pioneering starts with a vision, begins its journey with partners, forges its path with persistence, and solves problems through collaboration and innovation. Above all, the lasting impact of pioneers comes when their achievements are sustainable and visible through time. In the context of rare diseases we believe the key ingredient to pioneering is the ability to listen to and to understand the needs of patients, to choose the precise application of technologies, to co-create an efficient path to approval with regulators and physicians, and

the willingness to jointly author sustainable commercial solutions with budget holders that can allow therapies to be in place for a lifetime. Crucially, we believe that the culture of pioneering in the service of patients with rare diseases requires a small, agile, and human scale organisation that can stay responsive to the changing landscape of patient needs, science and society.

Driving innovation forward

We are a learning organisation where making several of little bets on great ideas can lead to value creation that changes the entire company's future. This means attracting and developing talented people who share our purpose, take on responsibility, and have the energy and enthusiasm to innovate in their work every day.

This is the purpose, the culture, and the learning mind-set that have allowed for the significant progress that Sobi has made over the past several years. Looking back, Sobi was in an entirely different place five years ago. We began our transition five years ago with an operational focus to restore our business segments to growth, to manage our capital allocation wisely, and to bring the company to profitability and, eventually, to a net positive cash position – over this period Sobi's market capitalisation has increased more than sevenfold. By focusing on meeting each of these objectives and building shareholder value I believe that we have set a solid foundation for the future.

Transforming our future

Our operational priority was in part intended to allow us to self-sufficiently invest in the preparation to launch two new, first in class haemophilia therapies developed in collaboration with Biogen. Over the past year we have assembled a world-class team of expert commercial, medical and patient access professionals in this field who share our purpose, collaborative mind-set, and energy. As we launch first Elocta, and then potentially Alprolix, we will bring our pioneering rare disease approach to this area. We can clearly see the transformational potential these therapies can have for people living with haemophilia, and we believe that we have a sustainable value approach that can allow them to become a new standard of care in the years to come.

With the platform of these two objectives in place we now turn our attention to building our future over the longer term. We will continue to follow the needs of patients by developing new indications and formulations for our current therapies. We are also working on several innovative early-stage biologics programmes, which we believe can make a major positive impact for patients. While we advance these internal programmes we are also turning our attention to a broader and more dynamic set of external partnerships, collaborations and investments to bring the cutting edge of precision medicine into the therapeutic areas where we have our experience and commitment.

Thank you for the interest and support you have for our work at Sobi. We are energised by our progress so far, and even more so by the process of building our future together and the next chapter of our story.

Geoffrey McDonough
CEO and President
Solna, Sweden

"Over this period Sobi's market capitalisation has increased more than sevenfold."

scan the QR-code to see an interview with our CEO

The key to pioneering is the ability to listen to and to understand the needs of your customers.

Our approach to the rare disease market

A company's ability to develop and deliver new and effective therapies for rare disease patients is mainly determined by its ability for success in terms of collaborative, patient-centric and sustainable practices.

A rare disease affects a small percentage of the population, and is often serious, life-threatening or chronically debilitating. Many rare diseases appear early in life and while nearly all genetic diseases are rare, not all rare diseases are genetic. Most genetic diseases are present throughout a person's life, even if the symptoms do not appear immediately. There are also very rare forms of infectious diseases, such as auto-immune diseases and cancers. To date, the cause remains unknown for many rare diseases.[1]

In Europe and North America alone, an estimated 60 million people are impacted by one of approximately 7,000 known rare diseases. Each disease is, in itself, rare but, together, rare diseases affect 1 in 14 people.

Although more and more therapies are becoming available, the majority of rare diseases are without treatment. Treatments for rare diseases, which could be orphan drugs, medicinal products, or in the US devices, are agents used to diagnose, treat and prevent rare diseases. These drugs have paved the way for treatments for many of the unmet clinical and therapeutic needs in patients with rare diseases.

[1] Orphanet – About rare diseases. www.orpha.net, accessed March 2015.

Collaborative

The pharmaceutical arena is highly regulated and subject to decisions by external stakeholders. Becoming a successful contributor in this arena requires collaboration. The history of rare disease treatments is one of shared responsibility, and of efforts by the community to bring about legislative change and incentives to support research into rare diseases and the development of new treatments; as well as improvements in diagnosis and availability to treatment and care.

seeking collaboration and partnerships

SOBI'S APPROACH:

Sobi aims to develop transformative treatments, with the aim of changing the course of the disease or condition. This requires long-term commitment and collaboration starting from the earliest phases of development. In rare diseases, when patients, disease information, expertise and specialist treaters are rare and scattered geographically, it makes sense to seek these collaborative solutions as early as possible. Sobi's way of working, which is based on collaboration and partnership, is a core element of our ability to be successful. We aim to accelerate development times and generate robust and compelling evidence and data, in order to secure timely access and sustained benefit, no matter where in the lifecycle of a product we find ourselves.

RARE DISEASES IMPACT 1 IN 14

60 MILLION

EU AND US CITIZENS ARE DIAGNOSED WITH A RARE DISEASE

APPROXIMATELY

7,000

DIFFERENT RARE DISEASES IDENTIFIED TODAY

Patient-centric

Patient organisations and rare disease patients are often the best experts in their own conditions. Since rare diseases are often chronic and debilitating, patients need early diagnosis and lifelong access to life-saving treatments.

APPROVED TREATMENTS ARE AVAILABLE FOR ONLY

5%

OF ALL RARE DISEASES

SOBI'S APPROACH:

Legislation exists in the EU and the US, as well as other regions, in order to stimulate the research, development and availability of treatments for rare conditions. Legislators believe that people should not lack treatments just because their condition or disease is rare. While rare disease patients are few, Sobi believes that healthcare systems should recognise that addressing the needs of this small patient group is an integral part of our shared commitment.

Sobi is committed to understanding and supporting the needs of patients at all stages of the patient journey, from early diagnosis to lifelong treatment. Sobi supports and partners with a wide range of patient organisations, both nationally and regionally, to reach the common goal of achieving the best outcomes for patients with rare diseases. We do this through research and by raising awareness, and by working collaboratively to ensure that patients have timely and reimbursed access to the treatments they need. We believe that true access for patients is far more relevant measure than market access, which is the industry norm. This will always be more productive and bring true results. We work according to a model called Patient- and Customer-Centric approach to Commercialisation (PC3) to guide our development and commercialisation process.

Sustainable

Ideally, patients are diagnosed early in life and cured or given access to effective treatment for the course of their lifetime. An effective treatment is one that is both available in the country where the patient lives and is affordable in the healthcare system. If any of these factors are missing, the treatment is of little use.

SOBI'S APPROACH:

Sobi aims to secure diagnosis and viable access to treatment. That also means being a sustainable company, and a sustainable part of the healthcare system. One of the most important factors is responsible pricing, thereby ensuring patient access to treatment and Sobi's continued ability to provide treatment.

Sobi believes that rare disease patients should have access to life-saving treatment regardless of where they are born. For this reason, Sobi has created a sustainable access programme providing people around the world in great medical need with access to innovative and effective treatments from Sobi's portfolio. This can only be achieved through multi-stakeholder dialogue and engagement, with the objective of finding shared and supportable solutions.

An increasing number of treatments

In 2015, the European Commission approved more medicines for rare diseases than ever before – of 93 newly approved medicines, 18 had an orphan designation. Similarly, the US Food and Drug Administration (FDA) approved 45 new therapies in 2015, of which 21 were orphan drugs. However, the key aspect of securing timely and sustainable patient access to these newly approved therapies remains.

The main driver of this growth is successful legislation combined with the availability of infrastructure and technological advancements that have helped to spur momentum worldwide.

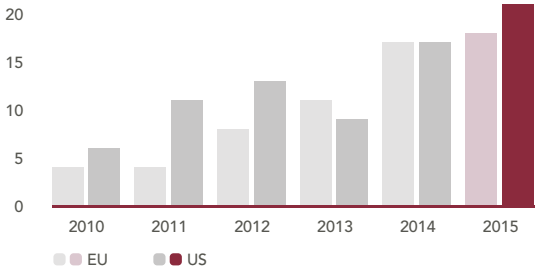
SOBI'S APPROACH:

Sobi's partner platform has been established to lower the threshold of bringing rare-disease and niche products to Europe, thereby making treatments available to patients. Sobi's expertise provides efficient distribution, market knowledge, and pricing and reimbursement competencies.

Sobi's innovation platform serves as the basis for the company's own development of transformative treatments for rare diseases. During 2015, Sobi and our collaboration partner Biogen received marketing approval in the EU for our product Elocta for the treatment of haemophilia A.

While the number of companies developing treatments for rare diseases as part of their operations has increased, Sobi is one of few companies with a clear focus on rare diseases.

NUMBER OF MEDICINES FOR RARE DISEASES APPROVED 2010–2015



Since 1983, the FDA has approved a total of 511 orphan drugs, granted 3,280 orphan drug designations and received more than 4,700 requests for an orphan drug designation.

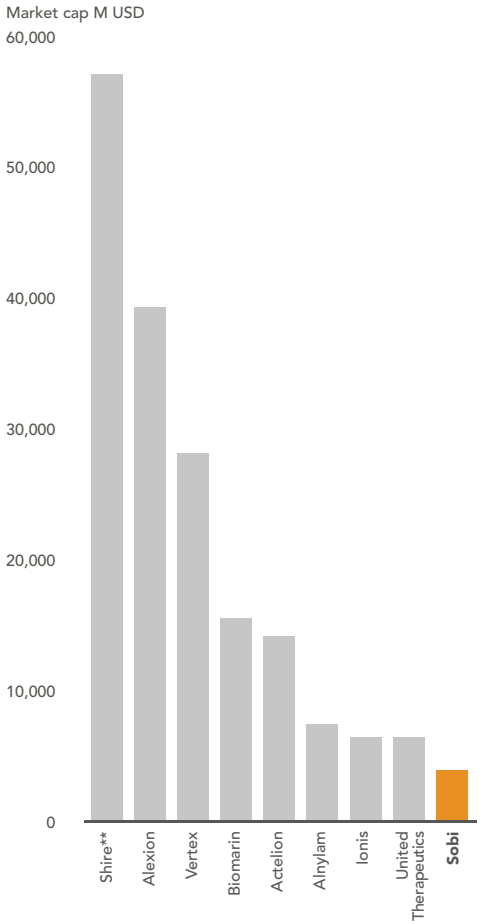
Ref: The FDA Law Blog. Feb 15, 2015. Hyman, Phelps & McNamara, P.C.

THE US ORPHAN DRUG ACT
was signed in 1983, and was followed by similar legislation in Japan, Australia, Singapore and the EU. 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.

The industry

TOP PUBLIC ORPHAN COMPANIES BY MARKET CAPITALISATION 2015*

Over the past five years Sobi has moved into the top tier of independent innovative rare disease companies.



* FactSet, 7 January 2016.
** Shire pro forma for share issuance associated with the Baxalta acquisition.

The US market

As early as 1983, the public health authorities, spurred on by the patients, realised that legislation on orphan drugs was needed, prompting the signing of the Orphan Drug Act.

A rare disease, in the US, is defined as one that affects fewer than 200,000 individuals in the US. A total of about 30 million Americans suffer from rare diseases.

Orphan drug status and marketing approval are two necessary stages before an orphan drug can be marketed. Each decision is taken by a special entity at the Food and Drug Administration (FDA).

Granting orphan drug status may enable:

- a 50 per cent tax credit on the cost of clinical trials undertaken in the US;
- a fast-track procedure for the FDA to evaluate registration files; and
- a seven-year period of market exclusivity following the marketing approval.

21
new orphan drugs were approved by the FDA in 2015.

It is possible for patients and treating physicians to access orphan drugs before a marketing approval is granted if the drug is intended for the treatment of a serious or life-threatening disease, if there is no alternative drug or treatment available and if the product is undergoing clinical trials and in an active phase of marketing approval.

There is only one market, but the budget-holder framework is quite complex, because it involves many private payers as well as many government budget holders.

NORD, the National Organization for Rare Disorders in the US was founded in 1993.

The European market

Inspired by the passage of the Orphan Drug Act in the US, the EU adopted legislation on orphan medicinal products in 1999 to encourage the development and availability of new treatments.

Rare diseases are defined in the EU as life-threatening or chronically debilitating conditions that affect no more than 5 in 10,000 people in the EU. About 30 million EU citizens are affected by a rare disease.

The orphan medicines procedure in the European Union is centralised, from a request for orphan designation to marketing authorisation. Orphan medicines are granted a marketing authorisation by the European Commission, valid in all EU Member States.

Granting orphan designation may enable:

- advice with development of the medicine;
- reduced fees for marketing authorisation applications for small and medium-sized enterprises; and
- ten years of market exclusivity from similar products following marketing authorisation.

18
new orphan medicinal products were approved in the EU in 2015.

Early access to a treatment for patients may be possible before marketing authorisation on individual request of a physician.

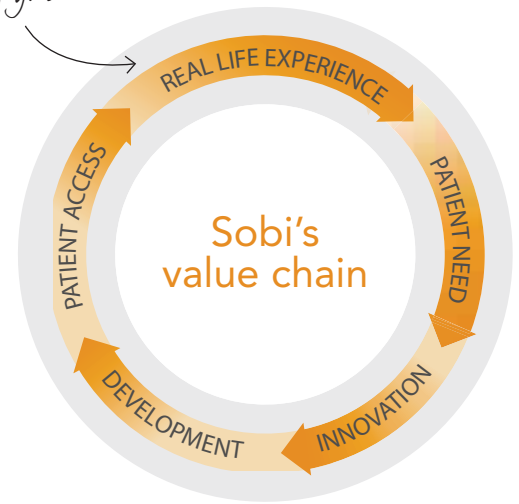
Despite marketing authorisation at a central level, each Member State decides individually on whether a treatment will be reimbursed and included in national healthcare systems. Therefore access to orphan medicines differs from country to country.

EURORDIS, the European Organisation for Rare Diseases, was founded in 1997.

Building value for all stakeholders

Drawing on more than 35 years of experience in the development of biopharmaceutical products (biologics) and 25 years in the commercialisation of these products for patients with rare diseases, Sobi is well-positioned to build value for patients, healthcare systems, the community and shareholders in a collaborative and sustainable manner.

The patient journey guides us



Read more on page 18

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

To develop and deliver innovative therapies and services to improve the lives of patients.

Strategic priorities

1. Diverse, growing, and profitable base business in Europe and North America focused on rare diseases.
2. Launching first-to-market extended halflife haemophilia factor treatments in Sobi territory – providing forward cash flow to continue to build the company.
3. Growing the business organically with new partner products and with a pipeline of early stage rare disease biologics.

Business model

Sobi's business model is based on an integrated and agile approach to product life cycles, by cross-functional collaboration from pre-clinical development and regulatory evaluation to commercialisation through successful inclusion in local healthcare systems. Medical needs throughout the patient journey have inspired us to continuously develop and provide new solutions. Sobi believes that stakeholders should be involved in all stages of the development process in order to deliver the most meaningful value for patients, the healthcare systems, the community and our shareholders.

Objectives for 2015	Achievements in 2015	Objectives for 2016
• Continue to build an engaged, learning and high-performing organisation.	– Focus on learning and people development. – Global IT-based processes put in place to support HR-activities and performance evaluation.	• Nurture our learning organisation. Read more on page 26
• Prepare for the successful launch of Elocta.	– Reached pivotal milestones within Haemophilia business with the approval of Elocta in the EU and the submission of a marketing authorisation application for Alprolix in the EU. – Haemophilia organisation in place to support the launch of Elocta in 2016.	• Conduct successful Elocta launch and successful potential launch of Alprolix.
• Grow the portfolio in Europe.	– Continued launch of Kineret for the CAPS indication in the EU. – Approval of Orfadin oral suspension and 20 mg capsule in the EU. – Focus on patient access to Orfadin treatment in Russia, North Africa and the Middle East region. – Extended agreement with PharmaSwiss for commercial rights in Europe to three new products.	• Expand the commercial portfolio and development pipeline through new indications, partnerships and acquisitions. • Advance the early-stage portfolio. • Ensure sustainable growth.
• Build operating momentum for the North American business.	– Rolled out a new distribution model and patient support programme. – Thinner 29 gauge needle for Kineret approved by the FDA and Health Canada. – Created a legal entity in Canada. – Restructured our distribution and gained more direct responsibility in Latin America.	
• Increase focus on preclinical development programmes.	– Presented three new research programmes in preclinical stage.	

With focus on the patient's journey - the case of Orfadin

Transition from child to adult care is a challenge in chronic diseases.

Orfadin, used in the treatment of the rare disease hereditary tyrosinaemia type-1 (HT-1), reflects Sobi's vision – that people who are affected by genetic disease are diagnosed at birth, and gain access to therapy that can sustainably improve their lives over the long term.

Maintaining a strong patient-centric approach is crucial, and Sobi is continuously developing initiatives based on the expressed needs of patients, healthcare providers and healthcare professionals. Working with the HT-1 community over the years has helped us to understand the ongoing medical needs of HT-1 patients. With a new dosage form and a new strength, which was approved in the EU during 2015, we will better be able to provide solutions that enable patients to pursue full and healthy lives within the boundaries of their disease.

25 years ago, before treatment was available, less than one-third of children born with HT-1 lived past their second birthday.[1] Treatment with Orfadin and a closely managed diet results in a higher survival probability and can change the course of this rare disease.[2] With early diagnosis and effective treatment, patients can look forward to leading a very different life than that possible in the past.

[1] van Spronsen FJ, et al. Hepatology. 1994;20(5):1187-1191.
[2] Orfadin SmPC June 2015.

Childhood

DIAGNOSIS AT BIRTH AND EARLY TREATMENT

As more countries introduce new-born screening for HT-1, infants are diagnosed earlier in life. As babies grow month by month, their dose is adjusted continuously. The new oral suspension of Orfadin for paediatric use aims to facilitate administration for infants.

Adolescence

ADOLESCENCE – STAYING ON TREATMENT

Sobi is actively involved in the collaborative development of tools that aim to address adherence challenges that have been identified through research. The first part of this work was developed in the UK, and introduced to the broader HT-1 healthcare community during the course of 2015.

REACHING ADULTHOOD

Today, people with HT-1 who are diagnosed and start treatment early in life are growing up to become teenagers and adults for the very first time in history. Since dosing is weight-adjusted, patients need progressively higher doses as they grow, and Sobi has developed the 20 mg capsule to facilitate treatment regimens that support adherence in adolescent and adult patients.

MATURE ADULTHOOD

People with HT-1 who, 25 years ago, had a short life expectancy due to the natural course of the disease, now have the option of therapeutic intervention that may even allow them to become parents.

Mature adulthood

Mid-life

A life-long treatment needs sustainable solutions.

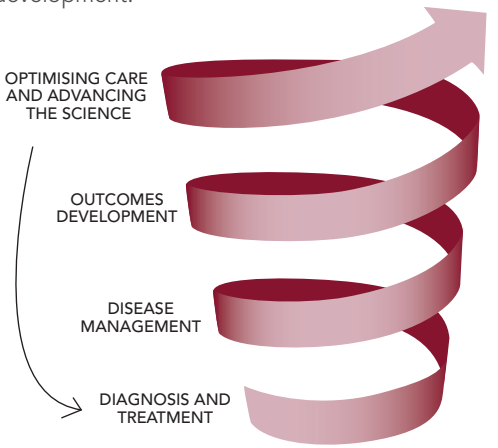
SUSTAINABLE ACCESS

In conjunction with the launch of Sobi's direct sales of Orfadin in the US, Sobi introduced Orfadin4U™ – a comprehensive support programme for patients and their caregivers that includes product and reimbursement support, and a call centre to assist with any questions patients or their families might have.

In 2015, Orfadin was approved for reimbursement in Jordan, making it the first reimbursed treatment for a rare genetic disease in the country.

THE PATIENT JOURNEY

Real-life experience and the patient journey, from diagnosis through disease management, outcomes development and finally resulting in advancing the standard of care, continuously fuel us to further development.



Expanding our international presence

We continue to expand our international presence and strengthen our product platform in Europe and North America. We currently have a offices in 17 countries, providing treatments for patients all over the world.

Haemophilia infrastructure in place

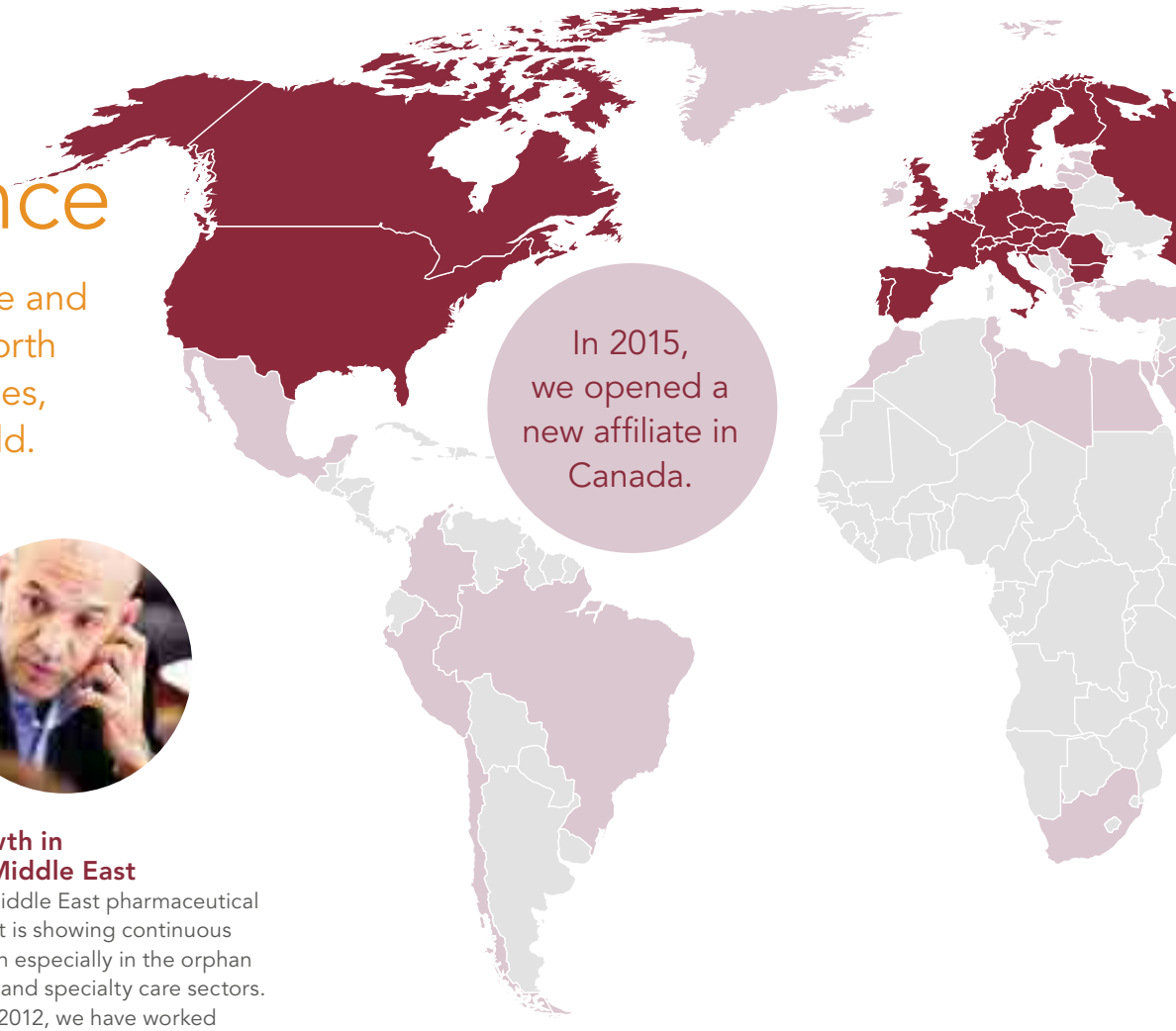
We have made a significant investment in preparation of the largest product launch in Sobi's history – Elocta – and built an organisation with more than 100 haemophilia and rare-disease experts. Sobi aims to make Elocta available to people living with haemophilia A in Sobi's territory, which includes Europe, certain countries in the Middle East, North Africa and Russia (EMENAR).

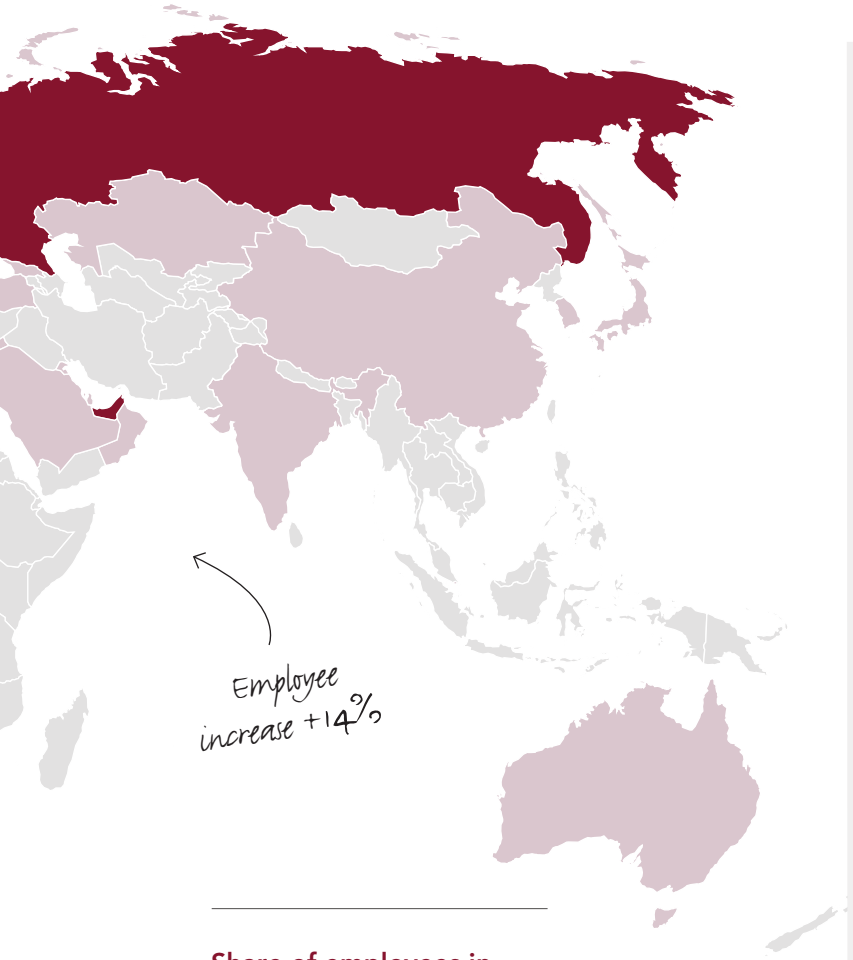
New offices

We opened a new office in Toronto, Canada, supporting our new Canadian affiliate. In Brussels, Belgium, we opened a new office supporting our European and Benelux business. The Brussels office will be an operational hub for Sobi's business for the EMENAR region. To support the new haemophilia organisation, an office was opened in London, UK. The French and Spanish offices also grew and found new, larger locations.

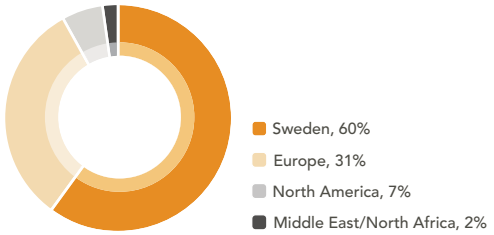
Growth in the Middle East

The Middle East pharmaceutical market is showing continuous growth especially in the orphan drugs and specialty care sectors. Since 2012, we have worked closely with local stakeholders to increase the awareness of rare diseases and highly specialised therapeutic areas to ensure patient access. The region is now the third largest contributor in the EMENAR in terms of sales.





Share of employees in geographic areas



A community approach

DURHANE WONG-RIEGER
President & CEO of the Canadian Organization of Rare Disorders (CORD)

Canada has long lacked an integrated framework for orphan drugs but much has happened recently. Can you tell us about this?

"A regulatory framework for orphan drugs has been in process for many years and is still yet to be implemented, but we are seeing a strong renewed willingness to make this real. We've come to the point where the regulators have said that they are willing to give an orphan drug designation, call them orphan drugs and treat them accordingly. This is real progress.

We don't want Canada to be a country that companies think of after other regions, so we want to mirror successful programmes. We have looked to the European approaches, in particular on access. For example, initiatives for early dialogue around pricing would mean that we can get a potential treatment into reimbursement without undue delay."

What are the critical success factors for these advancements?

"In May 2015, we launched the rare disease strategy, closely modelled on the European National Plans for Rare Diseases. We are now leading dialogue with the provinces to create understanding and a supportive environment beyond drugs alone. This includes centers of excellence, community support and access to therapies, so that rare diseases can be effectively diagnosed and treated. This dialogue has brought other parts of government and administration on board, giving us a bigger platform to work from."

What are the risk factors?

"A number of things. We need to a have an overall community approach. We want to encourage companies to contribute with a platform and engagement that truly supports the diagnosis, treatment and care of the rare disease. It cannot only be about getting the drugs out there. Clinicians, nurses, researchers also want to be a part of this, and we need every company to participate as a good citizen. We are all trying to act in a way to ensure sustainable, responsible access to therapies in the long term. If companies are only interested in getting the product on the market at the highest possible price, we are back to square one. We need to discuss at an international level what sustainable access means."

You have come a long way – are you celebrating?

"Far from it. You still need a telescope to see the finish line, but we are light years ahead of the position we were in a few years ago. We can soon say that Canada is open for business in terms of orphan drugs."

Sustainable high-quality patient care

Our collaborative, patient-centric and sustainable way of developing new and effective therapies is at the heart of our operations. Working with healthcare systems, we aim to improve the quality of life of patients with rare diseases all over the world.

Ideally, all stakeholders should be engaged in an ongoing dialogue around a medicinal product – physicians, legislators, budget holders, academics and patients – in order to understand the different needs, from the first phases of development for a new drug candidate and onwards 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.

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) Reporting Framework's requirements for engaging industry stakeholders, combined with Sobi's own analysis of issues raised by the media and other companies in the industry. 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 process resulted in a number of relevant aspects that reflect Sobi's financial, environmental and social impact and/or that affect judgments and decisions made by key stakeholder groups. The priorities remain unchanged for 2015.

Patient health and safety

Patient safety throughout the lifecycle of our products is one of Sobi's most important tasks. By having a robust pharmacovigilance system in place, Sobi continuously oversees the benefit/risk profiles of our products. We annually train all our employees to report any safety information relating to our products. By collecting and analysing safety data from all sources, our aim is to provide accurate and up-to-date information to regulators, healthcare professionals and patients.

Applying the latest industry standards

EFPIA DISCLOSURE CODE

CONSULTANCY FEE | PAYMENT FOR TRAVEL FEE | ATTENDING A CONGRESS FEE

During 2015 EFPIA's (European Federation of Pharmaceutical Industries and Associations) disclosure code was implemented. It outlines that all companies must disclose transfers of value made to healthcare professionals and organisations, such as sponsorship to attend meetings, speaker fees, consultancy and advisory boards. Greater transparency concerning this relationship is about strengthening the basis for collaboration in the future.

Access to healthcare and medicines

Sobi understands the need for an integrated approach to ensure that patients can access the medicinal products developed by the company, and can achieve the best possible results from the treatment. This requires a comprehensive and sustainable set of solutions: access to diagnosis and treatment, long-term commitment to the community and healthcare system, as well as responsible pricing. That ensures the sustainability of the treatment as well as the company. Sobi's Patient and Customer-Centric approach to Commercialisation (PC3) addresses each of these.

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.

see page 25

Sobi believes that rare disease patients should have access to treatment regardless of where they are born. During 2015, Sobi laid the foundation for a sustainable access approach to provide people around the world in great medical need access to innovative and effective treatments from Sobi's portfolio. The ambition is to work with local health communities to improve local health policies and ensure sustainable access to treatment globally. Examples of this are already in place.

75%

of people living with haemophilia worldwide have limited access to treatment.

Engagement with patient organisations

In rare diseases, patients and patient organisations are often the best experts in their diseases. Sobi recognises the importance of learning from patients and their families about the challenges they face in living with their rare disease and the successes and limitations of current treatment options. This gives us the opportunity to gain a holistic understanding of the needs of patients and their families and how we can develop and deliver treatments that help meet these needs.

To achieve this, we aim at engaging patient organisations in all our work, from research and disease awareness, to working with stakeholders to ensure that patients have timely and reimbursed access to the treatments they need. In this respect, we view engagement with patient organisations as a fully integrated part of Sobi's patient and customer-centric approach to rare diseases.

There are company-wide guidelines implemented to ensure compliance with ethical and transparency requirements throughout Sobi's territories.

MATERIALITY ANALYSIS

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

Regulatory and legal environment

Sobi operates in a highly regulated environment and must adhere to laws and regulations in production, research and marketing. There is a general trend today towards greater awareness of liability issues and legal risks and thus, also increased transparency requirements. In 2015, Sobi put particular focus on implementing standard processes to meet the new European transparency requirements which, from 2015, require pharmaceutical companies to publicly disclose the details of payments and transfers of value made to healthcare professionals and healthcare organisations.

A new regulatory environment is evolving around marketing authorisations and early availability of medicines. Applications for marketing authorisations are often conducted in a step-by-step process. Sobi is continuously exploring new ways to support conditional evaluations and authorisation.

Ethics and safety in clinical studies

Sobi strives to maintain the highest ethical, technical and scientific standards in all clinical research conducted. The safety of clinical trial subjects in our studies is of highest priority and is built on careful and scientifically based continuous evaluations by our clinical expertise in cooperation with regulatory authorities, independent ethics committees and stakeholders. Sobi adheres to the Declaration of Helsinki's ethical principles for medical research involving human subjects, and clinical studies sponsored by Sobi are conducted and reported in accordance with applicable laws and the international standard, Good Clinical Practice (GCP).

Sobi collaborates to a large extent with contract research organisations (CROs) when conducting clinical studies. This collaboration is governed by mutual high standards and procedures.

Sobi follows the Pharmaceutical Research and Manufacturers of America (PhRMA) & European Federation of Pharmaceutical Industries and Associations (EFPIA) "Principles for Responsible Clinical Trial Data Sharing" and the European Medicines Agency (EMA) Policy on publication of clinical trial data, which entered into force on 1 January 2015.

Anti-corruption

There is an increasing global focus on the implementation and enforcement of anti-bribery and anti-corruption legislation. Sobi has a zero tolerance policy towards bribery, which is supported by the Sobi Code of Conduct and Ethics as well as the Sobi Global Policy on Anti-Corruption, both of which have been translated into relevant business processes, such as those governing Sobi's interactions with healthcare professionals and organisations. To raise awareness of the policies in the organisation, a robust training programme is in place that is mandatory for all employees and must be completed on an annual basis. In 2015, particular focus was directed to the introduction of a due diligence process to ensure that suppliers of services meet the same standards that Sobi applies when it comes to anti-corruption efforts.

SOBI SUPPLY CHAIN

ORDER TO LOGISTICS CENTRE FOR HOME DELIVERY

In Europe, when pharmacies and clinics order products, these orders are normally managed by Sobi's logistics partners who ship the products within 24 hours. In the US, home delivery is an important part of patient support programmes and is increasingly provided by Sobi through dedicated partners.

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.

SUPPLY CHAIN

The single most important responsibility is to ensure that patients never risk being without their medication, which could be a life-threatening situation. Sobi has, therefore, built up a robust supply chain. Sobi sells and markets a wide range of products – some 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 supply 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.

Haemophilia humanitarian aid programme

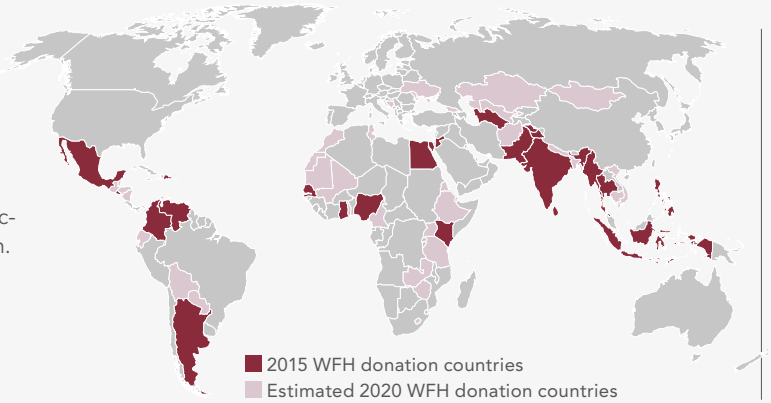
Access to treatment for those in need, regardless of location, is a key issue for Sobi. In collaboration with Biogen, our joint donation of up to 1 billion international units of haemophilia therapy over a 10 year period – the first up to 500 million earmarked for the World Federation of Hemophilia´s (WFH) humanitarian aid programme – is an essential part of this ambition.

The hospital in Thies, Senegal, now has regular access to treatment

The first shipments of much-needed haemophilia therapy donated by Sobi and Biogen started to arrive at treatment centres across the developing world in 2015. The WFH donation programme is designed to create a sustainable model for humanitarian aid with the potential to improve haemophilia care in regions of the world where, due to limited access to diagnosis and treatment, people with severe haemophilia often do not survive to adulthood. The first recipient countries of the donation include the Dominican Republic, Egypt, El Salvador, Ghana, India, Indonesia, Jordan, Kenya, Morocco, Myanmar, Nigeria, Pakistan, the Philippines, Senegal, Sri Lanka and Uzbekistan.

According to the WFH, an estimated 400,000 people worldwide suffer from haemophilia and of these, more than 300,000 live in areas with limited access to diagnosis and treatment. This commitment from Sobi and Biogen and the sustainable flow of medicine to WFH may help to provide access to treatment for not only emergency situations, but also acute bleeds, elective surgeries as well as regular prophylaxis for children.

Sobi regard healthcare innovation as a global commitment. By helping to address the global treatment gap and supporting the WFH's mission of treatment for all, we hope to enable meaningful change for people with haemophilia across the world.



Scan the QR code for more information

ABOUT THE WORLD FEDERATION OF HEMOPHILIA

For more than 50 years, the World Federation of Hemophilia (WFH), an international not-for-profit organisation, has worked to improve the lives of people with haemophilia and other inherited bleeding disorders. Established in 1963, WFH is a global network of patient organisations in 127 countries.

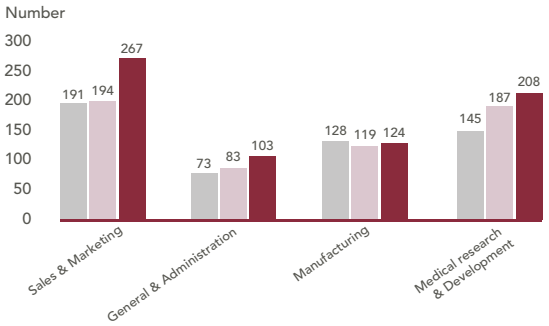
Building a learning organisation

Supporting a learning organisation drives Sobi's people focus. In 2015, recruitment and retention were particularly important aspects, especially in preparation for the launch of Elocta during 2016.

"The best way to predict the future is to create it."

Abraham Lincoln

EMPLOYEE INCREASE 2013–2015



Full-time equivalent (FTE) development for the company: 537 (2013) to 702 (2015)

One of Sobi's strategic objectives is to nurture our learning organisation and engage people working in high-performing teams in order to perform in a competitive market and reach challenging goals in an appropriate way. This means that Sobi nurtures a culture that encourages and supports continuous employee learning, critical thinking and collaborative new idea generation, laying the ground for a sustainable future.

Employees are expected to meet high expectations, which is essential for building an innovative and high-performing company culture. This is supported by a number of different initiatives.

On-boarding new employees

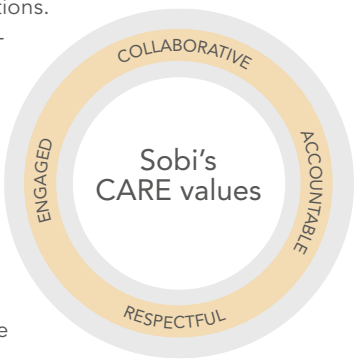
Sobi has grown fast, from 478 employees at the beginning of 2013, to 702 employees at the end of 2015. The company has recruited employees in all main functions.

Sobi puts a strong emphasis on on-boarding new employees. This takes place not only locally but also centrally at our head office in Stockholm, Sweden, through induction days. The goal of induction days is to create an understanding of Sobi's history, our strategy and organisation but, more importantly, Sobi's Patient and Customer-Centric approach to Commercialisation (PC3) and the Sobi CARE (Collaborative, Accountable, Respectful, Engaged) values.

Efforts to share and provide training in the company culture and values have played a key role in our growth, and particularly in the building of a strong haemophilia business.

Focus on learning

Through different learning activities, Sobi develops a change-ready mindset that supports innovation in a rapidly changing environment. The main part of this learning takes part as engaged individuals in day-to-day operations. However, 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. Continuous scientific, regulatory and compliance training is part of our people development.



Learning happens while doing things

Sobi also offers a comprehensive leadership development programme focusing on unleashing personal leadership potential and developing effective team leadership. This is carried out in close alignment with Sobi's culture and CARE values. Employees may also access training courses and e-learnings addressing specific managerial topics or skills.

Emphasis during the year was also placed on learning activities dealing with how to engage and nurture high quality relationships with internal and external parties, as well as specific product and disease training courses.

Performance-based evaluation

Individual objectives are linked to strategic business goals and all individuals are encouraged to coach each other. Sobi has established an annual performance management process that starts with setting objectives and ends with a performance evaluation. At Sobi, performance is not only about what individuals achieve but also how the objectives are achieved. Employees are expected to reach the results in line with the CARE values.

During 2015, global IT systems were put in place to support HR processes relating to performance management, salary review, short-term incentives and recruitment. Systems were also established for training programmes, serving as a platform for creating and sharing e-learning courses across the organisation.

Employee survey

Being a learning company, we take all opportunities to learn and understand how Sobi can offer the best work environment. In order to increase individual engagement and give employees a voice in our company, employee surveys are conducted every two years. The results from September 2015 show that Sobi performs on a par with or above the global average* in most comparable areas. For example, in the area "I believe in the company values" Sobi scores 28 per cent higher than other companies. A value-based organisation is an important driver of engagement. Employees also view Sobi as a great place to work, meaning we should continue working the way we do.

Sobi has been through a transformational period over the past years. This has created challenges consistent with a growing organisation, and seeking increased engagement in this process is a critical part of our focus. Being a learning organisation, Sobi will use the results of this survey to develop the company in areas where there is improvement potential.

Diversity

Sobi has expanded on an international basis in 2015, and the successful incorporation of new knowledge and influences will build our future company. Of the total number of employees in 2015, 42 per cent were men and 58 per cent were women. The corresponding figures for the Executive Leadership Team and Board of Directors were 70/30 per cent and 63/37 per cent respectively (excluding employee representatives).

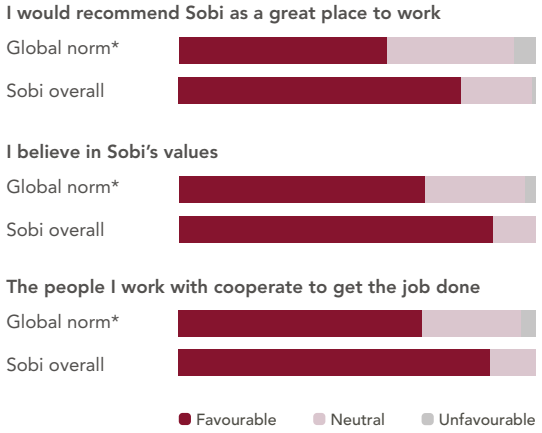
All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

* CEB survey database: 85% match to Sobi (similar company size/population/industry), consists of data from >300,000 employees globally.

GENDER DISTRIBUTION OF EMPLOYEES

58% **42%**

SOBI IS A GREAT PLACE TO WORK



Controlled risk-taking helps create long-term value

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

HOW WE MANAGE RISKS

Sobi's integrated risk management process aims to identify, assess and manage risks and uncertainties as early as possible. Our risk management policy demonstrates how proactive risk management and consistent identification, assessment and control create conditions for continued business growth.

Risk management is an integral part of Sobi's daily operations. The main risks that are most probable and that may have the largest impact on the company's operations are summarised below. The risks are not ranked but are categorised and described.

Operational risks

Bringing new medicines to the market

Bringing a new biopharmaceutical product to the market is a capital-intensive, complicated and risky process. Sobi's innovation model is used to determine a project's attractiveness and risk profile. Read more on pages 32-33.

Marketing authorisation

A product must demonstrate that it meets the rigorous demands on quality, safety and efficacy imposed by authorities in those countries or regions where it will be marketed. In order to ensure both timely and sustainable access as well as gain insights into the future requirements and follow-up Sobi collaborates and engages in dialogue with authorities from an early stage of the development process for a new medicinal product. Read more on pages 12-13 and 24.

A quality culture is instrumental for a company such as Sobi.

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 (GMP) regulations.

External risks

Seasonal dependant risks
Sobi has no risks that are seasonal because the treatment of chronic diseases is continuous over the year.

Competition
Sobi's competitors include other international pharmaceutical, biotechnology and speciality pharmaceutical companies. The products Sobi has under development risk being exposed to competition from similar products or entirely new product concepts that offer more value for the patient.

By identifying the relevant stakeholders at each stage of the patient journey, optimal outcomes are secured for everyone, and development and availability can be sped up or new opportunities identified.

Read more on pages 12–15

Prices
In most markets where Sobi is active, governments exercise control over pharmaceutical prices. Sobi's success depends on whether the products we develop or distribute are covered by, and eligible for, reimbursement under private or government-owned reimbursement systems in the healthcare sector. By engaging in a concerted, multi-stakeholder dialogue, Sobi aims to find shared solutions on a sustainable basis for the healthcare system and the company.

Product counterfeiting
The supply of prescription drugs is increasingly challenged by illegally produced medicinal products and by the availability of counterfeit products. Sobi's products have not yet been exposed to counterfeiting, however we are constantly vigilant and take part in the global serialisation effort that has been initiated. Sobi's distribution is set up according to Good Distribution Practice (GDP) to minimise the risk of counterfeiting.

Ethical and compliance risks

Issues concerning social responsibility and sustainable business play an increasingly significant role in competitiveness and profitability. At Sobi, the Risk Management and Compliance Committee continuously oversees the development and implementation of the Sobi compliance programme, which aims to reduce the risk of non-compliance with regulatory and legal requirements. Key components in the compliance programme include risk identification, promotion of clear messages, establishing clear policies and processes and training in addition to continuous follow-up.

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.

A growing portfolio for better lives

Sobi provides and develops innovative therapies and services to improve the lives of patients with rare diseases and their families. Our growing portfolio includes proprietary products, focused on haemophilia, inflammation and genetic diseases, as well as 35 products from 24 partners. We also contract manufacture the active ingredient in the haemophilia A treatment ReFacto AF.

In November 2015, Elocta was approved in the EU for the treatment of haemophilia A.

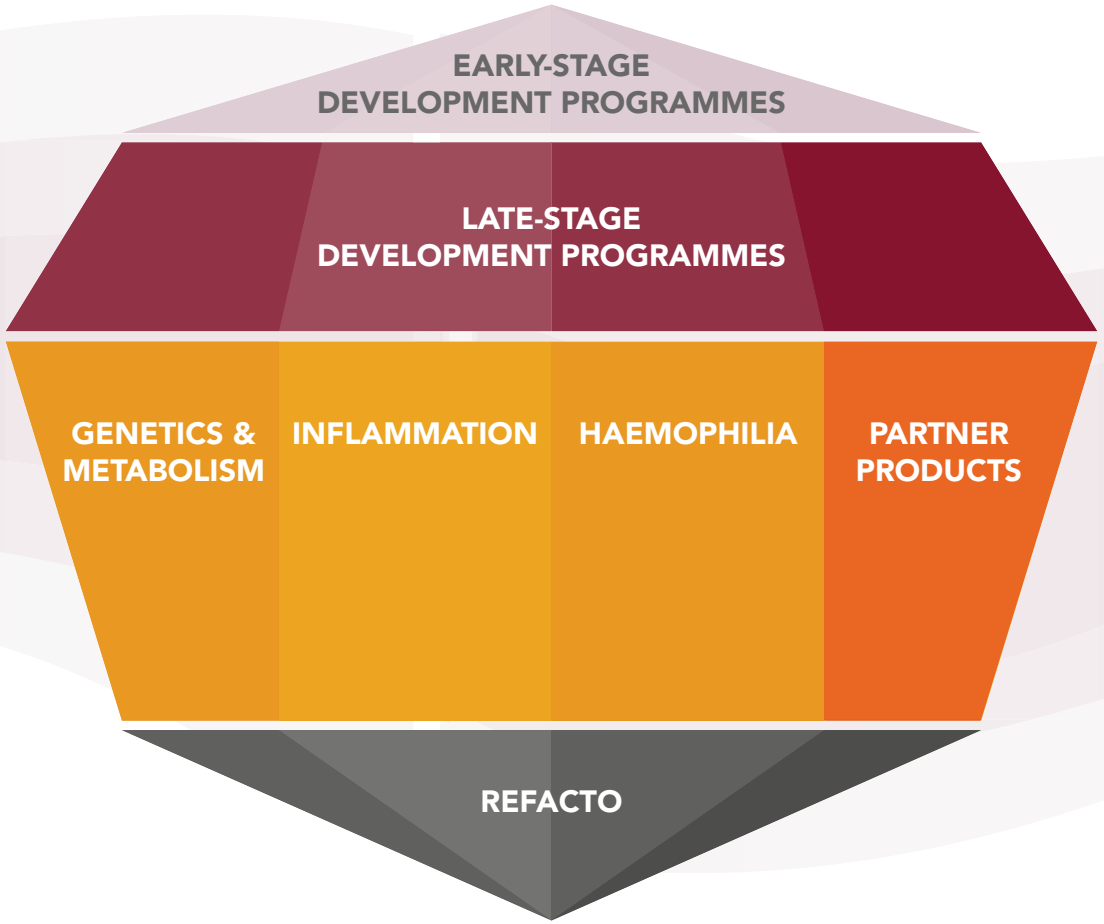
In the beginning of 2016, the launch of Elocta was initiated in Sobi's territory

SOME OF SOBI'S PRODUCTS

Sobi is marketing authorisation holder (MAH) for:

- Orfadin
- Kineret
- Kepivance®
- Ammonaps
- Xiapex

Sobi will become MAH for Elocta and Alprolix in Sobi's territory during 2016. Orfadin, Kineret and Kepivance® are Sobi proprietary products.



EARLY-STAGE DEVELOPMENT PROGRAMMES

Sobi's innovation model is based on three fundamental questions: Is there a patient need? Is it possible to develop a treatment? Can we ensure sustainable access to the treatment? Read more on pages 32–35.

LATE-STAGE DEVELOPMENT PROGRAMMES

Sobi develops solid clinical programmes for rare diseases. This includes development of new treatments, and the repurposing and lifecycle management of approved products. Read more on pages 34–35.

GENETICS & METABOLISM

Sobi provides treatments for certain inborn errors of metabolism that can be life-threatening if not treated. Read more on pages 46–48.

INFLAMMATION

Sobi's Inflammation business area is engaged in the development and sales of Kineret, which is used to treat inflammatory and auto-inflammatory diseases. Read more on pages 44–45.

HAEMOPHILIA

Sobi's development of extended half-life factor therapies in partnership with Biogen offers the potential to significantly improve the standard of care for people with haemophilia. At the end of 2015, Elocta was approved for the treatment of haemophilia A in all 28 EU member states, as well as Iceland, Liechtenstein and Norway. Read more on pages 38–43.

PARTNER PRODUCTS

Sobi offers small and mid-sized pharmaceutical and biotechnology companies a cost-efficient and integrated platform for the commercialisation of their specialty care products in Europe, the Middle East, North Africa and Russia. Read more on pages 50-52.

REFACTO

Sobi has been manufacturing the active ingredient in the haemophilia A product ReFacto AF for the global market on behalf of Pfizer for many years. Read more on page 53.

A deep understanding of our environment drives innovation

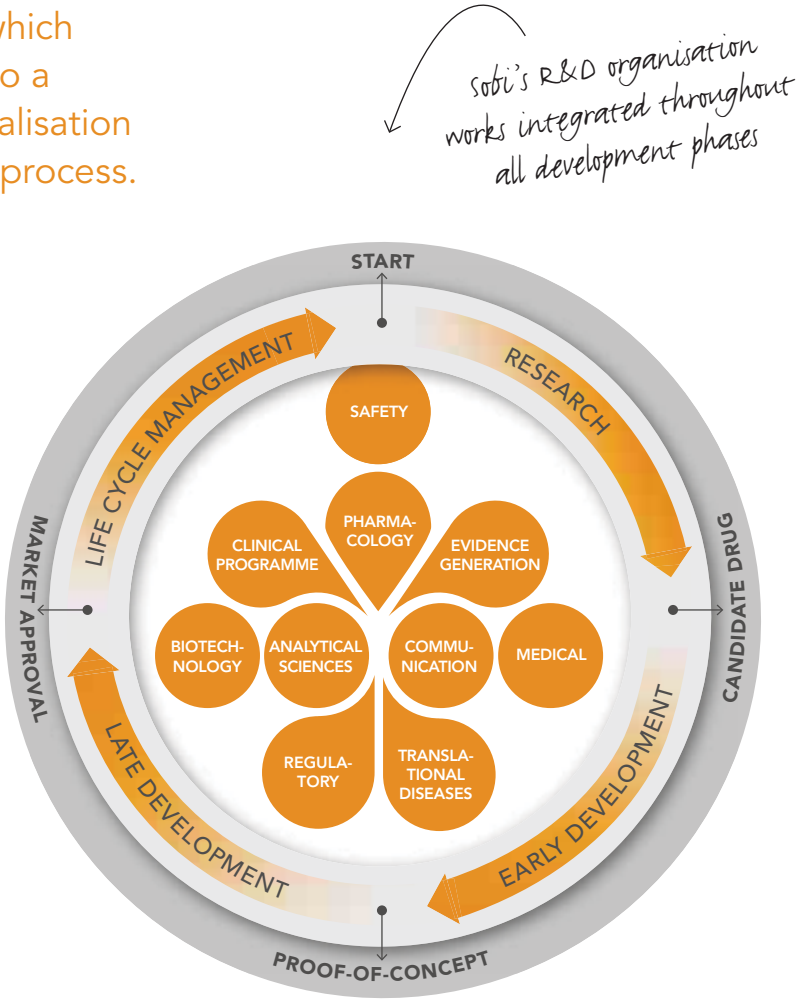
Our research and development (R&D) is based on a model in which biologics development and process scale-up are integrated into a modern Patient- and Customer-Centric approach to Commercialisation (PC3). We apply insights to patient needs throughout the R&D process.

Sobi's world-class capabilities in protein biochemistry and biologics manufacturing allow us to develop next generation biological products. Our in-house capabilities encompass the entire R&D value chain, from gene to patient, with a balanced portfolio of new biological entities and lifecycle management projects.

Sobi's R&D model is not linear, as the knowledge we gain throughout the process is continuously fed back into development. By working cross-functionally and identifying stakeholders at each stage, we aim to streamline the time it takes to bring treatments to patients, while also ensuring optimal outcomes and sustainable access.

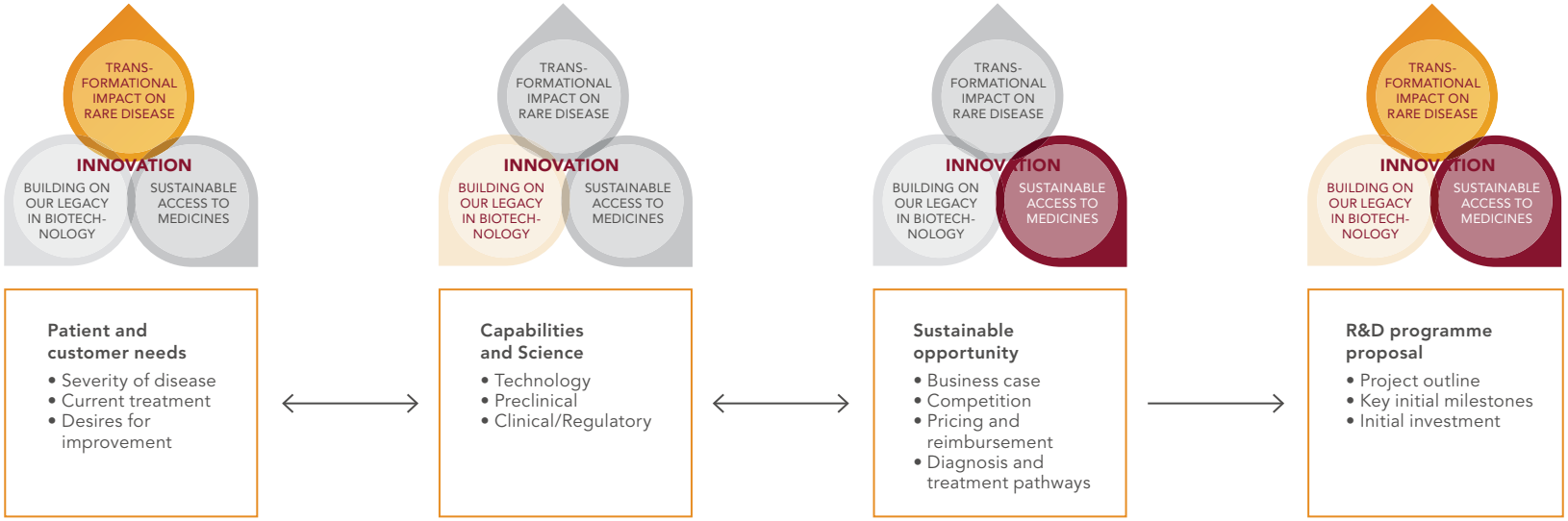
Manufacturing capabilities are key

Manufacturing and scale-up capabilities play a key role in early-stage development phases, by facilitating the continuous inclusion of production and product quality aspects such as technology transfers, throughout the R&D process. These capabilities also enable the evaluation, planning and implementation of process and product changes, and ensure compliance with global regulatory submissions and approvals, thereby improving efficiency and performance throughout the product's life cycle.



Sobi´s innovation model

Using a multi-disciplinary approach, cross-functional teams map and evaluate new R&D projects by applying the three lenses of our innovation model. This ensures that new projects are aligned with our corporate strategy, that we successfully utilise our strengths and assures that only projects with favourable risk profiles will be pursued.



1 A transformational impact in rare diseases

Sobi's innovation model revolves around the patient journey for people with rare diseases. We aim to define the real unmet needs of patients by collaborating with patients, their families, caregivers, and the medical community; and by continuously studying treatment outcomes. By doing so, we aim to achieve a transformative impact with our programmes – to substantially improve the lives of people living with rare diseases.

2 Expertise in biologics and process development

We believe that our R&D approach gives the potential to provide an interface between new discoveries and integrated research and development processes, and to offer benefits of scale that are appropriate for different projects, with the overall objective of maximising our programme value. The scientific/technological aspects of a proposed programme (drug molecule, processes, development plans) should be aligned with our capabilities and skill sets.

3 Providing sustainable access to medicines

By identifying the relevant stakeholders at each stage of the patient journey we aim to co-create and secure optimal outcomes along the development pathway. When we collaborate we believe that we are able to facilitate each step, resulting in smoother, and ideally faster development and delivery to patients.

4 R&D programme proposal

Projects are outlined with the aim of reaching key milestones where our pipeline programmes are sequentially de-risked to support further investments.

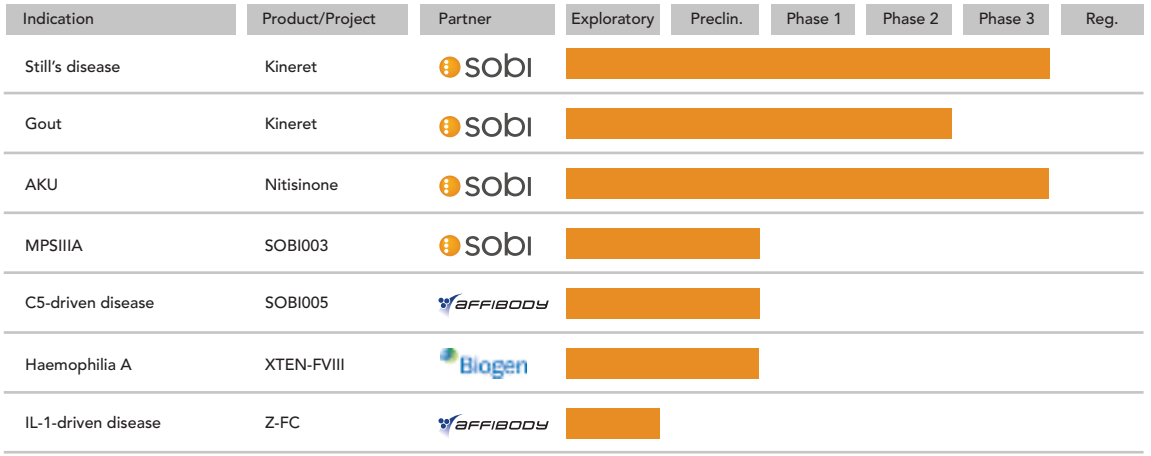
Our innovation pipeline

Sobi balances the financial investment in its R&D portfolio between life cycle programmes with limited risk and products in preclinical and clinical phases with higher risk. Innovation can come through at every stage when it is guided by patient needs.

3 new development programmes presented

Improved product formulations

For Orfadin, which was developed for the treatment of patients with hereditary tyrosinaemia type 1 (HT-1), two new formulations were approved by the European Commission in 2015. The oral suspension formulation is a demonstration of Sobi's commitment to the needs of infants and children diagnosed with HT-1 early in life. The 20 mg capsule facilitates adherence to treatment regimens by adolescent and adult patients. An application for marketing approval in the US and Canada is currently being reviewed.



Exploring disease mediators

Based on the needs of patient representatives and caregivers, Sobi continuously explores the potential to further develop approved medications for new indications. An increasing body of evidence suggests the involvement of interleukin 1 (IL-1) in a number of autoinflammatory diseases affecting an array of organs.[1] As more information becomes available, the number of identified IL-1-mediated diseases is growing, including systemic inflammatory diseases such as systemic juvenile idiopathic arthritis and adult-onset Still's disease, as well as more common inflammatory diseases such as gout.

IL-1 lowers pain thresholds and damages tissues. Blocking IL-1 activity in autoinflammatory syndromes, as seen in CAPS, results in a rapid and sustained reduction in disease severity.[2]

Several new areas where IL-1 blockade is used are under investigation to meet the medical need for effective treatment. Looking to build the early-stage pipeline, Sobi is capitalising on proprietary and partner platforms to develop the next generation of IL-1 blockers. This includes exploring the potential of Affibody molecules for new IL-1 receptor antagonists.

[1] Dinarello CA. Blood. 2011;117(14):3720-32
[2] Goldbach MR. Curr Rheumatol Rep. 2011;13:123–131

Patient-driven development

Alkaptonuria (AKU) is a genetic disease that damages the bones and cartilage, causes severe pain and leads to health problems such as osteoarthritis, heart disease and kidney infections. It is extremely rare and a total of approximately 950 people living with AKU are identified worldwide.

DevelopAKUre is a clinical trial programme for the drug nitisinone, the first potential treatment for AKU, run by a European consortium, which has been established and is led by patient groups. Sobi is a founding member of a group of 13 hospitals, pharmaceutical companies and consultancies, universities, biotech companies and national AKU patient organisations who are working towards developing nitisinone as a treatment for AKU.

Exploring a novel technological platform

In our complement C5 programme we are exploring a novel technological platform with our partner Affibody AB. Affibody molecules are a class of protein-targeting biological molecules that can be considered as an alternative platform to antibodies. We have utilised this technology to develop highly potent inhibitors to complement factor C5. The complement system is an important part of the immune system that is involved in the pathology of many severe diseases.

C5 is one of the central components in the complement cascade and has a clear therapeutic potential to target diseases such as PNH (paroxysmal nocturnal hemoglobinuria) and aHUS (atypical haemolytic uraemic syndrome). Sobi announced in 2015 that a second generation of Affibody-based C5 inhibitors are under development, where we leverage knowledge from the SOBI002 project, which was terminated in 2014, and reapply lessons learned. The new candidate contains a more stable C5 binding domain, which is fused to the IgG1-Fc for half-life extension. Fc fusion technology is something that is very familiar to Sobi and is, for example, applied in our haemophilia treatments.

Building our pipeline

Mucopolysaccharidosis type IIIA (MPSIIIA) is a lysosomal storage disease affecting one in 200,000 births. It is a rare genetic condition caused by a shortage of the enzyme sulfamidase. MPSIIIA causes progressive disability and severe neurological deterioration, and can result in childhood death. Currently there is no cure or treatment available that ameliorates or modifies disease progression. Using experimental biotechnology, Sobi has produced a modified variant of sulfamidase that has shown promising results in the brains of animals.

Building next-generation treatments

In 2014, Sobi elected to add the preclinical rFVIIIFc-XTEN-vWF fusion molecule to the company's collaboration with Biogen. The XTEN technology is proprietary to Amunix Operating, Inc. and has the potential to further extend FVIII half-life. The collaboration has similar terms to those of Elocta and Alprolix.

Our therapies help to improve the lives of patients with rare diseases.

A milestone for Sobi and for people with haemophilia

Sobi has a strong legacy in haemophilia. With the launch of Elocta (efmoroctocog alfa), we are poised to advance standards of care for haemophilia A. Alprolix (eftrenonacog alfa) is also coming closer to a potential approval for the treatment of haemophilia B.

DEDICATED LAUNCH-READY ORGANISATION WITH A BROAD EXPERIENCE

COMMERCIAL

A highly experienced team across haemophilia and rare diseases, with all personnel in early-launch markets recruited and fully trained.

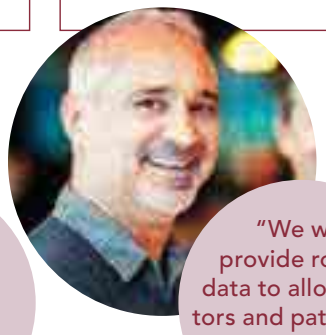
MEDICAL

A solid team with a strong clinical background and a long experience in haemophilia. Our scientific engagement in haemophilia stretches over three decades.

PATIENT ACCESS

A skilled patient access team to engage with patient organisations, HTA bodies, healthcare systems and budget holders. A concerted engagement programme with payer bodies was initiated in 2013 and is ongoing. First price dossier submissions are completed.

"We have a reliable supply chain to ensure that treatment is available."



"We will provide robust data to allow doctors and patients to make informed decisions."

"Sustainable access to treatments for people with haemophilia is key."

Elocta is a recombinant extended half-life factor VIII therapy for the treatment of haemophilia. The approval of Elocta in the EU in November 2015 was a milestone for Sobi, and for people living with haemophilia in Europe. This is the first haemophilia A therapy in the EU to offer extended protection against bleeding episodes, with the potential to also reduce the number of injections.

In addition to Elocta, Sobi collaborates with Biogen on the development and commercialisation of Alprolix, an extended half-life recombinant factor IX product candidate for the treatment of haemophilia B. Alprolix has been approved in the US, Canada, Australia, New Zealand and Japan and an application for marketing authorisation was submitted to the European Medicines Agency (EMA) in June 2015.

Revenue for the Haemophilia franchise was SEK 96 M (31), representing royalties equal to 2 per cent of the sales of Eloctate® and Alprolix in Biogen´s territories during the year.

Dedicated patient-centric organisation

Sobi has built the infrastructure and capabilities required to support a successful launch of Elocta in Sobi's territory. We have evolved from a few individuals to more than one hundred dedicated people, all with a broad range of qualifications and diverse experiences in both haemophilia and rare diseases. The organisation now consists of experts who are leaders in their field as clinical and academic specialists and professionals in market and patient access. Our focus now is to ensure timely and sustained access to Elocta for people living with haemophilia A throughout Sobi's territory. See map on page 40.

Sobi engages proactively with the relevant national and international stakeholders, such as healthcare providers, authorities and budget holders. Sobi also engages with umbrella patient organisations on a global and European level, as well as with local organisations representing people with haemophilia, in order to fully understand patient and medical needs in the community and to align with their priorities and act to support them.

The launch

The EU approval of Elocta covers all 28 EU member states, as well as Iceland, Lichtenstein and Norway. During the next couple of years we also expect to seek approval for, and launch, Elocta in other parts of our territory. Elocta will be available for the treatment and prophylaxis of bleeding episodes in people of all ages with haemophilia A, which increases treatment options and advances patient care.

Sobi strives to achieve timely access and has been actively engaged at local level to understand the unique challenges and opportunities in each country, followed by individual plans to reflect the varying pricing and reimbursement regulations within our territory. The launch will therefore be implemented on a country-by-country basis over the next couple of years. The first people with haemophilia will have access to treatment in 2016.

WHAT IS ELOCTA?

INDICATION: In the EU, Elocta (efmoroctocog alfa) is indicated for the treatment and prophylaxis of bleeding episodes in patients with haemophilia A (factor VIII deficiency) and can be used by people of all ages.[1]

PRODUCT DESCRIPTION: Elocta is a recombinant human factor VIII Fc fusion protein with an extended half-life that offers prolonged protection against bleeding episodes with prophylactic injections every three to five days. Elocta was developed by fusing B-domaindeleted factor VIII to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). This enables Elocta to utilise a naturally occurring pathway to prolong the time the therapy remains in the body. For full prescribing information visit www.elocta.com.

GEOGRAPHIC MARKET: EU, Iceland, Lichtenstein and Norway.

[1] Elocta Summary of Product Characteristics. 2015.

ELOCTA PACKAGING – A STORY OF INVOLVEMENT AND CO-CREATION

Sobi has a strong legacy in haemophilia. By listening to the haemophilia community across Europe – in an attempt to understand what it is like to live with a bleeding disorder – we were inspired to develop a new and more user-friendly package that could make life easier for children, adolescents and adults with haemophilia.

We initiated an open dialogue and collaboration with more than 100 representatives of the medical profession, and with people with haemophilia. The result: a compact and fully recyclable package, tailor-made for self-injection. We also learned how important it is to increase the grip area for smaller hands, and to facilitate injections for people with severe haemophilia and impaired grip function, and thus developed a new and innovative syringe plunger rod with horizontal ribs and an extra centre grip. This syringe has now been patented by Sobi.

This co-creation process has brought new insights into pharma packaging and we believe will add significant value for the haemophilia community as well as other disease areas with similar needs.

Our commitment goes beyond the therapy

The haemophilia market in Sobi's territory

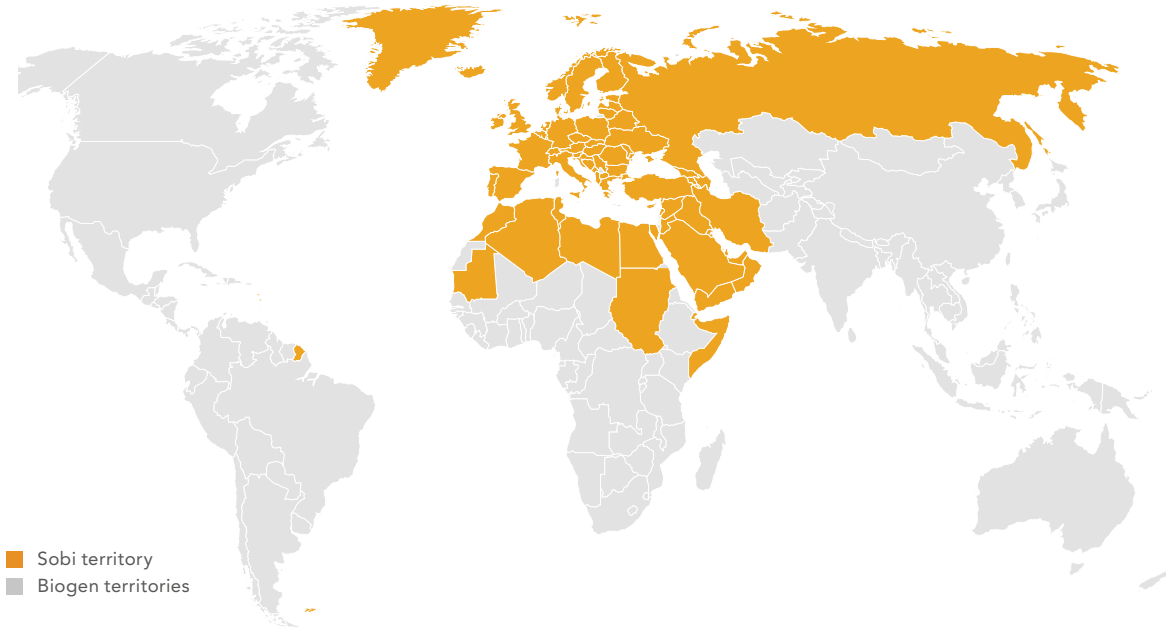
In Sobi´s territory, the number of people living with haemophilia A is approximately 59,000 and the market value is estimated to be USD 3.1 billion.

The market value for haemophilia B is approximately USD 420 million, and the estimated number of people living with haemophilia B is 11,000.

Compared with most other rare diseases served by Sobi, the haemophilia market – in terms of value and size – is larger and more competitive with several conventional treatment options available for people with haemophilia.

In addition to the extended half-life (EHL) products currently offered by Sobi and Biogen, other EHL products are anticipated to be approved in Europe over the next 1 to 2 years.

In Sobi´s territory, recombinant products currently account for up to 60 per cent of the market value for haemophilia therapies and plasma products for the remaining portion. Over the past decade, there has been a gradual shift from plasma-derived clotting factors to recombinant clotting factors; and from on-demand treatment of bleeding episodes to preventative, prophylactic regimens.



PEOPLE LIVING WITH HAEMOPHILIA

	Haemophilia A population	Haemophilia B population
Central & Eastern Europe	6,839	1,155
Germany, Austria and Switzerland	4,616	876
Belgium, Netherlands and Luxembourg	1,875	379
Italy and Greece	4,651	980
Nordics and Baltics	1,670	384
France	5,400	1,201
UK and Ireland	6,229	1,394
Spain and Portugal	2,217	388
TOTAL EUROPE	33,497	6,757
Middle East	16,770	3,632
North Africa	2,959	610
Russia	5,801	992

Source: 2014 WFH Annual Global Survey

FACTOR VIII CONSUMPTION

COUNTRY	Total FVIII consumption in IU*
UK[1]	486,591,948
Italy[2]	490,713,370
France[3]	453,161,500
Germany[4]	440,979,622
Spain[5]	262,080,000

Source and year:

[1] UKHCDO; Apr 2014–March 2015,
[2] IMS; Jul 14–Jun 15,
[3] GERS; Nov 13–Oct 14,
[4] DHR; 2013,
[5] IMS; 2014
* International Units (Measurements for haemophilia drug)

Haemophilia therapies

Extended half-life (EHL) clotting factor therapies use a mechanism that enables them to stay circulating in the blood for longer than conventional therapies after injection. There are different ways of achieving half-life extension, including the use of natural pathways as well as through chemical modifications to the clotting factor molecule. EHL treatments have the potential to improve clinical outcomes by providing increased protection against bleeding episodes in prophylactically treated patients, possibly with fewer injections. EHL treatments also have the potential to resolve more bleeds with a single injection compared to conventional factor treatments. In addition EHL products increase the possibilities to individualise the treatment for people with haemophilia.

The key to a successful long-term treatment outcome in children and adults with haemophilia is a prophylaxis regimen that prevents bleeding episodes. Prophylactic treatment with conventional therapy can offer significant protection, minimising the number of bleeding episodes and reducing the risk of joint arthropathy and life-threatening soft-tissue bleeds. However, breakthrough bleeds still occur, indicating that the need still exists to raise the standard of care in this area by further reducing bleeds, while at the same time reducing the treatment burden.[1,2]

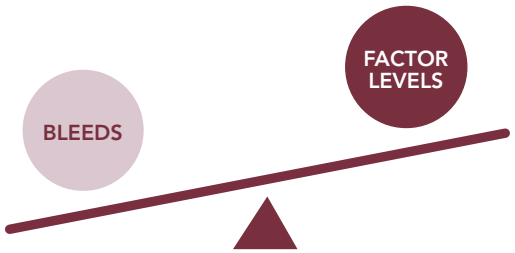
Intensifying prophylactic treatment with conventional clotting factors could also potentially reduce the number of bleeding episodes, but barriers such as increased treatment burden, compliance, higher factor consumption and associated cost implications prevent a widespread adoption.

Collaboration with Biogen

Sobi and Biogen are collaboration partners for the development and commercialisation of Elocta for haemophilia A and Alprolix for haemophilia B. Sobi holds final development and commercialisation rights in a pre-specified territory, which includes Europe, North Africa, Russia and certain countries in the Middle East. Sobi exercised its opt-in right to assume responsibility for the final development and commercialisation of Elocta in Sobi's territory in 2014, and of Alprolix in July 2015. Biogen leads development and manufacturing of the products and holds commercialisation rights in North America and all other regions in the world outside of the Sobi territory. Elocta is also approved in the U.S., Canada, Australia, New Zealand and Japan where it is known as Eloctate. Alprolix is currently approved for the treatment of haemophilia B in the U.S., Canada, Japan, Australia and New Zealand. Financial terms of the agreement between the companies are described in more detail in Note 19.

[1] Carcao M. Haemophilia. 2014; 20 (4):99–105.
[2] Peyvandi F., et al. The Lancet. 17 Feb 2016. Published online.
[3] Berntorp E., et al. Haemophilia. 2016; (1-8)

RAISING FACTOR LEVELS



EHL products can potentially raise factor levels with the same overall consumption as with conventional half-life factors while reducing bleeds.[3]

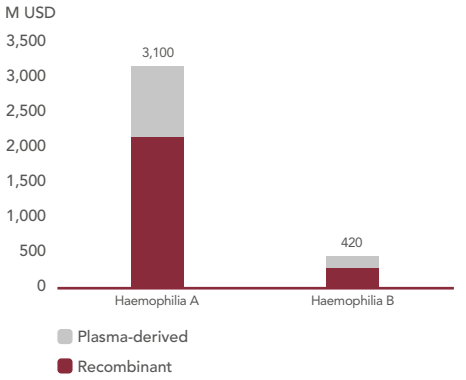
IDENTIFIED LIVING WITH HAEMOPHILIA A

59,000

PEOPLE IN SOBI'S TERRITORY

The actual number is believed to be higher. Not all persons living with haemophilia A have been diagnosed.

TOTAL MARKET SALES [4]



[4] Marketing Research Bureau, 2011 (including all patient groups)

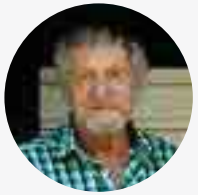
Goran Kapentovic, documentary film maker

Documentary series

Understanding the individual and varying challenges of people living with haemophilia is essential for supporting the haemophilia community, and for building sustainable access to treatment. Together with the European Haemophilia Consortium and award-winning documentary film maker Goran Kapetanovic, Sobi has co-produced a series of documentaries describing the lives of people with haemophilia in different EU countries. In Europe, access to treatment differs considerably for the people with haemophilia who live there.

PLEASE SCAN THE QR CODE TO SEE THEIR STORIES

Cassius Lister
Haemophilia A
UK



Gert Grekow
Haemophilia B
Sweden

Timothée Wiell
Haemophilia A
France

David Banu
Haemophilia A
Romania

Bojan Bojanov
Haemophilia B
Bulgaria

Brian O'Mahony
Haemophilia B
Ireland

Read more about Sobi's humanitarian commitment to improving access to treatment on page 25

ABOUT HAEMOPHILIA

Haemophilia is a rare, chronic, genetic disorder in which the ability of a person's blood to clot is impaired due to missing or reduced levels of a protein known as clotting factor. The most common type is haemophilia A, caused by a lack of the clotting factor VIII. People with haemophilia experience bleeding episodes that may cause pain, irreversible joint damage and life-threatening haemorrhages. Haemophilia A affects one in 5,000 male births each year, while haemophilia B, caused by a lack of the clotting factor IX, affects one in 25,000. Both types occur much less often in females. According to the World Federation of Hemophilia, 140,000 people worldwide are identified as living with haemophilia A, and 28,000 with haemophilia B.[1] Because many live in areas with limited access to treatment and diagnosis, the estimated number is likely greater – around 400,000 in total.[2]

[1] World Federation of Hemophilia. Annual Global Survey 2012.
[2] World Federation of Hemophilia. Treatment of Hemophilia.

Our heritage in haemophilia is a platform for tomorrow

Sobi has a strong legacy in haemophilia, and with Elocta we are poised to advance standards of care for haemophilia across our territory. In our pipeline for continued and future development in the area of haemophilia we can look forward to the potential launch of Alprolix and also in collaboration with Biogen, the development of the preclinical programme XTEN, which has the potential to extend the half-life for haemophilia treatment even further.

SOBI'S HISTORY OF INNOVATION IN HAEMOPHILIA – A LONG-TERM COMMITMENT

Our commitment drives us towards innovations in the treatment of haemophilia with the simple goal of providing people with haemophilia choices that help them to live the lives they want to lead.

1931–1993 Kabi/KabiVitrum/Kabi Pharmacia

1940s: Pioneered fractionation and production of plasma proteins.

1983: Began research and development of the first recombinant B-domain deleted factor VIII.

1993 Pharmacia AB

Since 1999: Production and supply of recombinant factor VIII for the haemophilia product ReFacto AF for the global market.

2001 Biovitrum

2006/2007: Collaboration with Syntonix (subsequently Biogen) to develop Alprolix and Elocta.

2010 Sobi

2012–2015: Sobi and Biogen completed pivotal phase 3 studies of Elocta and Alprolix in adults and children.

2015: Elocta approved in the EU. Sobi and Biogen applied for marketing authorisation for Alprolix in the EU.

Expanding the indications for Kineret

Kineret (anakinra) is a biologic that can reduce the activity of interleukin-1 (IL-1), a key driver of inflammation in autoimmune and autoinflammatory diseases. Kineret continues to grow across all major regions, supported by new indications.

Kineret was first approved in 2001 to ease the symptoms and to slow the progression of structural joint damage in moderate to severe rheumatoid arthritis (RA) in adults. In recent years, Sobi has focused on expanding the indications for Kineret to include paediatric autoinflammatory diseases. In 2012, Kineret became the first and only drug approved by the US Food and Drug Administration (FDA) for the treatment of neonatal-onset multisystem inflammatory disease (NOMID) in children and adults. In 2013, the European Commission approved Kineret for the treatment of cryopyrin-associated periodic syndrome (CAPS) in adults, and in children from eight months of age.

The approval of these indications is a key milestone for Sobi, and for the company's efforts to make innovative products available to patients with debilitating and often life-threatening diseases.

Kineret is Sobi´s largest product. Kineret recorded sales growth of 32 per cent in 2015 and grew across all regions, especially in the US.

WHAT IS KINERET?

INDICATION: Rheumatoid arthritis (RA) in adults, neonatal-onset multisystem inflammatory disease (NOMID) in children and adults (US), cryopyrin-associated periodic syndrome (CAPS) in adult patients, and in children from eight months and older (EU).[1,2]

PRODUCT DESCRIPTION: Kineret (anakinra) is a recombinant protein drug that blocks the biological activity of IL-1a and IL -1b by binding to interleukin-1 type 1 receptor (IL-1RI), expressed in a variety of tissues and organs, and thereby blocking interleukin-1 (IL-1) signalling. This signal blockade helps manage excess levels of IL-1 in the body, and consequently, inflammation and other symptoms.

GEOGRAPHIC MARKET: Global.

[1] Kineret Summary of Product Characteristics January 2016
[2] Kineret PI USA September 2015

Increased awareness of Kineret

The launch of Kineret for the treatment of CAPS is ongoing, with most of the major EU markets now covered, and we are engaged in dialogue with various stakeholders to facilitate access to the treatment by patients in need. The CAPS indication has also been approved in Australia[3] and Israel[4], with filings planned in more countries.

Following the US approval of Kineret for NOMID in 2012, we have now raised awareness of the treatment across the US. We have increased our collaboration with patient organisations, such as the Autoinflammatory Alliance, as well as treating physicians, and have invested in *Kineret On TRACK*, a robust patient support programme.

Expanding the number of indications

Interleukin-1 (IL-1) is a key mediator of local and systemic inflammation and a significant contributor to autoinflammatory diseases.[5] Many autoinflammatory diseases, such as CAPS and NOMID, have symptoms that are chronic from childhood or infancy. Blocking IL-1 activity in autoinflammatory syndromes results in a rapid and sustained reduction in disease severity.[6] Sobi is determined to continue exploring the full potential of Kineret in this area as well as other more common inflammatory diseases, such as gout.

In 2015, Sobi and its partner, A. Menarini Australia, were granted marketing authorisation for Kineret in Australia for the treatment of systemic juvenile idiopathic arthritis (SJIA), a rare form of juvenile chronic arthritis. Kineret was granted Orphan Drug Designation (ODD) for Still's disease by the FDA in September 2015 and Sobi will now begin to explore the use of Kineret in this disease state.

see page 34

[3] Kineret PI Australia March 2015
[4] Kineret SPC Israel September 2014
[5] Dinarello CA. Blood. 2011;117(14):3720-32
[6] Goldbach MR. Curr Rheumatol Rep. 2011;13:123–131

SHARE – for sharing knowledge

PROF. DR. NICO WULFFRAAT
Coordinator of the SHARE project

With financial support from the EU the SHARE* project was founded in 2013, containing initiatives on reviewing standards of care, sharing best practices, improving patient information and encouraging active participation across Europe for paediatric rheumatic diseases. The aim of the project is to define what is needed in order to provide optimal care to children and young people with rheumatic diseases. Prof. Dr. Nico Wulffraat is the coordinator of the SHARE project.

"Our first initiative has been to ensure patient participation. We created a survey to find out, from a patient's perspective, how care is provided. The survey was sent through the PRINTO** network across Europe, and we received 450 replies. The result showed that there is a difference in care practices between Western and Eastern Europe and also gave us a clear picture of the existence of specialty care and current treatment guidelines. The survey results are relevant to many and can hopefully be used as a platform in our dialogue with authorities, budget holders and national healthcare providers.

Our intention with the SHARE project is to produce robust reports, draw conclusions and share these with all parties involved. Long term our aim is that all young patients with rheumatic diseases will be given excellent access to paediatric care. To achieve this, we will have to make detailed recommendations and start partnering with patient organisations to influence both care and community support. We believe in making patients a partner – patients' voices must be given a key position in the development."

* SHARE – Single Hub and Access point for paediatric Rheumatology in Europe.
** PRINTO is a non-governmental international network for clinical trials in children with paediatric rheumatic diseases (PRD). Thanks to the data gathered through SHARE, PRINTO is updating a website for families. The site offers scientific information regarding PRD and lists of centres dealing with PRD and family associations, in more than 27 languages.

25 years on – still collaborating and learning

Inborn errors of metabolism represent a large class of genetic diseases involving metabolic disorders. Left untreated, these diseases can lead to permanent damage or death. However, treatment can be successful, especially if the diagnosis is made early in life.

SURVIVAL RATE UNTIL AGE TWO

29% survivors without treatment[1]

93% survivors with treatment[1]

APPROXIMATE NUMBER OF PEOPLE CURRENTLY LIVING WITH HT-1

1,000

For 25 years, Sobi has been engaged in the delivery of treatment for hereditary tyrosinaemia type 1 (HT-1), a severe genetic condition in which the body is unable to break down the amino acid tyrosine. Untreated, HT-1 is ultimately fatal.[2,3] Orfadin is approved in the EU, the US and several other countries, and in combination with the appropriate diet, is an essential part of effective HT-1 treatment.

Orfadin is the largest product in Sobi's Genetics & Metabolism business area, and Sobi's second-largest product overall in terms of revenues. In 2015, Orfadin recorded revenue growth of 45 per cent, and sales have more than doubled over the past two years, in part due to taking direct responsibility for the product in North and South America. Orfadin grew in all major markets, including Latin America.

In the Genetics & Metabolism business area, Sobi also provides therapies for urea cycle disorders (UCD). These products – Ammonaps, Ammonul and Ravicti – recorded, a year-on-year increase of 21 per cent in2015. Urea cycle disorders are a group of serious genetic conditions in which patients suffer from a deficiency of one of the enzymes responsible for removing ammonia from the bloodstream.

WHAT IS ORFADIN?

INDICATION: Treatment of adult and paediatric patients with confirmed diagnosis of hereditary tyrosinaemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.[4] People with HT-1 have problems breaking down tyrosine. Toxic by-products are formed and accumulate in the body, which can cause liver, renal and neurological complications.

PRODUCT DESCRIPTION: Orfadin (nitisinone) blocks the breakdown of tyrosine, thereby reducing the amount of toxic by-products in the body.

GEOGRAPHIC MARKET: Global.

[1] van Spronsen FJ, et al. Hepatology. 1994;20(5):1187-1191.
[2] Ashorn M, et al. Paediatr Drugs. 2006;8(1):47-54
[3] Angileri F, et al. JIMD Rep. 2015;19:43-58
[4] Orfadin Summary of Product Characteristics June 2015, Orfadin PI USA May 2014

Collaborating with the HT-1 community

The course of hereditary tyronisaemia has changed dramatically in recent decades, and most of the people who are diagnosed with HT-1 and receive therapy are now growing up to become teenagers and adults.

However, a strong patient-centric approach is crucial to Sobi´s mission to further improve the lives of HT-1 patients. This includes continued investment in life cycle management activities for Orfadin, such as new strengths and dosage forms, and a strong focus on treatment adherence in adolescents, to ensure that people with chronic and potentially degenerative conditions stay on their treatment plans.

- Sobi has developed an oral suspension formulation for infants and small children, and a 20 mg capsule dose to facilitate treatment regimens that support adherence in adolescent and adult patients. In 2015, both products were approved in the EU, and marketing authorisation applications were submitted to the FDA for the US. The 20 mg capsule was also submitted to Health Canada for Canadian approval.

- "Let's Talk" is one of several programmes developed together with the rare disease community intended to increase knowledge about rare diseases such as HT-1, and to support patients through a life-long journey from diagnosis to sustainable long-term treatment. The overall objective is to improve adherence to treatment and diet by using different behaviour-change techniques based on research in HT-1 patients. The programme includes patients and parents as well as healthcare professionals.

Tyrosinemia 2015 – a reference for the future

JANICK TREMBLAY
President of the organising committee for Tyrosinemia 2015.

In September 2015, the first ever international symposium *Tyrosinemia 2015* was held in the city of Saguenay in Quebec, Canada. Janick Tremblay, who herself was born with tyrosinaemia, was president of the organising committee:

"We wanted to arrange an international conference to celebrate the 50-year anniversary of the discovery of tyrosinaemia. Our goal was to provide information, to identify medical innovations and to explore future avenues to manage and treat the disease. The interest for the conference really exceeded our expectations. We had international speakers and more than 200 attendees, including many families affected by tyrosinaemia. The families came from the Quebec area but also from other parts of Canada, and from the US, Europe, Australia and even India. This kind of event is important for smaller patient populations and physicians who may never meet anyone else with the same condition.

The event made it possible for patients and families to meet with targeted professionals, share their expertise and create new partnerships. For example, there were discussions on ways to improve the transition from paediatric to adult care as more patients reach adulthood. I hope this conference now can serve as an international reference, because all these new relationships will bring new hopes and further improve the quality of life of children affected by tyrosinaemia."

QUEBEC
Quebec is home to 10 per cent of the world's HT-1 population. Due to the high concentration of HT-1 patients care and community support is well developed.

25 years with Orfadin – the result of ground-breaking research

Before pharmacological treatment was available, less than one-third of infants diagnosed with HT-1 before two months of age lived past their second birthday.[1] Treatment with Orfadin, combined with a dietary restriction of tyrosine and phenylalanine, coupled with more widespread screening of newborns leading to early diagnosis, has dramatically improved outcomes for HT-1 patients.[1]

Extending our footprint

Sobi strives to ensure sustainable access to treatment for patients in all parts of the world. The Middle East and Northern Africa have been focus areas for new market development, with increased activities to file for approval and seek treatment reimbursement for all the products in the Genetics & Metabolism business area. In Jordan, a first-ever reimbursement decision for a rare genetic disease has made Orfadin available to Jordanian HT-1 patients. In Russia, Sobi is working actively, patient-by-patient, in collaboration with physicians and budget holders, to ensure access to HT-1 treatment. Sobi has also supported an initiative to help families from all over Russia living with HT-1 to connect and to learn about the disease.

50 YEARS WITH TYROSINAEMIA

50 years ago

HT-1 IS IDENTIFIED

1982
Nitisinone is extracted from the bottle brush plant.

1989
Professor Lindstedt and his group at the University of Gothenburg presented ground-breaking research into HT-1. This established the primary aetiology behind the disease and led to the discovery of nitisinone.

1992
Clinical trial results on nitisinone presented in *The Lancet*.[2]

2002
US approval of Orfadin – four-year survival rate for HT-1 raised from 29 per cent to 93 per cent.

2005
EU approval of Orfadin.

2012
DevelopAKUre began to explore the use of nitisinone for treating AKU.

2014
Initiated direct sales and gained distribution responsibility for Orfadin in the US and Canada.

2015
Orfadin oral suspension and 20 mg capsule approved in the EU.

2015
First international symposium on tyrosiaemia held in Quebec, Canada.

2015
Marketing authorisation applications for Orfadin 20 mg capsule and oral suspension submitted to the US Food and Drug Administration (FDA).

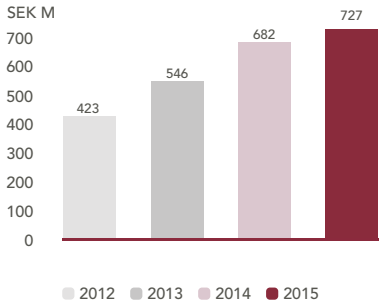
[1] van Spronsen FJ, et al. Hepatology. 1994;20(5):1187-1191.
[2] Lindstedt S, et al. Lancet. 1992 Oct 3;340(8823):813-7

Read about
Sam and 9 other
children living with
HT-1 in the book 10
Stories found on
www.sobi.com.

Bringing niche and rare disease products to Europe

25 years of responsible partnership providing cost-effective and sustainable ways of bringing niche products to patients.

REVENUE DEVELOPMENT



Sales development in 2015

In 2015, the Partner Products portfolio comprised 35 medicinal products from a total of 24 partners. Total revenues amounted to SEK 727 M, an increase of 7 per cent, and was mainly driven by the growth of Cometriq®, Kepivance and Xiapex.

In the beginning of the year, Sobi extended and restructured the distribution agreement with Exelixis for Cometriq (cabozantinib), a treatment for progressive, unresectable, locally advanced or metastatic medullary thyroid cancer (MTC).* Sobi is responsible for Cometriq in the EU, Switzerland, Norway, Russia and Turkey.

In December 2015, Sobi gained commercial rights from PharmaSwiss SA to distribute Relistor®, Deflux® and Solesta® in a territory including Western Europe, Czech Republic, Slovakia and Hungary, and for Relistor also in Russia. Sobi and PharmaSwiss have been collaborating since 2013 when a first distribution agreement was signed.

Extended usage of Xiapex

Sobi and Endo** have an agreement giving Sobi the exclusive rights to commercialise Xiapex for the treatment of Dupuytren's contracture and Peyronie's disease in 71 Eurasian and African countries. During 2015, Sobi actively expanded the indications for Xiapex, receiving approval for the treatment of Peyronie's disease in the EU in January and in Switzerland in October. Sobi also expanded the label for Dupuytren's contracture in November 2015 to include concurrent treatment of two palpable cords.

Dupuytren's contracture is a progressive hand disease that can present with multiple collagen cords limiting finger movement and hand function. Peyronie's disease is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis, which may cause bending of the penis during erection. We are continuing to work with the community to increase awareness and ensure that patients are given access to treatment. Several initiatives have been taken to increase knowledge and best-practice sharing among treating physicians.

* After the period, it was announced that Exelixis will terminate the agreement during 2016 as they have signed a new agreement with Ipsen concerning all indications areas for Cometriq.

** In 2013, Sobi signed the agreement with Auxilium Pharmaceuticals Inc. which was acquired by Endo Pharmaceuticals Inc. in 2015.

Our partner offering

By providing our partners with a cost-efficient distribution platform, we are able to make niche medicines available to patients with a high unmet medical need in Europe, the Middle East, North Africa and Russia.

The European market – a complex and evolving landscape

Smaller and medium-sized companies seeking to bring their innovative treatments to patients in Europe face a variety of challenges.

Despite the possibility of a single marketing authorisation, the EU and European landscape alone comprises more than 30 different country markets, each of which have their own legislation and requirements for inclusion of treatments in their local healthcare systems.

In addition, the region has evolved significantly in terms of requirements over the past years, from regulatory procedures through to supply, tracking and tracing as well as reporting requirements. Health technology assessments (HTA), pricing and reimbursement procedures differ from country-to-country and even region by region. Patient distribution, language, medical practice and guidelines and many other factors further complicate the patchwork that a company must seek to navigate to bring their treatment to the patients.

Setting up an own infrastructure in this landscape can result in heavy time and capital investments, which can be prohibitive in terms of a single-asset company; or which can add complexity and margins that are unsustainable, particularly in the case of a rare disease therapy or a niche product.

To bring a new therapy to the European market, a company must consider a variety of elements:

- Costs / capital
- Regulatory
- Pricing & Patient Access
- Pharmacovigilance
- Compliance
- Supply network
- Marketing capabilities
- Quality assured release
- Expert network
- IT structure
- Insurances

Sobi's pan-European presence

Sobi has more than 25 years of experience in bringing rare disease and niche treatments to the European market. Working with our partners, we seek to find sustainable solutions that address the needs of the company and the patient population, which we roll out across our in-country affiliate network covering countries in Europe, Middle East, North Africa and Russia.

Sobi's partnership offering is based on a full own structure, comprising efficient distribution capacity and extensive market knowledge and experience. Partnerships can span over many years; can cover the entire region or only parts of it and include engagement with the medical communities and all parts of the healthcare system that are vital to getting therapies to patients.

Sobi offers partner companies a cost-efficient and comprehensive platform of their commercialisation of products by:

- Medical, commercial, HTA and pricing and reimbursement teams;
- Regulatory strategy and delivery;
- Integrated supply chain, including provisions to support named patient use (NPU);
- Pharmacovigilance process and procedures; and
- Local and regional networks to develop and deliver successful access and commercialisation in partnership.

Value for all stakeholders

Sobi's Partner Products platform seeks to add value for all stakeholders. The main objective is to help to meet important medical needs in various therapeutic areas so that each patient is able to have access to optimal treatment, which might otherwise not be the case. In some cases, Sobi is the only supplier of antidotes, which can be critical in acute care settings. In other cases, a smaller company based outside Europe might simply not have the means to access each market successfully. By working in partnership, Sobi aims to continue to provide sustainable access and, thereby, value to all stakeholders, starting with early stages and continuing through to subsequent filings and lifecycle management. This is a proven platform and one that delivers significant and sustained earnings to both company and partners.

PARTNERS

Get access to strategic thinking, management and cost-effective solutions via a mature and experienced platform spanning the region.

PHYSICIANS

Meet a reliable and experienced partner in Sobi with a dedicated patient-centric approach.

PATIENTS

Receive access to innovative, new treatments.

BUDGET-HOLDERS & HEALTHCARE SYSTEMS

Provided with robust dossiers in order to evaluate treatments and include them in local healthcare systems.

sobi

Lower risk and spread investments.

Extensive manufacturing experience

Sobi has been manufacturing the active ingredient in the haemophilia treatment ReFacto AF for the global market on behalf of Pfizer for almost 20 years.

A constant commitment to improve environmental sustainability. Read more on www.sobi.com

ReFacto AF is a recombinant protein drug for the treatment of haemophilia A, which was developed by Sobi and its predecessors. Sobi manufactures the active ingredient in ReFacto AF for Pfizer, who sells the product globally. As Pfizer's global supplier, Sobi receives both manufacturing revenues and royalties on Pfizer's sales of ReFacto AF. The current supply agreement stretches until 2020 with an option to extend. The royalty agreement is in place until 2016/2017. The partnership with Pfizer began in 1998, based on Sobi's extensive experience and expertise in the development and manufacturing of recombinant protein drugs.

The active ingredient is produced in Sobi's Good Manufacturing Practice (GMP) certified biologics facility in Stockholm, Sweden.

Developments in 2015

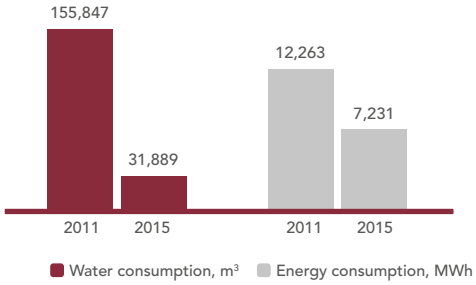
ReFacto has continuously contributed to Sobi's revenues over the years. In 2015, total revenues for ReFacto (manufacturing and royalties) amounted to SEK 660 M, an increase of 7 per cent compared to the preceding year. Manufacturing revenues amounted to SEK 504 M, and royalties to SEK 156 M.

SALES

SEK M	2011	2012	2013	2014	2015
Manufacturing revenues	452	436	492	466	504
Royalty revenues	123	130	127	152	156
TOTAL	575	566	619	618	660

SOBI'S COMMITMENT TO SUSTAINABLE MANUFACTURING

Sobi has ongoing projects to continually improve the energy efficiency of our sites, and we regularly review and monitor the operating costs of the buildings in which we operate. An energy management plan for the production facility in Stockholm was introduced in 2012. Measures include heating/cooling recovery, and the optimisation of run times for heating and ventilation. A programme to review and reduce water consumption at the facility was launched in 2011 and at 31 December 2015, water consumption had decreased by 80 per cent.



By working in a collaborative way, we believe it is possible to create a win-win environment for all parties.

The share's development

The Sobi share rose 70 per cent in 2015, due to a continued positive price trend in the pharmaceutical industry in general, strong sales growth for Sobi's operations and the expected milestone achievements for the haemophilia products Alprolix and Elocta. The share price reached a new record high of SEK 145.90 on 11 May 2015, in connection with takeover speculations. The lowest price paid was SEK 76,30 on 7 January 2015. The share (STO:SOBI) is listed on Nasdaq Stockholm, under the company name of Swedish Orphan Biovitrum, and is included in OMX Stockholm's Large Cap Index and the Pharmaceuticals & Biotechnology Sector Index, which rose 10 and 11 per cent, respectively, during the year.

Share capital

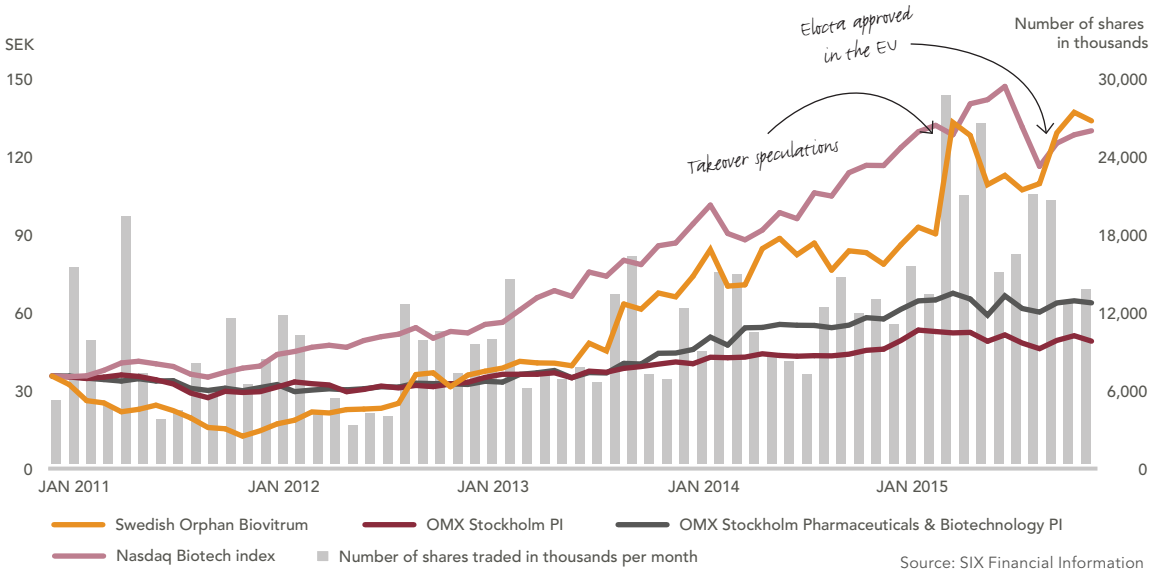
At year-end, the total number of shares outstanding in Sobi was 271,822,806, of which 270,389,770 were ordinary shares and 1,433,036 Class C shares, corresponding to a total of 270,533,074 votes. The ordinary shares carry one vote per share, and Class C shares 1/10 of a vote per share. The increased number of shares and votes is due to a new issue of 1,036,856 Class C shares, which will be used to secure obligations under Sobi's incentive programmes. At year-end, the share capital was SEK 149,150,658, distributed between 271,822,806 shares with a par value of approximately SEK 0.55.

LONG-TERM VALUE CREATION

The long-term price trend for the Sobi share depends mainly on how successful we are in our efforts to create value in Sobi through;

- Higher cash flow and profitability in our diversified commercial portfolio;
- Launching new and innovative medications for rare disease patients; and
- Our business model, with a focus on partnership in all areas, from early-stage biopharmaceutical research and development to the commercialisation of niche medicines in Europe.

SOBI SHARE PRICE AND TRADING VOLUME 2011–2015



Source: SIX Financial Information

Average daily trading volume in SEK for the Sobi share on Nasdaq Stockholm

SEK 1,000	2011	2012	2013	2014	2015
A shares	9,113	10,726	22,446	43,445	100,369

In 2015, the average daily trading volume in number of shares for the Sobi share on Nasdaq Stockholm was 860,000 shares.

Source: Yahoo Finance

Shareholders

At year-end, the number of shareholders was 21,096 (12,955). The holding of the largest shareholder, Investor AB, was at 39.6 per cent (39.8). Swedish legal entities, including institutions and funds, owned 65.6 per cent of the shares at year-end.

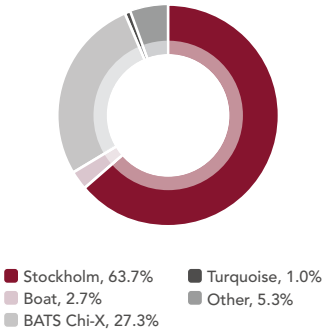
Treasury shares held by Swedish Orphan Biovitrum AB (publ) at year-end totalled 2,763,768 A shares and 1,433,036 C shares. During the year, 637,184 shares were used for allotment under the performance-based long-term share programme.

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

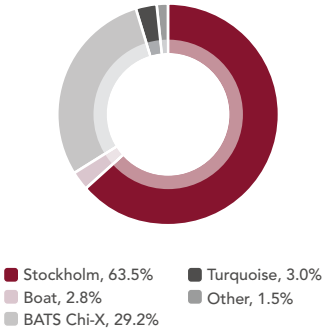
Dividend

For 2015, the Board proposes no dividend. For more information on Sobi's dividend policy please refer to the Corporate Governance Report.

TRADING PLACES 2014



TRADING PLACES 2015



Source: Fidessa

Market price for the Sobi share, SEK

	2015		2014	
	High	Low	High	Low
1st quarter	95.85	76.30	87.20	65.00
2nd quarter	145.90	89.45	89.65	65.55
3rd quarter	125.00	100.30	94.75	72.40
4th quarter	140.30	109.10	88.00	65.25

Shareholder categories

2015-12-31	% of capital
Foreign shareholders	29.4
Swedish shareholders	70.6
Of which:	
Institutions	94.9
Private persons	5.1

Source: Euroclear

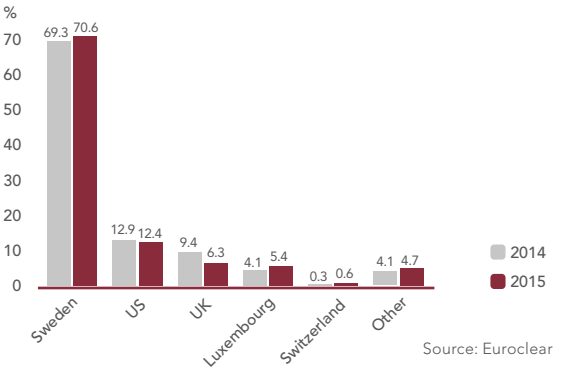
Recommendations from analysts, %	2013	2014	2015
Buy	75	70	75
Hold	13	20	25
Sell	12	10	0

Source: Based on analyst reports.

Analyst coverage	
Carnegie	Erik Hultgård
Danske Bank	Lars Hevreng
Deutsche Bank	Richard Parkes
Goldman Sachs	Eleanor Fung
Handelsbanken	Peter Sehested
Jefferies	Eun K. Yang
Nordea	Hans Mähler
Pareto Securities	Finlay Heppenstall
RX Securities	Samir Devani
SEB	Richard Koch
Swedbank	Johan Unnérus

Brief facts, the Sobi share	
Listing	Nasdaq Stockholm
Number of shares (A+C shares)	271,822,806
Market capitalisation, at year end	SEK 36 billion
Ticker	SOBI
ISIN	SE0000872095
CUSIP	870321106

SHAREHOLDERS BY COUNTRY



Source: Euroclear

Largest shareholders at 31 December 2015[1]

Shareholders	Number of A shares	Number of C shares	Share capital, %	Share votes, %
Investor AB	107,594,165	0	39.58	39.77
Skandinaviska Enskilda Banken S.A., W8IMY	10,785,798	0	3.97	3.99
Goldman Sachs & Co, W9	10,620,329	0	3.91	3.93
Swedbank Robur Fonder	9,450,901	0	3.48	3.49
Afa Insurance	7,018,728	0	2.58	2.59
Handelsbanken Funds	6,778,912	0	2.49	2.51
Fourth Swedish National Pension Fund	6,610,894	0	2.43	2.44
Catella Funds	6,110,503	0	2.25	2.26
AMF – Insurance + Funds	5,936,821	0	2.18	2.19
Biotech Target N.V.	5,409,334	0	1.99	2.00
SEB Investment Management	4,465,831	0	1.64	1.65
Swedish Orphan Biovitrum AB (publ)	2,763,768	1,433,036	1.54	1.07
CBNY-Norges Bank	3,756,246	0	1.38	1.39
JPM Chase NA	3,215,772	0	1.18	1.19
State Street Bank & Trust OMNIBUS	3,039,788	0	1.12	1.12
Total 15 largest shareholders	193,557,790	1,433,036	71.72	71.59
Other	76,831,980		28.28	28.41
TOTAL	270,389,770	1,433,036	100	100

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

FOR MORE INFORMATION ABOUT SOBI'S AMERICAN DEPOSITARY RECEIPT (ADR), CONTACT:

US Depositary
BNY Mellon Shareowner services
P.O. Box 30170, College Station, TX 77842-3170, USA
Email: shrrelations@cpushareownerservices.com
Toll free in the US: +1 888 269 23 77
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 – Group development

Income statement, SEK M	2011	2012[1]	2013	2014[1]	2015
Total revenues	1,911	1,923	2,177	2,607	3,228
Gross profit	975	1,040	1,284	1,548	2,007
EBITDA	131	400	241	–12	465
EBITA	50	367	211	–43	433
EBIT	–319	–55	–67	–325	146
Profit/loss for the year	18	–101	–93	–268	68
Capital, SEK M					
Total assets	6,700	6,307	6,519	6,371	8,311[2]
Capital employed	6,016	5,748	5,865	5,613	5,823
Equity	4,963	4,838	4,769	4,523	4,689
Cash and cash equivalents	219	457	445	519	904
Net cash (–)/debt (+)	481	143	352	298	–82
Cash flow, SEK M					
Cash flow from operating activities before changes in working capital	118	368	166	299	411
Cash flow from operating activities	103	406	185	234	507
Cash flow from investing activities	–44	–67	–405	–184	–143
Cash flow from financing activities	122	–100	207	20	22
Change in cash and cash equivalents	181	238	–13	70	386
Key figures, %					
Gross margin	51	54	59	59	62
Return on capital employed	–5.3	–0.9	–1.1	–5.8	2.5
Return on equity	0.4	–2.1	–2.0	–5.9	1.5
Debt/equity ratio	74	77	73	71	56[2]
Equity ratio	35	30	37	41	77[2]
Share ratio, SEK					
Earnings/loss per share	0.07	–0.38	–0.35	–1.01	0.26
Equity per share	18.7	18.2	17.6	16.7	17.3
Dividend	0	0	0	0	0
Cash flow per share	0.7	0.9	0.0	0.3	1.4
Cash flow from operating activities per share	0.4	1.5	0.7	0.9	1.9

[1] The figures for 2014 include write-downs of SEK 325 M for Kiobrina and SEK 25 M for Multiferon. The figures for 2012 include revenues of SEK 308 M from the sale of co-promotion rights to Pfizer.
[2] The change relates to the Elocta approval in the EU.

With our achievements in 2015 we have set a solid foundation for the future.

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Continued strong trend for Sobi

The strong trend for Sobi continued in 2015. Sales rose 24 per cent, market positions were strengthened and cash flow reached a new record high despite extensive investment and build-up of the sales, marketing and medical organisations in preparation for the launch of Elocta®.

Over the past five years, Sobi has evolved from a company with weak finances and non-existent sales growth, to a leading and fast-growing international player in rare diseases. Sales have grown from SEK 1.9 billion in 2011 to SEK 3.2 billion in 2015, the gross margin has strengthened to 62 per cent, and net debt of SEK 1,163 million in early 2011 was converted to net cash of SEK 82 million by year-end. I believe that this trend is due to determined efforts. After an initial consolidation, we developed our core business, expanded into new markets, and gradually strengthened cash flow to create resources for investments in our development projects.

A strong 2015

We can look back on a year of growth in all parts of our commercial operations. Revenues for Orfadin® rose a full 45 per cent to SEK 796 million with growth in all markets. Sales of Kineret® also rose, up 32 per cent to SEK 805 million, driven by indication expansion (CAPS and NOMID). Revenues for Partner Products increased 7 per cent, with continued growth for Cometriq®, Kepivance® and Xiapex®. Year-on-year sales for ReFacto also increased, up 7 per cent to SEK 660 million. Furthermore we intensified our efforts with the development portfolio during the year to increase the proportion of early-stage projects. Elocta was granted marketing authorisation at the end of the year as expected, and the launch commenced in the first markets in Europe in early 2016. We have built up an extensive haemophilia organisation in preparation for the launch, which has also meant that the number of employees at Sobi has increased by nearly 20 per cent in one year. In October, we adjusted our forecast upwards for sales, gross margin and operating profit in line with the positive trend in 2015, but this was also surpassed after the strong finish to the year.

Accounting changes 2016

Due to the ongoing launch of Elocta and the planned launch of Alprolix® during 2016, the cross royalty structure will change between Sobi and Biogen. Following the first commercial sales of Elocta and Alprolix, respectively, Sobi will in essence receive a royalty rate of 12 per cent from Biogen compared to the previous 2 per cent. At the same time, Sobi will pay Biogen a royalty rate of 12 per cent on Sobi's sales. Sobi will also assume a liability to Biogen for some of the development expenses. These will partly be included in the cross-royalty payments.

Sobi will also recognise revenue of 10 per cent of Biogen's sales of Elocta and Alprolix retroactively in 2016, since Sobi's royalty rate on Biogen's sales was only 2 per cent prior to the launch. This revenue will be recorded retroactively in 2016 and will reduce Sobi's liability to Biogen. The retroactive portion will have no impact on cash flow. (For full details, please refer to Note 19 of this report.)

I believe that with the anticipated incomes from the launch of our haemophilia products, continued market potential for our proprietary products and a growing partner and research portfolio, we have the tools needed to continue this positive development.

Mats-Olof Wallin, CFO

"A gradually strengthened cash flow created resources for investments."

Directors' Report

Highlights 2015

Financial highlights

- Total revenues were SEK 3,228 M (2,607), an increase of 24 per cent.
- Revenues from Key Therapeutic Areas amounted to SEK 1,841 M (1,307), an increase of 41 per cent.
- The gross margin was 62 per cent (59).
- EBITA was SEK 433 M (–43). 2014 includes impairment losses related to the Kiobrina® development project and the product Multiferon® (of SEK 325 M and SEK 25 M respectively).
- Profit for the year totalled SEK 68 M (–268), corresponding to earnings per share of SEK 0.26 (–1.01).
- Cash flow from operating activities amounted to SEK 507 M (234).

Business highlights

- Application for marketing authorisation in Europe submitted for Alprolix.
- Received marketing authorisation for Elocta in Europe.
- New formulations of Orfadin approved in Europe; oral suspension and 20 mg capsule.
- Received marketing authorisation in Australia for Kineret for the treatment of SJIA.
- Xiapex approved for the treatment of Peyronie's Disease in EU.
- Extended and restructured distribution agreement with Exelixis for Cometriq.
- Subsidiary established in Canada.

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 specialty and rare disease pharmaceuticals in Europe, the Middle East, North Africa and Russia in collaboration with various partner companies.

In 2015, the company generated revenues through:

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

Operating revenues

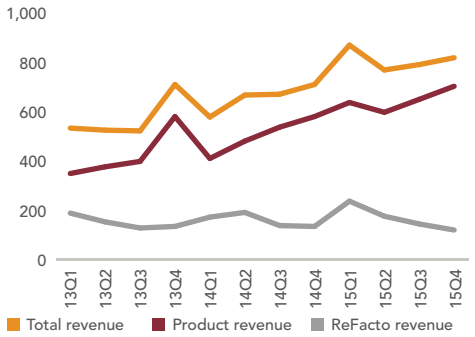
In 2015, revenues increased to SEK 3,228 M (2,607). Product sales in Key Therapeutic Areas increased 41 per cent, and for Partner Products with 7 per cent. Revenues relating to ReFacto also rose 7 per cent.

Key figures

SEK M	2015	2014
Operating revenues	3,228	2,607
Gross profit	2,007	1,548
Gross margin, %	62	59
EBITA	433	–43
EBIT	146	–325
Net profit/loss for the period	68	–268
Earnings/loss per share, SEK	0.26	–1.01

See page 59 for a five-year summary of revenues, costs and results.

Revenue trend, SEK M



Revenue by business line

SEK M	2015	2014
Key Therapeutic Areas	1,841	1,307
Partner Products	727	682
ReFacto	660	618
Total revenues	3,228	2,607

Gross margin
The gross margin was 62 per cent (59). The improvement was mainly due to a favourable product mix and positive currency effects.

Expenses
Operating expenses declined to SEK 1,876 M (1,913). The decline was due to impairment losses in 2014 of SEK 350 M related to Kiobrina and Multiferon. Costs related to the anticipated launches of the haemophilia programmes increased however. Operating expenses also reflect costs of SEK 45 M (51) attributable to the long-term incentive programmes. Cash flow was not affected by these programmes.

Sales and administrative expenses increased to SEK 1,344 M (1,032). The increase is partly due to the recruitments made to strengthen the haemophilia organisation, and increased investments in North America. Expenses for the year were also affected by unfavourable exchange rates of about 6 per cent compared with 2014, driven by the EUR and USD. Research and development expenses increased to SEK 513 M (501). Expenses in the haemophilia franchise increased in 2015, but were partly offset by lower costs for the discontinued Kiobrina and SOBI002 programmes.

Other operating revenues and expenses amounted to an expense of SEK –3 M (–341). The figures for 2014 included non-recurring impairment losses of SEK 350 M related to Kiobrina, and to Multiferon. Expenses for 2015 pertain to exchange-rate losses.

Profit/loss
EBITA amounted to SEK 433 M (–43). Amortisation of intangible assets amounted to SEK 287 M (282). EBIT was SEK 146 M (–325).

Net financial items
In 2015, net financial items amounted to SEK –58 M (6). Financial income of SEK 4 M (67) mainly consisted of interest income, while financial income in 2014 was largely attributable to exchange-rate gains. Financial expenses of SEK 63 M (61) mainly consisted of interest expenses.

Taxes
During the year, the tax expense amounted to SEK –22 M (–19) and deferred tax to SEK 3 M (70). Total tax recognised for the Group was SEK –19 M (51), due to the higher earnings.

Other comprehensive income
Other comprehensive income totalled SEK 58 M (5), net, and consisted of cash flow hedges attributable to interest payments from the bond loan, a hedge with the USD loan from Biogen against future inflows in USD, and revaluation of the pension commitments.

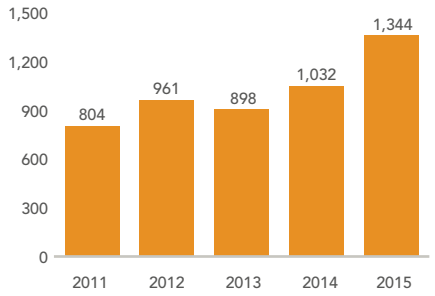
Cash flow and investments
Cash flow from operating activities was SEK 507 M (234). Cash flow from investing activities amounted to SEK –143 M (–184). The exercised opt-in right for Alprolix in Sobi's territory accounted for the largest investment during the year and amounted to SEK 82 M. In 2015, net investment in Elocta totalled SEK 1,704 M, but had no effect on cash flow (see Note 19 for more information).

A decrease in working capital impacted cash flow positively with SEK 96 M (–66). The decrease was primarily due to higher current liabilities, mainly personnel costs, and greater discounts, mainly for products in the US.

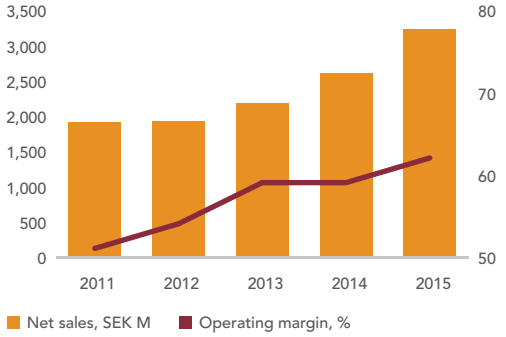
Financial position
At 31 December 2015, cash and cash equivalents and current investments amounted to SEK 904 M (519). Sobi has a bond loan, with a nominal amount of SEK 800 M. The bond loan has a variable interest rate of 3-month STIBOR +500 basis points, which has been converted to an average fixed rate of 6.6 per cent through interest-rate swaps. The interest-rate swaps matured in 2015 and the interest rate on the bond was 4.6 per cent on the balance-sheet date. The bond loan is listed on Nasdaq Stockholm and matures 26 June 2017.

At 31 December 2015, net cash was SEK 82 M, compared to a net debt of SEK 298 M at 31 December 2014. The Elocta debt is a non-interest-bearing liability and therefore not included in net cash/debt.

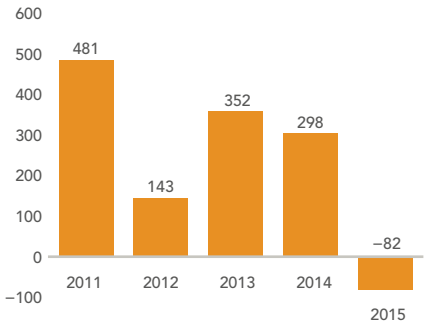
Sales and administrative expenses, SEK M



Net sales (SEK M) and operating margin (%)



Net cash (–)/debt (+), SEK M



Equity

At 31 December 2015, consolidated equity totalled SEK 4,689 M (4,523). In addition to profit for the year, the increase is attributable to sales of own shares and the cost of share programmes.

Sales

Key Therapeutic Areas

Sales in Sobi's Key Therapeutic Areas – Inflammation, Genetics & Metabolism and Haemophilia, with the products Kineret, Orfadin, Ammonaps®, Ammonul®, Ravicti®, Eloctate and Alprolix, rose 41 per cent to SEK 1,841 M (1,306). The increase at constant exchange rates (particularly the EUR and USD) was 26 per cent.

Sales of Kineret rose 32 per cent to SEK 805 M (609), driven by growth in most markets and the continued launch of CAPS and NOMID indications.

Sales of Orfadin rose 45 per cent to SEK 796 M (548). The year was characterised by continued strong growth in the US, Europe and South America. On 1 January 2015, Sobi also assumed distribution responsibility for Orfadin in Latin America.

In 2015, Sobi received royalties on Biogen's sales of Eloctate and Alprolix. Revenues for the full-year amounted to SEK 96 M (31), corresponding to royalties of 2 per cent on sales of Eloctate and Alprolix, respectively, in Biogen's territories.

Partner Products

Total revenues for Partner Products amounted to SEK 727 M (682), an increase of 7 per cent. Significant events during the year included an extension and restructuring of the agreement with Exelixis pertaining to Comtriq, and authorisation in the EU of Xiapex for the treatment of Peyronie's Disease. Growth in the portfolio was mainly driven by Cometriq, Kepivance and Xiapex.

For the three largest products, sales increased as follows: Xiapex rose by more than 9 per cent to SEK 138 M (126), Kepivance rose 12 per cent to SEK 99 (89) and Cometriq rose more then 100 per cent to SEK 76 M (31).

ReFacto

Total revenues for ReFacto from manufacturing and royalties amounted to SEK 660 M (618), whereof manufacturing revenues rose 8 per cent to SEK 504 M (466) and royalty revenue increased 3 per cent to SEK 156 M (152). In February 2012, Sobi and Pfizer extended their supply agreement for ReFacto AF/Xyntha until 31 December 2020, with an option to renew. The royalty agreement for ReFacto is valid until mid-2016 for all countries except the US, and until mid 2017 in the US.

Parent Company

The Parent Company's business objective is to develop, register, distribute and market medications for rare diseases. In 2015, Parent Company revenues totalled SEK 2,750 M (2,328). Operating profit was SEK 309 M (197). Profit for the year totalled SEK 218 M (-121). The figures for 2014 include an impairment loss of SEK 177 M on the holding in Arexis relating to Kiobrina, and a Group contribution of SEK 159 M. At 31 December 2015, cash and cash equivalents amounted to SEK 750 M (392). Equity amounted to SEK 5,832 M (5,510) at 31 December 2015, whereby the difference is attributable to the results during the year, costs linked to the company's share programme, sales of own shares and hedge accounting.

Five-year summary

SEK M	2015	2014	2013	2012	2011
Operating revenues	3,228	2,607	2,177	1,923	1,911
Cost of goods and services sold	–1,221	–1,059	–893	–883	–936
Research and development expenses	–513	–501	–456	–402	–556
EBIT	146	–325	–67	–55	–319
Financial items, net	58	6	–57	–51	–52
Profit/loss for the year	68	–268	–93	–101	18
Earnings/loss per share, SEK	0.26	–1.01	–0.35	–0.38	0.07
Earnings/loss per share after dilution, SEK	0.26	–1.01	–0.35	–0.38	0.07
Number of A shares, in thousands	270,390	270,390	270,390	265,227	265,227
Equity ratio	56%	71%	73%	77%	74%

Revenues by product category

SEK M	2015	2014
Inflammation: Kineret	805	609
Genetics & Metabolism: Orfadin	796	548
Genetics & Metabolism: Other	144	119
Haemophilia	96	31
Key Therapeutic Areas	**1,841**	**1,307**
Partner Products	**727**	**682**
Manufacturing revenues	504	466
Royalty revenues	156	152
ReFacto	**660**	**618**
Total revenues	**3,228**	**2,607**

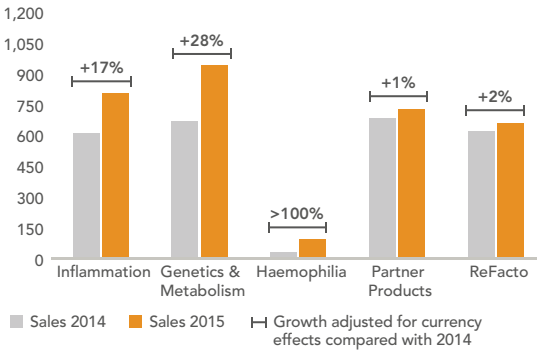
Product sales by region

(Excluding ReFacto manufacturing and royalty revenues)

SEK M	2015	2014	Change
Europe	1,391	1,196	16%
MENAR[1]	231	181	28%
North America	861	579	49%
RoW[2]	85	33	157%
Total	2,568	1,989	29%

[1] Middle East, North Africa and Russia
[2] Rest of the world

Revenues by product category, SEK M



Products per business line

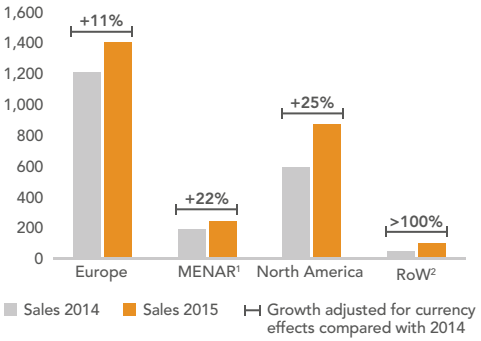
Key Therapeutic Areas	Partner Products	ReFacto
Inflammation	Aloxi®	Manufacturing
Kineret	Betapred	Royalty
Genetics & Metabolism	ChondroCelect®	
Orfadin	Cometriq	
Ammonaps	Ferriprox®	
Ammonul	Kepivance	
Ravicti	Ruconest®	
Haemophilia	PharmaSwiss portfolio	
Elocta	Xiapex	
Alprolix (from Biogen)	Yondelis®	
Eloctate (from Biogen)	Other	

Development

Sobi's development projects include two pipeline programmes, in various stages, in haemophilia, Alprolix and XTEN. In 2015, Sobi renewed its pre-clinical development projects with a number of new programmes, and projects focused on life-cycle management of existing products.

A new programme in the pre-clinical phase was presented in 2015, with the aim of developing a modified sulfamidase, SOBI003, for the treatment of the lysosomal storage disease MPSIIIA.

Product sales by region (excluding ReFacto manufacturing and royalty revenues), SEK M



[1] Middle East, North Africa and Russia
[2] Rest of the World

In 2015, the phase 1 trial of SOBI002 was suspended due to the observation of transient side effects. Subsequently, a new, more stable candidate molecule in the same area was presented.

Positive results from Kids B-LONG

Sobi and Biogen presented positive results from the phase 3 Kids B-LONG trial. The trial evaluated the safety, efficacy and pharmacokinetics of Alprolix.

Marketing authorisation application for Alprolix in Europe

Biogen submitted a marketing authorisation application to the European Medicines Agency (EMA) for Alprolix, which was subsequently validated.

New data regarding Elocta presented

Interim results from ASPIRE, an open-label phase 3 extension study, were presented in collaboration with Biogen and showed that people with severe haemophilia A on extended-interval prophylaxis regimens with Elocta experienced low bleeding rates. Most participants were able to maintain protection against bleeding episodes with Elocta consumption consistent with that observed in the A-LONG and Kids A-LONG studies. In addition, data from ASPIRE also showed that Elocta may help to control target joint bleeds in people with haemophilia A.

New data regarding Alprolix presented

Interim results of the B-YOND, an open-label phase 3 extension study, were presented in collaboration with Biogen during the year supporting the safety and efficacy of Alprolix for long-term treatment for children and adults with severe haemophilia B. Participants of the study maintained low bleeding rates with prophylactic injections every one to two weeks. Furthermore, data from the pivotal phase 3 study B-LONG, were presented and showed that Alprolix may help to control target joint bleeds in people with haemophilia B.

Marketing authorisation for Elocta in Europe
Sobi and Biogen received a positive opinion on the marketing authorisation for Elocta from the European Medicines Agency's Committee for Medicinal Products for Human USE (CHMP) followed by an approval by the European Commission for the treatment of haemophilia A in all 28 EU member states, plus Iceland, Liechtenstein and Norway. Elocta thereby became the first haemophilia A treatment in the EU to provide prolonged protection against bleeding episodes with prophylactic injections every three to five days.

New formulations of Orfadin approved
The European Commission approved the new Orfadin oral suspension formulation and 20 mg capsule for the treatment of hereditary tyrosinaemia type 1 (HT-1).

The US Food and Drug Administration (FDA) has commenced an evaluation of Orfadin oral suspension.

Marketing authorisation of Kineret for SJIA
Sobi received marketing authorisation approval for Kineret in Australia for the treatment of SJIA, a rare form of chronic arthritis in children.

Kineret granted orphan drug designation for treatment of Still's disease
The FDA approved Sobi's application for orphan drug designation of Kineret for the treatment of Still's disease.

Xiapex approved for Peyronie's Disease
The European Commission approved Xiapex for the treatment of adult men with Peyronie's Disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of treatment. The Swiss Agency for Therapeutic Products, Swissmedic, also approved Xiapex for the treatment of adult men with Peyronie's Disease.

Xiapex approved for the treatment of two Dupuytren's contracture cords
The European Medicines Agency (EMA) approved Xiapex for the concurrent treatment of two Dupuytren's contracture cords.

Other information

Canadian subsidiary
A new subsidiary, Swedish Orphan Biovitrum (SOBI) Canada, Inc, was established in Canada during the year.

Change in management
Lars Dreiøe was appointed Senior Vice President, Chief Quality & Compliance Officer (CQCO) in December 2015. Lars Dreiøe was most recently at the global pharmaceutical company ALK in Denmark, where he served as the international Head of Quality. Lars brings 20 years of experience in the biotech and pharmaceutical industry in the fields of quality, manufacturing, product safety and regulatory affairs. He assumed his new position at Sobi in January 2016.

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

Sobi's production facility in Stockholm holds a permit for hazardous operations for facilities that produce organic substances through industrial-scale biological reactions. Compliance with permit conditions is disclosed annually in an environmental report to the local supervisory authority. In Solna the company has facilities that are subject to a reporting obligation for the professional production, through chemical or biological reactions, of organic or inorganic substances in trial, pilot or laboratory scale or other non-industrial scale production. The conditions for this permit mainly relate to water emissions and include a requirement to adjust the pH of the process water. In 2015, 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 holds a permit to work with radioactive substances from the Swedish Radiation Safety Authority. In 2015, no such activities took place. 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 amounted to SEK 149,150,658, distributed between 271,822,806 shares, with a par value per share of about SEK 0.55. On 31 December 2015, the total number of shares outstanding was 270,389,770 ordinary shares, which carry one vote per share, and 1,433,036 Class C shares, which carry 1/10 of a vote per share. On 31 December 2015, the single largest shareholder in Sobi was Investor AB, with a total of 107,594,165 shares, representing 39.77 per cent of the voting rights and 39.58 per cent of the capital.

Share repurchases
At the Annual General Meeting on 30 June 2015, Sobi´s Board of Directors was authorised to issue and repurchase Class C shares for hedging of 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 2015, Sobi held 2,763,768 ordinary shares and all 1,433,036 Class C shares in treasury. The total number of shares in the company, the number of different classes of shares and the rights the shares gives the company can be read more in depth in the share section, on page 56.

Sobi's values

Sobi promotes a good working environment. Sobi strives to comply with all health and safety-related laws and regulations 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 creating innovation and driving for results in teams - within and across functions, and with external partners.

Accountable – I take ownership for my results and maintain focus to consistently deliver on my commitments.

Respectful – I relate to my colleagues and customers based on credibility and trust, supporting the integrity of my relationships with honest feedback.

Engaged – I make a positive impact on our results by bringing all of my energy, by sharing my experience, and by taking the initiative to make the most of our opportunities.

Compliance with the company's values is evaluated every year in Sobi's performance management process. 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 2015, the average number of employees was 672 (589), of whom 406 (389) were based in Sweden. Salaries and other remuneration amounted to SEK 678 M (523), of which the Parent Company accounted for SEK 344 M (297).

Of the total number of employees in 2015, 58 per cent were women and 42 per cent men. All employees are treated equally, and are offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

Guidelines and remuneration 2016

The guidelines for remuneration to senior executives that will be proposed to Sobi's Annual General Meeting 2016, will be published on www.sobi.com in late April/May 2016. For current guidelines and remuneration in 2015 valid until the AGM 2016, see Note 12.

Events after the balance-sheet date

Commercial launch of Elocta in the first European countries

Sobi has commenced the commercial launch of Elocta in the first European countries. Following the first commercial sales in January, Sobi received a one-time credit of SEK 322 M, corresponding to 10 per cent of Biogen's total sales of Eloctate in its territories.

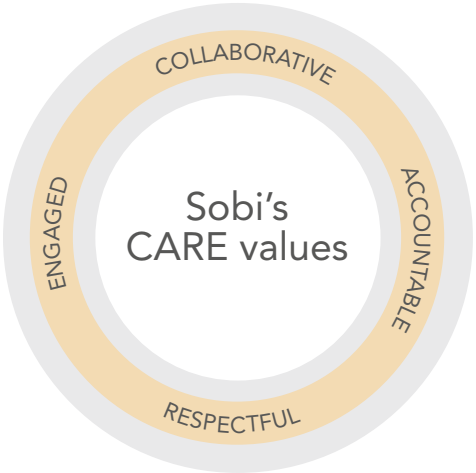
Sobi received commercialisation rights to three products from PharmaSwiss

Sobi has received commercialisation rights from the Swiss company PharmaSwiss to distribute Relistor®, Deflux® and Solesta® in major parts of Europe, including Western Europe, the Czech Republic, Slovakia and Hungary, as well as Russia for Relistor.

European patent granted for Orfadin oral suspension

The European Patent Office (EPO) decided to grant a European patent for the Orfadin oral suspension formulation, which was approved by the European Commission in 2015 for the treatment of hereditary tyrosinaemia type 1 (HT-1).

The CARE model



Chief Medical Officer Birgitte Volck to leave Sobi

Sobi announced that Birgitte Volck, Senior Vice President Development and Chief Medical Officer (CMO) will be leaving Sobi in 2016.

Clinical pipeline programmes for acute gout and Still's disease, and a new patent for a new formulation of Kineret

Sobi announced the intent to initiate two clinical pipeline programmes for Kineret, with the goal of evaluating two new potential indications: acute gout and Still's disease.

Sobi was also granted a patent for a citrate-free formulation of Kineret in the US, which extends until 2032. The corresponding European patent application is complete, and a patent may be granted in 2016.

Bo Jesper Hansen to step down as Chairman of the Board of Sobi

Bo Jesper Hansen informed Sobi's Nomination Committee that he will not be standing for re-election at the 2016 AGM. Bo Jesper Hansen has served as Chairman since the merger of Biovitrum and Swedish Orphan International in 2010. The Nomination Committee intends to propose that shareholders elect Håkan Björklund, former CEO of Nycomed who currently serves as an Industry Executive at Avista Capital Partners, as the new Chairman of Sobi.

Sobi and Biogen received CHMP recommendation for Alprolix for the treatment of haemophilia B

The CHMP recommended that Alprolix be granted marketing authorisation in EU. If approved, Alprolix will be one of the first therapies in the EU to offer people with haemophilia B prolonged protection against bleeding episodes with prophylactic injections.

Adjusted purchase price for Elocta

The anticipated purchase price to Biogen for Elocta has been estimated to be USD 5 M lower than previously reported. Total sum is now USD 210 M. The final purchase price will be determined in Q2 2016 and is expected to be USD 210 M.

The COMP recommended that Alprolix should maintain orphan designation

The Committee for Orphan Medicinal Products (COMP) of EMA recommended the European Commission to maintain the orphan designation for Alprolix.

Outlook for 2015

At the publication of the Q3 results in October 2015, Sobi raised its outlook for the full-year expecting revenues of SEK 3,000–3,200 M, a gross margin of 59–61 per cent, and full-year EBITA of SEK 350–400 M.

The outlook for 2015 excluded revenues from the potential launch of Elocta in Europe. The outcome for the full year is shown in the table below.

Outcome and outlook

2015	Outcome	Outlook
Revenues	3,228	3,000–3,200
Gross margin, %	62	59–61
EBITA	433	350–400

Outlook for 2016[1]

For the full-year 2016, Sobi expects revenues of between SEK 4,800 and 5,000 M. Revenues will include one time credits for Elocta of SEK 300-325 M, and for Alprolix SEK 300-325 M, which will not impact cash.

Gross margin is expected to be in the range of 68–70 per cent. Sobi will continue to invest in the launches of Elocta and Alprolix and will also take on incremental cost of SEK 250–300 M, reflecting its 50 per cent share of Biogen's ongoing development costs for the products. Sobi will assume these costs when it becomes marketing authorisation holder for Elocta expected in Q1 2016; and for Alprolix in the second half of the year. These incremental costs are included in this outlook.

EBITA for the full-year is expected to be in the range of SEK 1,200–1,300 M.

[1] The outlook was published on 29 February 2016.

Proposed appropriation of profit

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

SEK	
Share premium reserve	4,156,270,871
Profit carried forward	508,627,754
Profit/loss for the year	217,539,623
Total	**4,882,438,248**

The Board of Directors proposes that no dividend be paid for 2015.

The Board proposes that the funds at their disposal, SEK 4,882,438,248, be carried forward.

Risk Management

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

The Sobi Risk Management & Compliance Committee is responsible on behalf of management to establish a common organisational approach to risk management and to ensure consistent and efficient risk identification, assessment and control. The Committee has regular meetings throughout the year and includes the heads of the major functions and ad hoc members on an agenda-driven basis.

The Chairman of the Committee is Sobi's General Counsel and the Compliance manager is the Secretary. Reports are presented on a quarterly basis to the Executive Leadership Team, to the Audit committee and a review of the work is presented quarterly to the Board of Directors. The risk management processes follow the established Committee of Sponsoring Organizations of the Treadway Commission – Enterprise Risk Management Integrated Framework (COSO – ERM), which forms the foundation for Sobi's Risk Management Policy.

Sobi also has a Crisis Management Policy and a Crisis Management Team in place, with the objective of developing effective management and preventative measures in the event of a crisis. These measures are an important part of the company's efforts to optimally handle any potential crisis. The Crisis Management Team meets on a regular basis for planning and training purposes.

It is Sobi's policy to encourage and support employees, who have a good faith belief that any of Sobi's management or other employees are in violation of the Code of Conduct & Ethics, any law, or any company policy, to report the possible violation and also to prohibit any retaliatory action against them for making a good faith report. A third party report hotline is in place to support anonymous reporting.

Objective and definitions

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

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

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

Key risk areas

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

Development risks

Bringing new drugs to the market

Sobi currently has a number of projects in clinical development and several projects in preclinical development. To develop a new biopharmaceutical product up to and including market launch is a capital-intensive, complex and risky process. The likelihood of successfully reaching the market increases as the project advances in the development process, however, the risks remain substantial even up to and including phase 3 clinical development, while the costs increase at a growing pace as the project progresses into the later clinical phases.

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

Preclinical and clinical development is a time-consuming and costly process that is affected by numerous factors, including factors beyond the company's control such as changes in requirements from authorities. During clinical development it may emerge that the biopharmaceutical candidates are not sufficiently effective or they may prove to have undesirable or unintended side effects, toxicities or other properties. This may disrupt, delay or stop clinical development and prevent or limit the commercial application of the candidate drug.

Sobi's innovation model is used to determine a project's attractiveness and risk profile.

Obtaining and maintaining regulatory approvals for new products

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

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

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

Through Sobi's integrated and cross functional approach and collaboration with external stakeholders, we aim to forsee and take into consideration the expectations of the market, the regulatory bodies, budget holders and medical community upon a potential marketing approval, with the objective of ensuring timely and sustainable access as well as the future requirements and follow-up.

Collaborations and partnerships

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

Intellectual property rights and patent risks

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

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

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

Manufacturing of biopharmaceuticals and quality

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

The manufacture of Sobi's products requires precise and high-quality manufacturing processes and controls, therefore the company must ensure that all manufacturing processes and methods and all equipment meet the Good Manufacturing Practice (GMP) requirements.

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

Slight deviations in any part of the manufacturing process may result in delays or batch failure. GMP requirements regulate all aspects of the manufacturing of pharmaceuticals, including quality control and quality assurance, manufacturing processes and documentation. Furthermore, Sobi must perform extensive audits of its distributors, contract laboratories and suppliers who are also covered by these requirements.

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

The company's research and development involves the controlled use of biological and hazardous materials and waste. The company is subject to laws and regulations controlling the use, manufacture, storage, handling and disposal of such materials and waste products.

External risks

Competiton

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

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

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

The market in which Sobi operates is increasingly price conscious. The increased cost of healthcare in many countries leads to governments and other budget holders becoming more aware of the costs. In most markets where Sobi is active, governments exercise a certain degree of control over the price of pharmaceuticals. This control and its effects vary from country to country, and various methods are being used on both the supply and the demand side to control pharmaceutical costs.

Sobi's success is dependant on if the company's products are covered by, and entitled to, reimbursement/payment through private or state payment systems within the healthcare sector. Legislation and regulatory proposals in various European countries and in the US include measures that could restrict or prevent payment for treatment with certain pharmaceuticals.

The use of pharmaceuticals may also be affected by guidelines, recommendations and studies published by authorities and organisations.

By identifying the relevant stakeholders at each stage of the patient journey, we aim to secure optimal outcomes for everyone, and development and availability can be sped up or new opportunities identified.

Product counterfeiting

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

Sobi's products have not yet been exposed to counterfeiting, however we are constantly vigilant and take part in the global serialisation effort that has been initiated by regulatory bodies globally. Sobi's distribution 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 competitiveness and profitability. At Sobi, the Risk- and Compliance Committee continuously oversees the development and implementation of the Sobi compliance programme, which aims to reduce the risk of non-compliance with regulatory and legal requirements. Key components in the compliance programme include risk identification, promotion of clear messages, establishing clear policies and processes and training in addition to continuous follow-up.

Financial risks

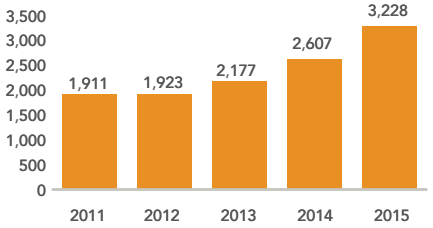
The company's business is exposed to currency risk. The majority of the company's expenses are incurred in SEK, while a significant proportion of its revenues are in other currencies. As a result of the company's international expansion, a reduction in the exchange rate of US dollars and the Euro, in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

Consolidated statement of comprehensive income

SEK 000s	Note	2015	2014
	1–4		
Operating revenues	5–6	3,227,867	2,606,976
Cost of goods and services sold		–1,220,968	–1,059,176
Gross profit		**2,006,899**	**1,547,800**
Sales and administration expenses	13	–1,344,340	–1,031,489
Research and development expenses		–513,370	–500,486
Other operating revenues	8	14,783	39,897
Other operating expenses	9	–17,929	–380,697
Operating profit/loss	7, 10, 12, 14, 17, 19, 20, 32	**146,043**	**–324,975**
Financial income	15	4,326	66,941
Financial expenses	16	–62,679	–60,531
Financial items, net		**–58,353**	**6,410**
Profit/loss before tax		**87,690**	**–318,565**
Income tax for the year	18	–19,297	50,733
Profit/loss for the year		**68,393**	**–267,832**
Other comprehensive income[1]			
Items that will not be reclassified to profit or loss			
Actuarial gains/losses on defined-benefit plan		–3,340	812
Items that may be subsequently reclassified to profit or loss			
Translation differences		–1,505	3,783
Cash flow hedges		74 736	679
Tax effect of cash flow hedges		–16,442	–151
Other comprehensive income		**53,449**	**5,123**
Comprehensive income for the year		**121,842**	**–262,709**
Earnings/loss per share (SEK)[2]		0.26	–1.01
Earnings/loss per share after dilution (SEK)[2]		0.26	–1.01
Number of shares (ordinary)		270,389,770	270,389,770
Average number of shares		267,278,339	266,158,798
Number of Class C shares held in treasury		1,433,036	396,180
Number of ordinary shares held in treasury		2,763,768	3,674,140
Number of shares after dilution		270,389,770	270,389,770
Average number of shares after dilution		267,278,339	266,158,798

[1] In accordance with the revised version of IAS 1, all changes in equity other than those resulting from transactions with owners are to be presented in the consolidated statement of comprehensive income. Translation differences are entirely related to shares in foreign subsidiaries.
[2] For calculation, refer to Consilidated statement of changes in equity.

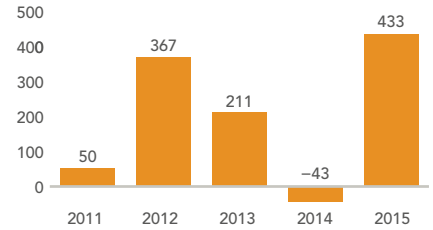
Operating revenues, SEK M



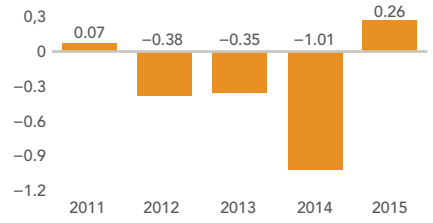
Operating revenues

Revenues for the full-year amounted to SEK 3,228 M (2,607), an increase of 24 per cent. Adjusted for currency effects, the increase was 14 per cent.

EBITA, SEK M



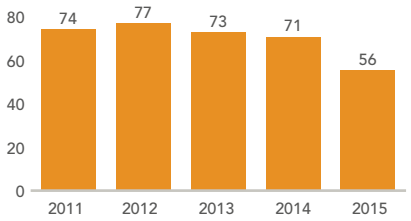
Earnings/share, SEK



Consolidated balance sheet

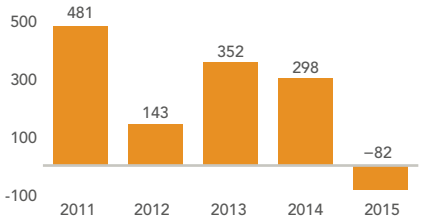
SEK 000s	Note	31 Dec 2015	31 Dec 2014
ASSETS	1–4		
Fixed assets			
Intangible fixed assets	19	5,787,036	4,247,488
Tangible fixed assets	20	108,506	115,229
Financial assets	22	1,791	2,862
Deferred tax assets	23	97,219	69,953
Total fixed assets		**5,994,552**	**4,435,532**
Current assets			
Inventories	24	775,854	763,935
Accounts receivable	25, 28	451,229	480,025
Other receivables	25	67,576	61,850
Prepaid expenses and accrued income	26	117,847	110,255
Cash and cash equivalents	27, 28	903,660	519,147
Total current assets		**2,316,166**	**1,935,212**
TOTAL ASSETS		**8,310,718**	**6,370,744**

Debt/Equity ratio, %



The reduction is due to the approval of Elocta

Net cash (-) / debt (+), SEK M



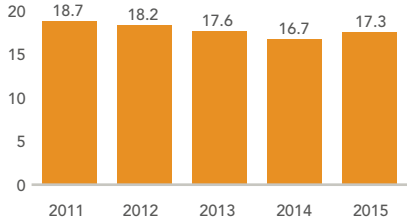
SEK 000s	Note	31 Dec 2015	31 Dec 2014
EQUITY AND LIABILITIES			
Equity			
Share capital		149,150	148,580
Other contributed capital		4,928,765	4,883,930
Reserves		2,461	–50,785
Profit/loss carried forward		–459,425	–191,023
Profit/loss for the year		68,393	–267,832
Equity attributable to owners of the Parent		**4,689,344**	**4,522,870**
Liabilities			
Non-current liabilities			
Deferred tax liabilities	23	311,892	272,164
Bond loan	28, 29	795,158	791,775
Other liabilities	28, 30	1,184,646	24,036
Provision for pension commitments	32, 33	9,576	12,915
Total non-current liabilities		**2,301,272**	**1,100,890**
Current liabilities			
Accounts payable	28	183,193	235,972
Tax liabilities		12,197	10,913
Other liabilities	28, 31	574,844	48,611
Accrued expenses and deferred income	34	549,868	451,488
Total current liabilities		**1,320,102**	**746,984**
TOTAL EQUITY AND LIABILITIES		**8,310,718**	**6,370,744**
Pledged assets and contingent liabilities – Group			
Pledged assets	35	200,000	200,000
Contingent liabilities		—	—

Consolidated statement of changes in equity

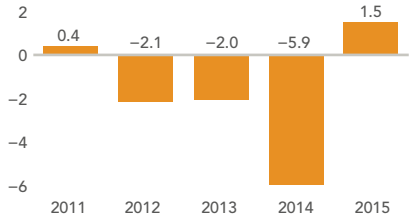
SEK 000s	Share capital	Other contrib-uted capital	Other reserves	Profit/loss carried forward	Total equity
Opening equity, 1 Jan. 2014	**148,362**	**4,867,595**	**–55,908**	**–190,805**	**4,769,244**
Comprehensive income					
Profit/loss for the year	—	—	—	–267,832	–267,832
Other comprehensive income					
Cash flow hedges	—	—	528	—	528
Actuarial loss/gain	—	—	812	—	812
Exchange-rate differences	—	—	3,783	—	3,783
Total comprehensive income	**—**	**—**	**5,123**	**–267,832**	**–262,709**
Transactions with shareholders					
Issue/repurchase of shares	218	—	—	–218	—
Share-based remuneration	—	16,335	—	—	16,335
Total transactions with shareholders	**218**	**16,335**	**—**	**–218**	**16,335**
Closing equity, 31 Dec. 2014	**148,580**	**4,883,930**	**–50,785**	**–458,855**	**4,522,870**
Opening equity, 1 Jan. 2015	**148,580**	**4,883,930**	**–50,785**	**–458,855**	**4,522,870**
Comprehensive income					
Profit/loss for the year	—	—	—	68,393	68,393
Other comprehensive income					
Cash flow hedges	—	—	58,294	—	58,294
Actuarial loss/gain	—	—	–3,340	—	–3,340
Exchange-rate differences	—	—	–1,505	—	–1,505
Total comprehensive income	**—**	**—**	**53,449**	**68,393**	**121,842**
Transactions with shareholders					
Issue/repurchase of shares	570	—	—	–570	—
Sale of ordinary shares	—	—	—	22,230	22,230
Share-based remuneration	—	22,605	—	—	22,605
Other	—	—	–203	—	–203
Total transactions with shareholders	**570**	**22,605**	**–203**	**21,660**	**44,632**
Closing equity, 31 Dec. 2015	**149,150**	**4,906,535**	**2,461**[1]	**–368,802**	**4,689,344**

[1] At 31 December 2015,other reserves consisted of translation differences of SEK –25,064 K (–23,559), pensions according to IAS 19 of SEK –26,462 K (–23,122), cash-flow hedges (see table on right) of SEK 54,190 K (–4,104), related to cash flow hedging of the liability to Biogen for Elocta, and other of SEK –203 K.

Equity/share, SEK M



Return on equity, %



Cash flow hedges, SEK 000s	2015	2014
Opening balance cash flow hedges	–4,104	–4,632
This year's value change hedging instrument	58,294	528
Recognised in income statement	—	—
Closing balance cash flow hedges	54,190	–4,104

At year-end, Sobi's share capital was SEK 149,150,658, distributed between 271,822,806 shares with a par value of approximately SEK 0.55. Issued shares are distributed between 270,389,770 ordinary shares and 1,433,036 Class C shares. The 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. The Class C shares are intended to be used for the hedging of commitments according to incentive programmes. The company held 2,763,768 ordinary shares in treasury at the balance-sheet date. The own shares item corresponds to 1.5 per cent of the total number of shares in the company.

Earnings per share
Earnings per share before dilution is 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 held in treasury.

	2015	2014
Earnings/loss attributable to Parent Company shareholders	68,393	–267,832
Weighted average number of ordinary shares outstanding (thousands)	267,278	266,159
Earnings per share before dilution (SEK per share)	0.26	–1.01

To calculate earnings/loss per share after dilution, the weighted average number of ordinary shares outstanding has been adjusted for the dilutive effect of all potential ordinary shares.

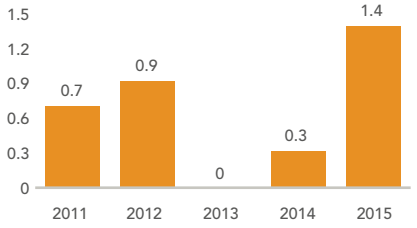
	2015	2014
Earnings/loss attributable to Parent Company shareholders	68,393	–267,832
Weighted average number of ordinary shares outstanding (thousands)	267,278	266,159
Earnings per share before dilution (SEK per share)	0.26	–1.01

Group cash flow statement

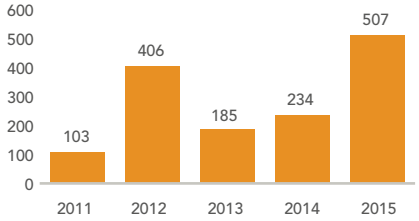
SEK 000s	2015	2014
Operating activities		
Profit/loss for the year	68,393	–267,832
Adjustments for non-cash items	342,843	567,230
Cash flow from operating activities before changes in working capital	**411,236**	**299,398**
Cash flow from changes in working capital		
Decrease (+) / Increase (–) in inventories	–11,919	–73,096
Decrease (+) / Increase (–) in operating receivables	14,588	–92,081
Increase (+) / Decrease (–) in operating liabilities	93,300	99,549
Cash flow from operating activities	**507,205**	**233,770**
Investing activities		
Acquisition of intangible fixed assets[1,2]	–118,728	–160,284
Acquisition of tangible fixed assets	–27,374	–22,858
Acquisition of financial assets	—	–445
Divestment of tangible fixed assets	2,250	84
Divestment of financial assets	435	—
Cash flow from investing activities	**–143,417**	**–183,503**
Financing activities		
Sale of shares	22,230	—
Raising of loan[3]	—	20,000
Cash flow from financing activities	**22,230**	**20,000**
Change in cash and cash equivalents	**386,018**	**70,267**
Cash and cash equivalents at 1 Jan.	**519,147**	**445,097**
Exchange-rate differences in cash flow	**–1,505**	**3,783**
Cash and cash equivalents at 31 Dec.	**903,660**	**519,147**

[1] The largest investment of the year is the opt-in for Alprolix, see Note 19.
[3] The Elocta debt is not included in the cash flow, since an actually payment was not done.
[3] Raising of loan pertains to a loan of SEK 20 M from AB Svensk Exportkredit.

Cash flow/share, SEK M



Cash flow from operations, SEK M



Supplemental disclosures to the consolidated cash flow statement

SEK 000s	2015	2014
Interest paid and received		
Interest received	4,342	3,257
Interest paid	56,206	55,778
Tax paid	21,081	15,067
Adjustments for non-cash items		
Depreciation and impairment of fixed assets, see Notes 19 and 20	318,987	581,548
Impairment of inventories	—	36,711
Pensions, see Note 32	–6,679	4,573
Cost of share programmes[1]	22,605	16,335
Deferred tax, see Note 23	12,462	–71,183
Other items	–4,532	–754
Total	**342,843**	**567,230**

[1] IFRS expense associated with the share programmes that is recognised in equity.

Parent Company income statement

SEK 000s	Note	2015	2014
	1–4		
Operating revenues	5–6	2,750,027	2,328,277
Cost of goods and services sold		–1,167,702	–973,783
Gross profit		**1,582,325**	**1,354,494**
Sales and administrative expenses	13	–813,653	–623,686
Research and development expenses		–472,285	–469,908
Other operating revenues	8	27,623	46,087
Other operating expenses	9	–14,757	–110,144
Operating profit/loss	7, 10, 12, 14, 17, 19, 20	**309,253**	**196,843**
Profit/loss from participations in Group companies	11	—	–174,663
Financial income	15	29,507	97,069
Financial expenses	16	–62,595	–60,678
Financial items, net		**–33,088**	**–138,272**
Group contributions		—	–158,844
Appropriations		—	**–158,844**
Profit/loss before tax		**276,165**	**–100,273**
Income tax for the year	18	–58,625	–20,452
Profit/loss for the year		**217,540**	**–120,725**

Parent Company statement of comprehensive income

SEK 000s	2015	2014
Profit/loss for the year	217,540	–120,725
Items that may be reclassified subsequently to profit or loss		
Cash flow hedges	74,736	679
Tax effect of cash flow hedges	–16,442	–151
Other comprehensive income	**58,294**	**528**
Comprehensive income for the year	**275,834**	**–120,197**

Parent Company balance sheet

SEK 000s	Note	31 Dec 2015	31 Dec 2014
ASSETS	1–4		
Fixed assets			
Intangible fixed assets	19		
Patent, licenses and product rights		2,656,257	933,023
Advance payments for intangible assets		82,400	73,503
Tangible fixed assets	20		
Land and buildings		3,927	4,261
Plant and machinery		41,824	42,537
Equipment, tools, fixtures and fittings		35,626	50,094
Construction in progress		10,902	7,130
Financial assets			
Participations in Group companies	21	3,882,138	3,882,069
Receivables from Group companies		16,604	16,329
Deferred tax assets	23	—	19,799
Other long-term financial receivables	22	21	621
Total fixed assets		**6,729,699**	**5,029,366**
Current assets			
Inventories	24		
Raw materials and consumables		14,991	10,745
Work-in-progress		316,001	401,587
Finished goods and goods for resale		342,563	267,935
Current receivable			
Accounts receivable	25	184,035	194,003
Other receivables	25	47,623	46,714
Receivables from Group companies		670,947	697,482
Prepaid expenses and accrued income	26	109,406	100,042
Cash and cash equivalents			
Cash and bank balances	27	750,398	392,424
Total current assets		**2,435,964**	**2,110,933**
TOTAL ASSETS		**9,165,663**	**7,140,299**

SEK 000s	Note	31 Dec 2015	31 Dec 2014
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		149,150	148,580
Statutory reserve		800,257	800,257
Total restricted equity		**949,407**	**948,837**
Non-restricted equity			
Share premium reserve		4,156,272	4,132,928
Profit/loss carried forward		508,627	549,398
Profit/loss for the year		217,540	–120,725
Total non-restricted equity		**4,882,439**	**4,561,601**
Total equity		**5,831,846**	**5,510,438**
Liabilities			
Non-current liabilities			
Deferred tax liabilities	23	58,568	—
Bond loan	29	795,158	791,775
Other liabilities	30	1,179,468	20,000
Total non-current liabilities		**2,033,194**	**811,775**
Current liabilities			
Accounts payable		165,093	200,659
Liabilities to Group companies		307,221	309,596
Tax liabilities		40	3,424
Other liabilities	31	545,207	30,867
Accrued expenses and deferred income	34	283,062	273,540
Total current liabilities		**1,300,623**	**818,086**
TOTAL EQUITY AND LIABILITIES		**9,165,663**	**7,140,299**
Pledged assets and contingent liabilities – Parent Company			
Pledged assets	35	206,000	206,000
Contingent liabilities		—	—

Parent Company statement of changes in equity

	Restricted equity		Non-restricted 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. 2014	**148,363**	**800,257**	**4,123,896**	**549,087**	**5,621,603**
Cash flow hedges	—	—	—	528	528
Issue/repurchase of shares	217	—	—	–217	—
Share-based remuneration of 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**	**5,510,438**
Opening equity, 1 Jan. 2015	**148,580**	**800,257**	**4,132,928**	**428,673**	**5,510,438**
Cash flow hedges	—	—	—	58,294	58,294
Issue/repurchase of shares	570	—	—	–570	—
Sales of own shares	—	—	—	22,230	22,230
Share-based remuneration of employees	—	—	23,344	—	23,344
Profit/loss for the year	—	—	—	217,540	217,540
Closing equity, 31 Dec. 2015	**149,150**	**800,257**	**4,156,272**	**726,167**[1]	**5,831,846**

At year-end, Sobi's share capital was SEK 149,150,658, distributed between 271,822,806 shares with a par value of approximately SEK 0.55. Issued shares are distributed between 270,389,770 ordinary shares and 1,433,036 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. The company held 2,763,768 ordinary shares in treasury at the balance-sheet date. The own shares item corresponds to 1.5 per cent of the total number of shares in the company.

[1] Cash flow hedges	2015	2014
Opening balance cash flow hedges	–4,104	–4,632
This year's value change hedging instrument	58,294	528
Recognised in income statement	—	—
Closing balance cash flow hedges	54,190	–4,104

Parent Company cash flow statement

SEK 000s	2015	2014
Operating activities		
Profit/loss for the year	217,540	–120,725
Adjustments for non-cash items	217,257	320,581
Cash flow from operating activities before changes in working capital	**434,797**	**199,856**
Cash flow from changes in working capital		
Decrease (+) / Increase (–) in inventories	6,713	–15,681
Decrease (+) / Increase (–) in operating receivables	25,768	–11,400
Increase (+) / Decrease (–) in operating liabilities	2,719	3,681
Cash flow from operating activities	**469,997**	**176,456**
Investing activities		
Acquisition of subsidiaries	–69	–1,036
Acquisition of intangible fixed assets[1, 2]	–118,644	–160,284
Acquisition of tangible fixed assets	–16,390	–16,215
Divestment of tangible fixed assets	850	—
Cash flow from investing activities	**–134,253**	**–177,535**
Financing activities		
Raising of loan[3]	—	20,000
Sale of shares	22,230	—
Cash flow from financing activities	**22,230**	**20,000**
Change in cash and cash equivalents	**357,974**	**18,921**
Cash and cash equivalents at 1 Jan.	**392,424**	**373,503**
Cash and cash equivalents at 31 Dec.	**750,398**	**392,424**

[1] The Elocta liability is a non-interest bearing debt and therefore not included in net cash/debt.
[2] The largest investment of the year is the opt-in for Alprolix, see Note 19.
[3] Raising of loan pertains to a loan of SEK 20 M from AB Svensk Exportkredit.

Supplemental disclosures to cash flow statement – Parent Company

SEK 000s	2015	2014
Interest paid		
Interest received	4,065	3,540
Interest paid	56,364	55,925
Tax paid	85	3,348
Adjustments for non-cash items		
Depreciation/amortisation and impairment of assets	121,053	293,771
Deferred tax attributable to loss carry-forwards	78,367	17,253
Cost of share programmes[1]	23,344	9,032
Other items	–5,507	525
	217,257	**320,581**

[1] IFRS expense associated with the share programmes that is recognised in equity.

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.

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

The Company has been listed on the Stockholm Stock Exchange, 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 Swedish Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 1, 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 in the preceding year.

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 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. Sobi is currently evaluating the effect that the standard will have on the Group's accounting.

The standard IFRS 15 Revenue from Contracts with Customers, will be effective for financial years commencing on or after 1 January 2018. 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.

The Group will adopt the new standard in its entirety. In 2015, the Group conducted a preliminary review of IFRS 15 and its effects, which may be subject to changes following more detailed analysis in 2016. Sobi is considering the proposed clarifications issued by IAS in July 2015 and will continue to follow any further developments in this area.

IFRS 16 is another upcoming standard which concerns leasing that is under evaluation by the company.

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 on which 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 a contingent consideration classified as a provision are recognised in the statement of comprehensive income. All transaction costs attributable to an acquisition are expensed. Identifiable assets acquired, as well as liabilities and contingent liabilities assumed through a business combination are 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 plus 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.

Currency

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

>> Note 2, cont.

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 of a jointly developed product.

Depending of 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 the work is carried out. Revenue from research collaborations are 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 reduced employer's contributions for research performed for commercial purposes, which is utilised in full, and research grants from the EU. A minor part of Sobi's projects are financed through government grants.

Other operating revenues/expenses
Other operating revenues are revenues from activities outside the normal operations. The item includes exchange-rate effects 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. Current receivables and liabilities fall due within one year of the balance sheet date. Non-current receivables and liabilities consist essentially of the amounts for which payments are due more than one year from 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 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 carried at cost less accumulated impairment write-downs. Gains or losses upon disposal of a unit includes residual carrying amount of the goodwill pertaining to the disposed unit.

Product and marketing rights
Product and marketing 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 (5–20 years). Amortisation is adapted to the expected earnings for each product and marketing right. Amortisations are 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 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 these are incurred. Costs directly associated with identifiable software products developed specifically for Sobi that are controlled by the company

and 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's useful life, up to a maximum of three years.

Tangible fixed assets

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

All tangible 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

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	
Laboratory equipment and other investments	3–7 years
Other major investments, such as redevelopment of property	5–20 years
Equipment, tools, fixtures and fittings	
Servers and other major computer hardware items	3–5 years
Furniture, fixtures and fittings	5–10 years
Land and buildings	
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 or 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) Loans and accounts receivable
2) Financial instruments measured at fair value through profit or loss (including derivatives not classified as hedging instruments)
3) Other financial liabilities
4) Available-for-sale financial instruments (including derivatives classified as hedging instruments)

Classification depends on the purpose for which the instrument was acquired. Management determines how the instruments will be classified in connection with initial recognition and reviews this decision on each reporting occasion.

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

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) Loans 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.

>> Note 2, cont.

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 through profit or loss (including derivatives not classified as hedging instruments)
Financial assets measured at fair value through 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. Derivatives held for risk management in the financial operations 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) Available-for-sale financial instruments (including derivatives classified as hedging instruments)
Available-for-sale financial assets are assets that have been identified as available for sale, or are not classified in any of the other categories. They are included in fixed assets unless management intends to dispose of the asset within twelve months of the balance sheet date.

A change in value in a financial asset in this category is recognised in other comprehensive income. When assets in this category are sold or impaired, the accumulated fair value adjustments are transferred from equity to profit or loss as gains and losses from financial instruments. This category includes financial instruments identified as hedges. These are either recognised as assets or liabilities depending on whether the fair value is positive or negative. Hedge accounting of financial instruments is specified in the paragraph below.

Financial instruments and hedging measures
The Group uses derivative instruments and loans to manage foreign-exchange risk, and derivative instruments for interest-rate risk in financing. All derivatives are assigned a market value and recognised in the balance sheet at fair value, both initially and in subsequent remeasurements. 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, the nature of the hedged item. If a loan is designated as a hedging instrument for foreign-exchange risk, the loan is measured at amortised cost in the balance sheet.

The entire fair value of a derivative that is a hedging instrument is classified as a fixed asset or long-term liability when the hedged item's remaining maturity is longer than 12 months, and as a current asset or current liability if the hedged item's remaining maturity is less than 12 months. Derivative instruments that do not constitute hedging instruments are always classified as current assets or current liabilities.

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 if a hedge no longer meets the criteria for hedge accounting and accumulated gains or losses from the hedge are recognised in equity, the gains or losses on the hedge remain as a separate component of equity and are recognised when the hedged item is finally recognised in profit or loss. If a loan is designated as a hedging instrument for foreign-exchange risk, the effective portion of the remeasurement effect pertaining to exchange rate fluctuations is recognised in the same way as for derivatives, while other parts of the loan are recognised as a loan that is not included in a hedge.

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.

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.

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 settle 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 settle 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 that substantially change the way in which the 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 equity. See also Notes 18 and 23.

Employee benefits
Pensions
Sobi has both defined-contribution and defined-benefit 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 valued 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 32.

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. Actuarial gains and losses are recognised in other comprehensive income in the period in which they arise.

Interest expenses, less the estimated return on plan assets, are classified as financial expenses. Other expense items in the pension costs are charged to operating profit/loss.

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

Commitments for retirement pensions and family pensions for white-collar employees in Sweden are insured through Alecta. According to statement UFR 3 issued by the Swedish Financial Reporting Board, this is a defined-benefit plan covering multiple employers. For the 2005–2015 financial years, the company 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 estimated on the issue date by applying a generally accepted modelling technique, the Monte Carlo simulation model, also taking into account conditions that are market-related. 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 also has two long-term cash-based incentive programmes comprising all employees in the US that do not constitute share-based remuneration. Since remuneration under these programmes 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, at 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

>> Note 2, cont.

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 further information see Note 32.

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, reports all group contributions received/provided as appropriations.

Basis for preparation of the parent company's and the consolidated financial statements
The Parent Company's functional currency is 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 (000s) unless otherwise indicated. Assets and liabilities are carried at the historical acquisition values, except for certain financial assets and liabilities, which are carried at fair value.

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

Assessments made by management in conjunction with the implementation of IFRS that have a significant influence on the financial 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 2014. 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.

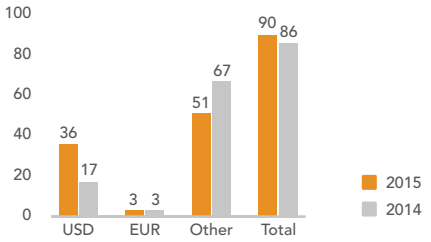
Financial risk is managed at the central level by Sobi's treasury department, which is also responsible for providing solutions for liquidity management and supporting the business in finance-related issues.

The finance policy, which is adopted by the Board, describes the rules and delegation of responsibilities pertaining to financial matters between the Board, 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 – Commercial transaction risk
Commercial transaction risk is the risk of changes in exchange rates having a negative impact on operating profit during the period until a transaction is settled. Since the Group's subsidiaries generally have most of their commercial flows in local currencies, this risk is limited, except in the Parent Company, which has significant flows in foreign currencies, primarily EUR and USD.

This risk is managed by matching all transactions in their respective currency, and by limiting any nominal net exposure of a sufficiently large amount compared with a fixed measure by entering into financial instrument agreements, such as currency futures. The currencies with the largest net exposures (including currency derivatives) are shown in the graph below. The amounts shown in the graph correspond to the net amounts restated in operating profit. At 31 December 2015, the exposure was linear and amounted to SEK 90 M (86). An instantaneous and permanent change in all rates against the SEK of +/– 10 per cent would have an impact of +/– SEK 9 M (9) on operating profit before tax.

Commercial transaction exposure
SEK M

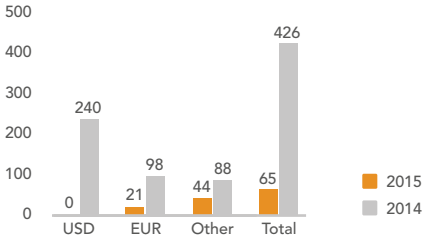


Currency risk – Financial transaction risk
Financial transaction risk refers to the risk of changes in exchange rates having a negative impact on net financial items. The loans and investments of subsidiaries are managed by the company's treasury department and are generally transacted in the local currencies of the subsidiaries. The financial transaction risk is thus centralised in the Parent Company.

This risk is managed by matching all transactions in their respective currency, including receivables, liabilities and other items restated in net financial items, and by limiting any nominal net exposure of a sufficiently large amount compared with

a fixed measure by entering into financial instrument agreements, such as currency futures. The currencies with the largest net exposures (including currency derivatives) are shown in the graph below. The amounts shown in the graph correspond to the net amounts (including derivatives) restated in net financial items. At 31 December 2015, the exposure was linear and amounted to SEK 65 M (426). An instantaneous and permanent change in all rates against the SEK of +/– 10 per cent would have an impact of +/– SEK 7 M (43) on operating profit before tax. The outstanding derivatives on the balance-sheet date are presented in the table below.

Financial transaction exposure
SEK M

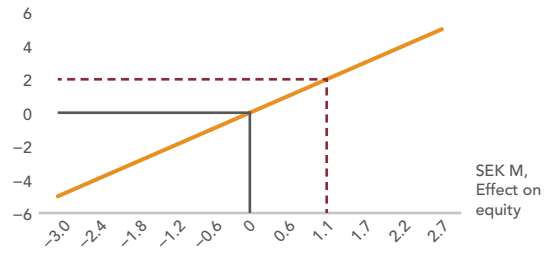


Outstanding derivatives (nominal amounts in millions, local currency)

	2015	2014
EUR	–20	–10
USD	–22	0
GBP	–1	0

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 graph for translation risk 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, for example, the SEK weakened 2 per cent against other currencies, the translation effect on consolidated equity would amount to SEK 1.1 M (0.7).

Translation risk
Currency change in SEK, %



Interest-rate risk
Interest-rate risk is the risk that Sobi would be adversely impacted by 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 since Sobi's general principle is to minimise its earnings volatility.

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 interest-rate risk. Sobi's long-term interest-bearing financing consists of a bond loan of SEK 800 M with variable interest, which will mature on 26 June 2017. Sobi also has a variable interest rate loan of SEK 20 M 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 that matured on 26 June 2015, where the flows from these swaps were matched with the bond. There were no interest-rate derivatives outstanding on the balance-sheet date. The liability to Biogen is non-interest bearing by the agreement, but is discounted in the financial statements and, therefore, recognised as an interest expense.

The sensitivity to interest-rate changes on profits is measured by assuming a sustained interest rate change of 1 percentage point. At 31 December 2015, such a change would have had an annual impact of SEK 6 M (4) on net financial items. At 31 December 2015, Sobi's interest-bearing liabilities amounted to SEK 822 M (818).

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. At the balance-sheet date, these amounted to SEK 451 M, of which SEK 127 M is due for payment, see Note 25 for information about 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 2015, such provisions amounted to SEK 25 M (12). 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.

>> Note 3, cont.

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 and long-term forecasts of the Group's liquidity are compiled on an ongoing basis to ensure the availability of sufficient cash funds to meet the needs of operating activities. Investment of any surplus liquidity should be made in instruments with low credit risk and high 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 should also be a liquidity reserve of which the size is 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. At 31 December 2015, the company had unutilised granted credit facilities totalling SEK 315 M (315).

Long-term financing consists of a bond loan of SEK 800 M maturing on 26 June 2017. The bond loan is subject to the usual provisions, one of which relates to limits on the Group's net debt in relation to operating profit before interest, tax, depreciation and amortisation (EBITDA), which applies under certain conditions if the Group should take on additional financial liabilities. The loan agreement for the bond also contains restrictions regarding any significant change in the company's ownership structure, so-called change-of-control, as well as limitations on dividends. 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	More than 5 years
At 31 December 2015				
Bond[1]	37,181	818,030	—	—
Derivatives	—	—	—	—
Borrowings	20,039	—	—	—
Accounts payable	183,193	—	—	—
Other liabilities[2]	464,456	318,464	945,695	—
Total	**704,869**	**1,136,494**	**945,695**	**—**
At 31 December 2014				
Bond[3]	42,096	42,096	820,414	—
Derivatives	8,120	—	—	—
Borrowings	253	20,055	—	—
Accounts payable	235,972	—	—	—
Other liabilities	1,704	4,036	—	—
Total	**288,145**	**66,187**	**820,414**	**—**

[1] The interest rate has been calculated using an interest rate of 4.6 per cent, the interest rate is undiscounted.
[2] Other liabilities relates mainly to the debt to Biogen. Repayment of the USD-denominated liability to Biogen is primarily done via USD royalty revenues from Biogen, see Note 19
[3] The interest rate has been calculated using an interest rate of 5.3 per cent, the interest rate is undiscounted.

Capital risk

The goal of Sobi's capital structure is to generate high returns for shareholders, benefits for other stakeholders, and to maintain an optimal capital structure in order to keep capital costs at a reasonable level. The capital structure can be adapted to the needs that arise by changing the dividend to shareholders, repaying capital to shareholders, issuing new shares or selling assets to reduce liabilities.

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:

	2015	2014
Equity	4,689,344	4,522,870
Total assets	8,310,718	6,370,744
Equity ratio, %	56.4	71.0

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 or liabilities.
- **Level 2:** Observable data for the asset or liability other than quoted prices included in Level 1.
- **Level 3:** Data for the asset or liability that is not based on observable market data.

At 31 December 2015	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value through profit or loss				
Derivative instruments held for trade	—	9,255	—	9,255
Total assets	**—**	**9,255**	**—**	**9,255**
At 31 December 2014	**Level 1**	**Level 2**	**Level 3**	**Total**
Financial liabilities measured at fair value through profit or loss				
Derivative instruments held for trade	—	2,616	—	2,616
Financial liabilities held for sale				
Derivative instruments used for hedging purposes	—	5,260	—	5,260
Total liabilities	**—**	**7,876**	**—**	**7,876**

All derivatives are measured at fair value based on market data in accordance with IFRS. At 31 December 2015, the recognised value of derivatives in the balance sheet was SEK 9 M (–8), also see Note 28.

Note 4

Important estimates and assumptions, and judgements for accounting purposes

The Group makes estimates and assumptions about the future, and judgements 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 commitments. See also Note 2 on revenue recognition of licensing fees and milestones.

Inventories

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 project 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 once a year.

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 assets are capitalised and amortised on a straight-line basis. Capitalisation commences when the company can demonstrate 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, product rights and market rights. The goodwill stems from the acquisition of Swedish Orphan. Annual impairment testing of goodwill, research projects, product rights and market 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 conducts regular impairment testing 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 2015, Sobi's goodwill amounted to SEK 1,554 M (1,554). The impairment testing did not result in any impairment.

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 and market 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. Since the carrying amounts of these product rights are highly significant for the Group, they are tested annually for impairment. The Company has determined that most of this depreciation is attributable to sales costs, since the intangible assets classified as product rights mainly pertain to marketing rights. The product and licensing rights are not related to any inventory or production cycle, nor is it necessary to otherwise bring the product to its current location and condition. 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.

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, impairment of this product right may be 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.

>> Note 4, cont.

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 32.

Inventory
Obsolescence
Stock consists of raw materials for manufacturing, manufactured semi-finished and finished products of Ammonaps, Elocta, Kepivance, Kineret and Orfadin, and finished goods inventory for other products. For this stock, no provision for obsolescence is made. Stock levels for Kepivance are expected 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. The production of ReFacto has two components: cultivation and purification. If a certain portion of the stock 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 inside and outside Sweden. The company also 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	2015	2014
Total revenues by major type of income		
Product sales	2,432,424	1,932,501
Manufacturing and contract development	503,841	465,927
Royalty revenues	250,589	172,515
Licensing and milestone revenues	69	15,433
Service fee	40,944	20,600
Total	**3,227,867**	**2,606,976**
Revenues by geographic market[1]		
Europe[2]	2,050,674	1,814,447
MENAR[3]	231,396	180,689
North America	861,058	578,881
Rest of the world	84,739	32,959
Total	**3,227,867**	**2,606,976**

Net sales in the parent company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 2,750 M (2,328) of which SEK 1,136 M (964) reffered to sales to Group companies.

PARENT COMPANY	2015	2014
Operating revenues by major revenue type		
Product sales	1,954,584	1,653,802
Manufacturing and contract development	503,841	465,927
Royalty revenues	250,589	172,515
Licensing and milestone revenues	69	15,433
Service fee	40,944	20,600
Total	**2,750,027**	2,328,277
Revenues by geographic market[1]		
Europe[4]	1,955,728	1,711,325
MENAR[3]	86,160	84,279
North America	623,400	497,507
Rest of the world	84,739	35,166
Total	**2,750,027**	2,328,277

[1] The geographic distribution is based on where end-customers are located.
[2] Sales in Sweden amounted to SEK 113 M (112).
[3] Middle East, North Africa and Russia.
[4] Sales in Sweden amounted to SEK 113 M (112).

Revenues by product category

GROUP	2015	2014
Inflammation: Kineret	805,361	609,302
Genetics & Metabolism: Orfadin	795,714	547,900
Genetics & Metabolism: Other	143,561	118,468
Haemophilia	96,252	30,922
Key Therapeutic Areas	**1,840,887**	**1,306,592**
Partner Products	**727,048**	**682,222**
Manufacturing revenues	503,841	465,927
Royalty revenues	156,092	152,235
ReFacto	**659,932**	**618,162**
Total	**3,227,867**	**2,606,976**

Note 6

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 660 M (618), corresponding to 20 per cent (24) 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 2015 and 2014. 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	2015	2014
Depreciation/amortisation according to plan by type of asset		
Capitalised software expenses	–8,399	–3,634
Patents and licenses	–54,925	–54,149
Product rights	–223,816	–223,816
Land and buildings	–334	–334
Plant and machinery	–8,970	–8,791
Equipment, tools, fixtures and fittings	–20,390	–20,569
Cars	–2,153	–1,975
Total	**–318,987**	**–313,268**
Depreciation/amortisation according to plan by function		
Cost of goods and services sold	–17,651	–18,181
Sales and administrative expenses	–298,716	–293,259
Research and development expenses	–2,620	–1,828
Total	**–318,987**	**–313,268**
Impairment losses by asset		
Goodwill	—	–94,149
Research and development	—	–174,131
Total	—	**–268,280**
Impairment losses by function		
Other operating expenses	—	–268,280
Total	—	–268,280

PARENT COMPANY	2015	2014
Depreciation/amortisation according to plan by type of asset		
Capitalised software expenses	–8,115	–3,561
Patents and licenses	–3,254	–2,406
Product rights	–82,503	–82,503
Land and buildings	–334	–334
Plant and machinery	–8,970	–8,791
Equipment, tools, fixtures and fittings	–17,877	–18,741
Total	**–121,053**	**–116,336**
Depreciation/amortisation according to plan by function		
Cost of goods and services sold	–17,594	–18,181
Sales and administrative expenses	–101,013	–96,504
Research and development expenses	–2,446	–1,651
Total	**–121,053**	**–116,336**

Note 8

Other operating revenues

GROUP	2015	2014
Exchange-rate gains	14,547	39,116
Other	236	781
Total	**14,783**	**39,897**

PARENT COMPANY	2015	2014
Exchange-rate gains	8,119	35,573
Further invoiced costs to subsidiaries	19,504	10,009
Other	—	505
Total	**27,623**	**46,087**

Note 9

Other operating expenses

GROUP	2015	2014
Exchange-rate losses on operating receivables/liabilities	–17,873	–31,966
Impairment of Multiferon[1]	—	–25,246
Impairment of Kiobrina[2]	—	–324,898
Other	–56	1,413
Total	**–17,929**	**–380,697**

PARENT COMPANY	2015	2014
Exchange-rate losses on operating receivables/liabilities	–14,757	–31,966
Impairment of Multiferon[1]	—	–25,246
Impairment of Kiobrina[2]	—	–55,918
Other	—	2,986
Total	**–14,757**	**–110,144**

[1] In 2014, Sobi decided to discontinue the manufacture of Multiferon, a treatment for malignant melanoma. The discontinuation resulted in an impairment loss of SEK 25 M.
[2] The Kiobrina research project was impaired in the first quarter of 2014, since the phase 3 trial did not meet its primary endpoints.

Note 10

Leasing fees for operational leasing

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

	Group		Parent Company	
	2015	2014	2015	2014
Within one year	64,947	62,889	57,052	59,618
Between 1–5 years	204,723	215,970	183,899	209,850
Later than five years	88,120	119,221	88,120	119,221
Total	**357,790**	**398,080**	**329,071**	**388,689**
Leasing costs for the year	65,836	63,472	58,621	58,552

Contracted future minimum lease payments for non-cancellable contracts, due for payment as follows:

	Group		Parent Company	
	2015	2014	2015	2014
Within one year	6,727	6,126	331	353
Between 1–5 years	13,013	11,288	324	155
Total	**19,740**	**17,414**	**655**	**508**
Leasing costs for the year	7,490	8,052	349	489

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.

Note 11

Profit/loss from participations in Group companies

PARENT COMPANY	2015	2014
Dividends from subsidiaries	—	2,772
Impairment of participations in Group companies	—	–177,435
Total	**—**	**–174,663**

In 2014, impairment for the year was attributable to the Arexis AB subsidiary, since parts of the Kiobrina research project were recognised as an asset in this company.

Note 12

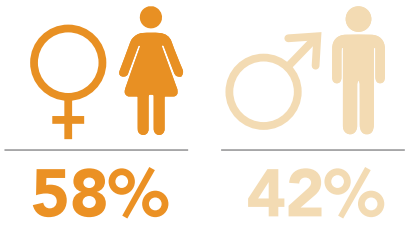
Personnel, personnel costs and remuneration to Board members and senior executives

Average number of employees[1]

GROUP	2015	% of whom women	% of whom men	2014	% of whom women	% of whom men
Sweden	406	62	38	389	62	38
Denmark	14	77	23	12	83	17
Finland/Baltics	12	54	46	11	62	38
Norway	7	71	29	8	73	27
United Kingdom	34	43	57	30	40	60
France	27	66	34	23	61	39
Germany	32	55	45	19	61	39
Italy	21	54	46	19	51	49
Spain	18	57	43	15	64	36
Belgium	15	45	55	6	69	31
Russia	6	71	29	5	49	51
Switzerland	2	36	64	1	100	0
Austria	4	74	26	2	67	33
Central and Eastern Europe	16	53	47	15	65	35
US	43	38	62	29	29	71
Canada[2]	3	68	32	–	–	–
UAE	11	20	80	6	17	83
Total	**672**	**58**	**42**	**589**	**57**	**43**

[1] Number of FTEs per 31 December 2015 amounted to 702 people.
[2] The Canadian company was established 1 November 2015.

GENDER DISTRIBUTION OF EMPLOYEES



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	2015	2014
Board of Directors		
Men	5	5
Women	3	3
Total	**8**	**8**
CEO and other senior executives		
Men	7	8
Women	3	4
Total	**10**	**12**

Salaries, other remuneration and social security costs

	2015		2014	
GROUP AND PARENT COMPANY	Salaries and remunerations	Social security costs	Salaries and remunerations	Social security costs
Parent Company	343,914	199,572	297,406	154,345
(of which pension cost)		*(65,510)*		*(52,639)*
Subsidiaries	333,595	55,312	225,432	53,023
(of which pension cost)		*(11,277)*		*(15,872)*
Group, total	677,509	254,884	522,838	207,368
(of which pension cost)		*(76,787)*		*(68,511)*

>> Note 12, cont.

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

	2015		2014	
	Board and CEO	Other employees	Board and CEO	Other employees
Parent Company				
Salaries and other remuneration	6,368[1]	337,546	13,783	283,623
(of which bonus)	*(0)*	*(43,390)*	*(1,803)*	*(32,101)*
Subsidiaries				
Salaries and other remuneration	8,827[1]	324,768	—	225,432
(of which bonus)	*(2,701)*	*(63,627)*	*(—)*	*(39,094)*
Group, total	**15,195**	**662,314**	**13,783**	**509,055**
(of which bonus)	*(2,701)*	*(107,017)*	*(1,803)*	*(71,195)*

[1] The CEO's salary for 2015 has mostly been paid by the US subsidiary, where the CEO also has his domicile.

Guidelines and remuneration 2015

The 2015 Annual General Meeting (AGM) adopted the following guidelines for remuneration of senior executives.

Guidelines for remuneration of senior executives
The Board of Directors proposed that the AGM resolves to approve the Board's proposed guidelines for remuneration of the company's senior executives according to the following, and for the period until the 2016 AGM. Senior executives in this context refers to Sobi'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 ensure that the company can attract and retain the best employees to support the company's vision and strategy. The basis for remuneration of senior executives is to be the total remuneration. Total remuneration is to be competitive, but not leading in relation to competitors in each local market. Market comparisons should be relative to a peer group of companies of similar size, that operate in a similar sector and are equally complex. The guidelines should enable employment in international contexts, and support diversity among senior executives. Remuneration may include the following components:
– Fixed salary
– Variable remuneration – or "short-term incentives"
– Long-term incentives
– Pensions
– Other benefits

Should a Board member perform assignments on behalf of the company or another Group company, in addition to Board work, consulting fees and/or other remuneration for such work may be payable.

Fixed salary
The fixed salaries of senior executives are determined on the basis of their expertise, responsibilities and performance. The company uses an international evaluation system to determine the scope and responsibilities of each position.

Variable remuneration
The annual short-term incentive programme is based on attainment of the annual performance targets (company-specific, department-specific and individual). There is no payment unless these targets are met. The annual performance targets are determined in advance by the Compensation & Benefits Committee and adopted by the Board.

Long-term incentive programmes
Sobi may introduce long-term incentive programmes to all, or some, of its employees. The aim of such programmes would be to harmonise the interests of employees and shareholders, to create long-term commitment to the company, to provide a tool for attracting and retaining managers and top talent, to give participants an opportunity to share Sobi's long-term success and value creation, and to help provide competitive total remuneration.

Remuneration and other benefits to the Board, CEO and other senior executives[1]

	Fixed salary/ fees	Variable remunera-tion	Pension cost	Other benefits	Financial instru-ments, etc.	Total
2015[2]						
Chairman of the Board						
Bo Jesper Hansen[3]	2,408					2,408
Other Board members[4]						
Helena Saxon	388					388
Hans GCP Schikan	410					410
Adine Grate Axén[5]	410					410
Lennart Johansson	398					398
Hans Wigzell	360					360
Matthew Gantz	364					364
Annette Clancy	382					382
Chief Executive Officer						
Geoffrey McDonough	5,399	2,701	135	1,835	4,263[6]	14,333
Other senior executives[1]	18,243	8,780	4,941	968	5,746[6]	38,678
Total	**28,764**	**11,481**	**5,076**	**2,803**	**10,009**	**58,133**

[1] Other senior executives refers to Sobi's Leadership Team, comprising nine people in addition to the CEO at 31 December 2015.
[2] The table shows the company's costs (excluding social security costs).
[3] Bo Jesper Hansen's employment and his monthly salary is not linked to his position as Chairman of the Board.
[4] For more information about Board fees, see the Corporate Governance Report.
[5] The fee includes the Board fee excluding social security contributions. The gross payment to the Board member's company was SEK 539 K, which includes compensation for social security contributions.
[6] Refer also to allotment and fulfillment of long-term incentive programmes for the 2012 share programme.

Pensions
The preferred form of pension plans at Sobi are defined-contribution plans. However defined-benefit pension plans exist and may be established if required by law or other regulations. In such cases, the defined-benefit level is not to exceed the required level.

Other benefits
Fixed salary during notice periods and for severance pay, including compensation for possible restrictions on competition, shall not exceed a total amount equivalent to the fixed salary for two years. In addition to this limitation, the total severance pay is to be limited to the existing monthly salary for the remaining months up to 65 years of age.

Additional remuneration may also be paid in extraordinary circumstances, provided that such arrangements are designed to recruit or retain senior executives, and that they are only agreed on a case-by-case basis. Such extraordinary arrangements may, for example, include a one-time cash payment, a benefit package in the form of relocation assistance, tax filing assistance, a retention bonus or severance pay in the event of changed ownership, or similar.

Deviations from the guidelines
The Board may decide to disregard the above guidelines if it considers the guidelines inappropriate in a specific case.

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 two cash-based programmes for US employees. All programmes have a vesting period of three years. The performance conditions are related to Sobi's share price trend.

Conditions and remuneration for senior executives
Sobi aims to offer competitive terms, enabling the company to recruit and retain competent 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 Leadership Team. In 2015, there was a total of nine 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 2015 was maximised at 50 per cent of gross 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 pension agreement, for which Sobi paid a contribution of SEK 135 K (1,196) in 2015. Gross salary, including pension provisions, amounted to SEK 5,534 K (4,810) in 2015. 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 the Leadership Team 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 executives[1]

	Fixed salary/fees	Variable remuneration	Pension cost	Other benefits	Financial instruments, etc.	Total
2014[2]						
Chairman of the Board						
Bo Jesper Hansen[3]	2,268	—	—	—	—	2,268
Other Board members[4]						
Helena Saxon	392	—	—	—	—	392
Hans GCP 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	3,614	1,803	1,196	2,353	3,247[7]	12,213
Other senior executives[1]	18,217	5,912	5,726	1,069	3,732[7]	34,655
Total	**26,647**	**7,715**	**6,922**	**3,422**	**6,979**	**51,685**

[1] Other senior executives refers to Sobi's Leadership Team, consisting of eleven persons other than the CEO at 31 December 2014.
[2] The table shows the company's costs (excluding social security costs).
[3] Bo Jesper Hansen's employment and his monthly salary is not linked to his position as Chairman of the Board.
[4] For more information about Board fees, see the Corporate Governance Report.
[5] The fee includes the Board fee excluding social security contributions. In 2014, the gross payment to the Board member's company was SEK 477 K, which includes compensation for social security contributions.
[6] Annette Clancy has been a Board member since the 2014 AGM. Remuneration pertains to work carried out during this period.
[7] Refer also to allotment and fulfillment of long-term incentive programmes for the Share programme 2011 and long-term share programmes for the CEO, in annual report 2014

>> Note 12, cont.

Remuneration and other benefits to the Board, CEO, other senior executives and CEOs in subsidiaries

	2015	2014
Parent Company and Subsidiaries		
Parent Company		
Salaries and other remuneration	33,359[1]	36,085
(of which bonus)	*(4,463)*	*(5,596)*
Pensions	4,003	6,258
Number of persons (excl. employee representatives)	14	17
Subsidiaries		
Salaries and other remuneration	47,599[1]	30,397
(of which bonus)	*(12,725)*	*(6,600)*
Pensions	3,374	2,136
Number of persons	17	15
Group		
Salaries and other remuneration	80,958	66,482
(of which bonus)	*(17,188)*	*(12,195)*
Pensions	7,377	8,394
Number of persons (excl. employee representatives)	**31**	**32**

[1] The Group CEO's salary for 2015 has mostly been paid by the US subsidiary, where the CEO also has his domicile.

Long-term incentive programmes

Annual General Meetings in 2012–2015 resolved in accordance with the Board's proposals to establish long-term incentive programmes. The aim has been to create a long-term commitment to Sobi, to offer the participants an opportunity to share in the company's long-term success and value creation, and to enable the company to attract and retain senior executives and key employees. Below is a presentation of the long-term share-based remuneration programmes in the company.

The performance share programmes for 2012–2015 are structured according to similar principles.

- The programmes have a three-year vesting period.
- The programmes requires 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 is able to receive differs between the organisational levels.
- The employee must be permanently employed during the entire vesting period and keep the investment shares during this period in order 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 2012 (paid 2015)

In May 2015, the Board resolved that the following performance conditions and other vesting terms were fully met in conjunction with redemption of the 2012 share programme on 11 June 2015. In the Leadership Programme for managers and key employees, 637,184 shares with a market value of SEK 68 M were therefore allotted, of which the CEO's portion comprised 208,507 shares with a market value of SEK 22 M. In the Employee Programme, 31,167 shares with a market value of SEK 3 M were allotted.

In December 2012, the Board resolved that the following performance conditions must be fully met.

Performance Condition for the Management program: A maximum allotment of performance shares would require a minimum increase of 75 per cent in the price of Sobi's share.

Performance Condition for the Employee programme: a maximum allotment for the Employee Programme (100 shares per employee) would require a minimum increase of 25 per cent in the price of Sobi's share.

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 15–75 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 increase is below 15 per cent and straight-line allotment takes place between 15 and 75 per cent.

Share programme 2013

	Number of performance shares	No. of matching shares	Value in SEK
CEO and other senior executives in the Group, 8 people	292,932	72,445	8,917,511
Total	**292,932**	**72,445**	**8,917,511**

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 15–75 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 increase is below 15 per cent and straight-line allotment takes place between 15 and 75 per cent.

Share programme 2014

	No. of performance shares	No. of matching shares	Value in SEK
CEO and other senior executives in the Group, 9 people	157,794	157,794	8,732,332
Total	**157,794**	**157,794**	**8,732,332**

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 is to increase 15–75 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. The turnover should also be 95–105 per cent relative to the average budget over three years.

Share programme 2015
The 2015 AGM approved a long-term share programme that encompasses the CEO, senior executives and managers, plus a programme for other employees.

Participation requires personal investment in Sobi's ordinary shares, referred to as "saving shares" in the programme.

After a lock-up period of three years:
The CEO is alloted performance shares (no matching shares), provided the share price performance achieves a certain target. Performance shares are allotted in the CEO Programme provided that the share price, with adjustment for any dividends, has exceeded the threshold value and increased more than 20 per cent. If the share-price performance increases 20–100 per cent, the proportional number of performance shares is allotted. The maximum possible allotment of performance shares is 400,000.

Participants in the Leadership Programme are allotted one matching share for each saving share, plus additional performance shares provided that the share price performance achieves a certain target. For a maximum allotment of performance shares, the price of Sobi's ordinary share, with adjustment for any dividends, must exceed a minimum target of 75 per cent. If the share price, with adjustment for any dividends, has increased by 15–75 per cent, programme participants will receive a straight-line allotment of performance shares. The maximum possible allotment of performance shares is 108,975.

Participants in the Employee Programme are allotted two matching shares for each saving share. To qualify for the allotment of matching shares, programme participants must have kept the saving shares they acquired until the end of the lock-up period. The maximum possible allotment of performance shares is 443,746.

Cash-based programme 2015
The 2015 AGM approved a long-term cash-based programme comprising all employees in the US. The performance target is that the share price is to increase 15–75 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 increase is below 15 per cent and straight-line allotment takes place between 15 and 75 per cent. The turnover should also be 95–105 per cent relative to the average budget over a three-year period.

Share programme 2015

	No. of performance shares	No. of matching shares	Value in SEK
CEO and other senior executives in the Group, 9 people	501,710	7,265	19,879,518
Total	**501,710**	**7,265**	**19,879,518**

The 2013–2015 Share Programmes are expensed according to the following parameters:

	Start date	End date	No. of matching shares	No. of performance shares	Vesting period (months)	Fair value of matching share	Fair value of performance share	Expected employee turnover, %	Max. allotment of shares
Share programme 2013:1	15 May 2013	15 May 2016	292,401	662,007	36	42.62	19.69	5	954,408
Share programme 2013:2	14 Nov 2013	14 Nov 2016	15,299	27,347	36	65.00	29.70	5	42,646
Share Programme 2014:1	9 May 2014	9 May 2017	132,068	246,499	36	81.78	37.41	5	378,567
Share Programme 2014:2	17 Nov 2014	17 Nov 2017	39,093	139,962	36	83.34	34.03	5	179,055
Share programme 2015	19 Aug 2015	19 Aug 2018	117,874	434,847	36	116.40	43.20	5	552,721
Share Programme 2015 CEO	24 Sep 2015	24 Sep 2018	n/a	400,000	36	n/a	36.60	—	400,000

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 peer company share prices during the same period, as well as the correlation between all share prices.

Note 13

Remuneration of auditors

GROUP	2015	2014
EY		
Auditing assignments[1]	–2,773	–2,577
Audit activities in addition to the auditing assignment	–2,302	—
Tax consultancy	–636	–100
Other services	–391	–756
Total EY	**–6,102**	**–3,433**
Other		
Auditing assignments[1]	–178	–455
Audit activities in addition to the auditing assignment	—	—
Tax consultancy	–464	–48
Other services	—	–214
Total other	**–642**	**–717**
Total	**–6,744**	**–4,150**

PARENT COMPANY	2015	2014
EY		
Auditing assignments[1]	–1,310	–1,305
Audit activities in addition to the auditing assignment	–2,302	—
Tax consultancy	–496	–100
Other services	–391	–676
Total EY	**–4,499**	**–2,081**
Other		
Other services	—	–124
Total other	**—**	**–124**
Total	**–4,499**	**–2,205**

[1] Auditing assignment refers to the statutory audit in order to submit the audit report and audit consultancy.

Note 14

Costs according to type of cost

GROUP	2015	2014
Raw materials and consumables	–966,540	–817,535
Other external costs	–774,560	–673,196
Costs for remuneration of employees	–1,018,591	–787,152
Depreciation	–318,987	–313,268
Other operating expenses[1]	–17,929	–380,697
Total	**–3,096,607**	**–2,971,848**

PARENT COMPANY	2015	2014
Raw materials and consumables	–913,268	–732,156
Other external costs	–837,193	–732,286
Costs for remuneration of employees	–582,126	–486,599
Depreciation	–121,053	–116,336
Other operating expenses[2]	–14,757	–110,144
Total	**–2,468,397**	**–2,177,521**

The above costs correspond to: Cost of goods sold and services, selling and administrative expenses, research and development costs and other operating costs in the functionally divided income statement.

[1] In 2014, other operating expenses included impairment losses of SEK 350 M related to Kiobrina and Multiferon.
[2] In 2014, other operating expenses included impairment losses of SEK 81 M related to Kiobrina and Multiferon.

Note 15

Financial income

GROUP	2015	2014
Interest income, other	2,929	4,228
Exchange-rate gains	—	62,713
Other	1,397	—
Total	**4,326**	**66,941**

PARENT COMPANY	2015	2014
Interest income, Group companies	26,637	30,954
Interest income, other	1,695	3,436
Exchange-rate gains	—	62,679
Other	1,175	—
Total	**29,507**	**97,069**

Net accounting of exchange-rate effects for the comparative year has been introduced and thereby adjusted from the previous year. Differences in exchange rates deriving from larger net assets in US dollars in 2014 compared to 2015 and the rise of the dollar in relation to the SEK during the same period.

Note 16

Financial expenses

GROUP	2015	2014
Interest expenses, borrowings	–51,903	–54,415
Interest expenses, other	–2,807	–2,206
Exchange-rate losses[1]	–3,581	—
Management expenses	–3,464	–3,656
Other	–924	–254
Total	**–62,679**	**–60,531**

PARENT COMPANY	2015	2014
Interest expenses, Group companies	–784	–500
Interest expenses, borrowings	–51,903	–54,415
Interest expenses, other	–2,180	–1,853
Exchange rate losses[1]	–3,340	—
Management expenses	–3,464	–3,656
Other	–924	–254
Total	**–62,595**	**–60,678**

Net accounting of exchange-rate effects for the comparative year has been introduced and thereby adjusted from the previous year.

[1] Includes realised and unrealised exchange-rate effects from derivatives of SEK -2 M (-3), previous year reported under Note 15 in exchange-rate gains.

Note 17

Exchange-rate differences affecting operating profit/loss

GROUP	2015	2014
Exchange-rate differences affecting operating profit/loss	–3,326	7,150
Total	**–3,326**	**7,150**

PARENT COMPANY	2015	2014
Exchange-rate differences affecting operating profit/loss	–6,637	3,607
Total	**–6,637**	**3,607**

See Notes 8 and 9.

Note 18

Income tax

GROUP	2015	2014
Current tax expense (–) / tax income (+)		
Tax expense/income for the period	–25,665	–16,093
Adjustment of tax attributable to previous years	3,300	–3,348
Total current tax for the Group	**–22,365**	**–19,441**
Deferred tax relating to:		
Provision for pensions	–272	1,107
Change in tax allocation reserve and excess depreciation	–39,546	–8,800
Internal gains in stock	18,455	40,073
Amortisation of intangible fixed assets	19,765	38,148
Cash flow hedges, financial instruments	–2,840	—
Loss carry-forwards	—	–35,514
Revaluation of deferred tax	—	31,772
Other	7,506	3,388
Total deferred tax for the Group	**3,068**	**70,174**
Total tax for the Group	**–19,297**	**50,733**

PARENT COMPANY	2015	2014
Current tax expense (–) / tax income (+)		
Tax expense/income for the period	—	—
Adjustment of tax attributable to previous years	3,300	–3,348
Total current tax for the Parent Company	**3,300**	**–3,348**
Deferred tax relating to:		
Loss carry-forwards	—	–10,976
Cash flow hedges, financial instruments	–2,840	—
Temporary difference reducing balance method	–59,085	–6,128
Total deferred tax for the Group	**–61,925**	**–17,104**
Total tax for the Parent Company	**–58,625**	**–20,452**

Reconciliation of effective tax

GROUP	2015	2014
Profit/loss before tax	**87,690**	**–318,565**
Tax according to the applicable tax rate for the Parent Company	–19,292	70,084
Effect of foreign tax rates	–2,210	5,340
Non-deductible expenses	–1,495	–1,251
Non-taxable income	299	878
Adjustment of tax attributable to previous years	3,300	–3,348
Impairment of goodwill	—	–20,713
Deferred tax assets previously unrecognised	—	–258
Recognised effective tax	**–19,297**	**50,733**

PARENT COMPANY	2015	2014
Profit/loss before tax	**276,165**	**–100,273**
Tax according to the applicable tax rate for the Parent Company	–60,756	22,060
Non-deductible expenses	–1,490	–1,232
Adjustment of tax attributable to previous years	3,300	–3,348
Non-taxable income	220	1,362
Impairment of participations in subsidiaries[1]	—	–39,036
Revaluation of deferred tax	—	–258
Recognised effective tax	**–58,625**	**–20,452**

[1] Pertains to impairment of participations in the subsidiary Arexis AB, linked to the Kiobrina research project.

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

Note 19

Intangible fixed assets and impairment testing

GROUP	Goodwill	Research & development	Licenses & patents	Product & market rights	Advance payment	Capitalised software expenditure	IT software in progress	Total
1 January–31 December 2014								
Opening carrying amount	1,648,307	172,274	400,260	2,399,733	—	10,956	5,498	4,637,028
Acquisitions	—	—	11,907[1]	51,160[1]	73,503[1]	4,087[1]	18,907[1]	160,284
Reclassification of cost	—	1,857	–1,857	—	—	55	—	55
Impairment losses	–94,149[2]	–174,131[2]	—	—	—	—	—	–268,280
Depreciation	—	—	–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	1,648,307	283,277	609,477	3,432,433	73,503	72,393	24,405	6,143,795
Accumulated depreciation and impairment losses	–94,149	–283,277	–253,316	–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 January–31 December 2015								
Opening carrying amount	1,554,158	—	356,161	2,227,077	73,503	12,184	24,405	4,247,488
Initiation of construction in progress	—	—	—	—	—	31,794	–31,794	—
Acquisitions	—	—	750[3]	1,706,088[3]	82,400[3]	—	33,178[3]	1,822,416
Reclassification of cost	—	—	–63,994	137,497	–73,503	600	3,671	4,272
Depreciation	—	—	–54,925	–223,816	—	–8,399	—	–287,140
Closing carrying amount	**1,554,158**	—	**237,992**	**3,846,846**	**82,400**	**36,179**	**29,460**	**5,787,036**
At 31 December 2015								
Cost	1,554,158	—	546,233	5,276,018	82,400	104,787	29,460	7,970,484
Accumulated depreciation and impairment losses	—	—	–308,241	–1,429,172	—	–68,608	—	–2,183,447
Carrying amount	**1,554,158**	—	**237,992**	**3,846,846**	**82,400**	**36,179**	**29,460**	**5,787,036**

[1] Acquisitions in 2014 pertain to Elocta, recognised as an advance payment (SEK 74 M), XTEN (SEK 51 M), IFS ERP-system (SEK 19 M), Affibody (SEK 11 M) and other (SEK 6 M).
[2] The impairment loss in 2014 pertains to the Kiobrina research project. Management deemed these assets to be of no value.
[3] Acquisitions in 2015 pertain to Elocta (SEK 1,704 M), Alprolix recognised as an advance payment (SEK 82 M), IFS ERP-system (SEK 17 M), and other (SEK 19 M), divided among all intangible items.

PARENT COMPANY	Licenses & patents	Product & market rights	Advance payment	Capitalised software expenditure	IT software in progress	Total
1 January–31 December 2014						
Opening carrying amount	95,255	825,768	—	8,226	5,498	934,747
Acquisitions	11,907[1]	51,160[1]	73,503[1]	4,807[1]	18,907[1]	160,284
Reclassification of cost	—	—	—	–35	—	–35
Depreciation	–2,406	–82,503	—	–3,561	—	–88,470
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	73,503	66,084	24,405	1,424,890
Accumulated depreciation and impairment losses	–8,409	–353,308	—	–56,647	—	–418,364
Carrying amount	**104,756**	**794,425**	**73,503**	**9,437**	**24,405**	**1,006,526**
1 January–31 December 2015						
Opening carrying amount	104,756	794,425	73,503	9,437	24,405	1,006,526
Initiation of construction in progress	—	—	—	31,794	–31,794	—
Acquisitions	750[2]	1,706,088[2]	82,400[2]	—	33,093[2]	1,822,331
Reclassification of cost	–63,994	137,497	–73,503	—	3,672	3,672
Depreciation	–3,254	–82,503	—	–8,115	—	–93,872
Closing carrying amount	**38,258**	**2,555,507**	**82,400**	**33,116**	**29,376**	**2,738,657**
At 31 December 2015						
Cost	49,921	2,991,318	82,400	97,878	29,376	3,250,894
Accumulated depreciation and impairment losses	–11,663	–435,811	—	–64,762	—	–512,236
Carrying amount	**38,258**	**2,555,507**	**82,400**	**33,116**	**29,376**	**2,738,657**

[1] Acquisitions in 2014 pertain to Elocta, recognised as an advance payment (SEK 74 M), XTEN (SEK 51 M), IFS ERP-system (SEK 19 M), Affibody (SEK 11 M) and other (SEK 6 M).
[2] Acquisitions in 2015 pertain to Elocta (SEK 1,704 M), Alprolix recognised as an advance payment (SEK 82 M), IFS ERP-system (SEK 17 M), and other (SEK 19 M), divided among all intangible items.

>> Note 19, cont.

Testing for impairment of intangible fixed assets

Goodwill

The assessment of the value of the Group's goodwill is based on value in use of the smallest cash-generating unit, which for Sobi is deemed to be the Group (excluding ReFacto).

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- to ten-year period have been extrapolated using an estimated growth rate of 2 per cent. At 31 December 2015, Sobi's goodwill amounted to SEK 1,554 M (1,554). There is no indication of goodwill impairment at Group level.

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

PARAMETER, %	2015	2014
Growth rate beyond the initial five-year period	2	2
Discount rate before tax	11.3	11.2
Discount rate after tax	8.8	8.7

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: 5.7 per cent (6.1).

Beta coefficient: Sobi's beta coefficient is calculated at 1.25 (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 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 2015

Sobi did not make any material impairments in 2015.

Contractual commitments for acquisitions of intangible assets

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

Agreement with Biogen

According to the agreement between Sobi and Biogen regarding the development and commercialisation of Elocta, Alprolix and XTEN. Biogen takes full responsibility for development and production, plus the associated costs, 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 territory and Biogen's distribution territory). Sobi and Biogen receive a royalty on each other's sales in the respective company's territory according to the royalty rates set out in the table on next page.

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 assume responsibility for the final regulatory process and other commercialisation activities in Sobi's territory by making a deposit of USD 10 M for each programme.

Liability arising from pipeline programmes

If granted regulatory approval by the EU, Sobi will be liable to reimburse Biogen for 50 per cent of the total development and production costs for clinical manufacturing of the product, development costs for the product as of 1 October 2009 until the date on which Sobi is registered as the marketing authorisation holder (MAH), or, 90 days after approval, as well as some 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.

Liability settlement
Sobi's reimbursement to Biogen for each pipeline programme takes the following three forms:

- When regulatory approval is granted in the EU, the deposit of USD 10 M is transferred to Biogen and offset against Sobi's liability.

- With the first commercial sales of each of its products, Sobi will be able to credit a retroactive royalty revenue on the difference between the base rate and the 2 per cent already received on Biogen's sales. This amount is offset against the liability. The amount will be recorded as a revenue but have no cash effect.

- From Sobi's first commercial sales, the royalty rates between the companies are adjusted until the liability has been repaid in full (see the table).

If full reimbursement has not been achieved within six years of Biogen's first commercial sales 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 sales.

Elocta
In October 2014, Sobi's collaboration partner Biogen submitted an MAA for Elocta to the EMA. The MAA, together with the delivery of data from Biogen to Sobi, triggered Sobi's exclusive opt-in right to assume the final development and commercialisation of Elocta in Europe, North Africa, Russia and most Middle Eastern countries. In November 2014, Sobi exercised its opt-in right and paid a deposit of USD 10 M, in accordance with the agreement. Total payment is expected to be about USD 216 M. On 24 November 2015, Sobi and Biogen announced that the European Commission had approved Elocta for the treatment of haemophilia A in all 28 EU member states, plus Iceland, Liechtenstein and Norway. In connection with the approval, the deposit was transferred to Biogen and set off against the liability, which on 31 December 2015 amounted to SEK 1,639 M (USD 196 M), and corresponded to the discounted value of the nominal liability, which amounted to USD 206 M. In connection with its first commercial sales in January 2016, Sobi credited a retroactive royalty revenue of SEK 322 M against the liability.

Alprolix
In June 2015, Sobi's partner Biogen submitted an MAA for Alprolix to the EMA. The MAA to the EMA, together with the delivery of data from Biogen to Sobi, triggered Sobi's exclusive opt-in right to assume the final development and commercialisation of Alprolix in Europe, North Africa, Russia and most Middle Eastern countries. On 16 July 2015, Sobi exercised its opt-in right and paid a deposit of USD 10 M, in accordance with the agreement. The deposit was recognised in the balance sheet as an advance payment under intangible fixed assets. The total liability is expected to be about USD 187 M. On 26 February 2016, Sobi and Biogen received a recommendation for marketing authorisation approval for Alprolix for the treatment of haemophilia B, from the Scientific Committee for Human Medicinal Products (CHMP) at the EMA.

XTEN
In September 2014, Sobi decided to include the preclinical development programme for the potentially long-acting haemophilia A treatment XTEN, in the agreement with Biogen. Under the agreement between Sobi and Biogen, Sobi will thus have an exclusive opt-in right to the programme, and the possibility to obtain the commercial rights in Sobi's territory according to the principles described above.

			Percentage rates after the first commercial sales in Sobi´s territory if Sobi exercises its opt-in right[3]		
PERCENTAGE RATES FOR ROYALTIES AND REIMBURSEMENT BETWEEN THE COMPANIES	Method	Rate before first commercial sales in Sobi's territory, %	Base rate[4], %	Adjusted royalty rate during repayment period[4]	Net royalty payment during repayment period[5], %
From Sobi to Biogen based on net sales in Sobi's territory	Royalty on sales	N/A	12[6]	Base rate plus 5%	17
Biogen to Sobi based on net sales in North America	Royalty on sales	2	12[6]	Base rate minus 5%	7
Biogen to Sobi based on net sales in Biogen's territory outside North America	Royalty on sales	2	17[7]	Base rate minus 5%	12
Biogen to Sobi based on the net profit[1] from Biogen's distribution territory[2]	Royalty on net profit	10	50	Base rate minus 15%	35

[1] Net profit pertains to Biogen's revenues before tax from distributors (third-party), less expenses incurred by Biogen for supporting these sales.
[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 that Sobi will make according to its opt-in right, in an amount equal to the difference between the royalty payments that Biogen made to Sobi on sales in Biogen's territory during certain periods before the first sales in Sobi's territory, and the rate that would otherwise have been payable on such sales.
[4] Base rate impacts the results. Repayment of the liability is based on the difference between the base rate and the adjusted royalty.
[5] Actual payments that impact cash flow.
[6] 10 per cent if Sobi only exercises its opt-in right for one of the programmes.
[7] 15 per cent if Sobi only exercises its opt-in right for one of the programmes.

Note 20

Tangible fixed assets

GROUP	Land & buildings	Plant & machinery	Equipment, tools, fixtures & fittings	Cars	Construction in progress	Total
1 January–31 December 2014						
Opening carrying amount	4,595	36,712	72,418	7,469	4,585	125,779
Initiation of construction in progress	—	4,585	—	—	–4,585	—
Acquisitions	—	8,755	4,799	2,211	7,092	22,858
Reclassification of cost	—	—	–51	–1,633	38	–1,646
Disposals	—	—	—	–1,128	—	–1,128
Depreciation	–334	–8,791	–20,569	–1,975	—	–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	7,130	634,909
Accumulated depreciation and impairment losses	–2,467	–364,225	–150,107	–2,880	—	–519,679
Carrying amount	**4,261**	**41,261**	**56,598**	**5,979**	**7,130**	**115,229**
1 January–31 December 2015						
Opening carrying amount	4,261	41,261	56,598	5,979	7,130	115,229
Acquisitions	—	9,106	9,812	4,581	3,875	27,374
Reclassification of cost	—	—	—	—	–103	–103
Disposals	—	–574	—	–1,306	—	–1,880
Depreciation	–334	–8,970	–20,390	–2,153	—	–31,847
Exchange-rate differences	—	—	–268	—	—	–268
Closing carrying amount	**3,927**	**40,824**	**45,572**	**7,101**	**10,902**	**108,506**
At 31 December 2015						
Cost	6,728	409,544	216,517	10,299	10,902	653,920
Accumulated depreciation and impairment losses	–2,801	–368,720	–170,765	–3,128	—	–545,414
Carrying amount	**3,927**	**40,824**	**45,572**	**7,101**	**10,902**	**108,506**

PARENT COMPANY	Land & buildings	Plant & machinery	Equipment, tools, fixtures & fittings	Construction in progress	Total
1 January–31 December 2014					
Opening carrying amount	4,595	37,988	68,468	4,585	115,635
Initiation of construction in progress	—	4,585	—	–4,585	—
Acquisitions	—	8,755	367	7,092	16,215
Reclassification of cost	2	—	—	38	40
Depreciation	–334	–8,791	–18,741	—	–27,866
Reclassification of accumulated depreciation	–2	—	—	—	–2
Closing carrying amount	**4,261**	**42,537**	**50,094**	**7,130**	**104,022**
At 31 December 2014					
Cost	6,728	400,510	191,331	7,130	605,853
Accumulated depreciation and impairment losses	–2,467	–357,973	–141,237	—	–501,830
Carrying amount	**4,261**	**42,537**	**50,094**	**7,130**	**104,022**
1 January–31 December 2015					
Opening carrying amount	4,261	42,537	50,094	7,130	104,022
Acquisitions	—	9,106	3,409	3,875	16,390
Reclassification of cost	—	—	—	–103	–103
Disposals	—	–849	—	—	–849
Depreciation	–334	–8,970	–17,877	—	–27,181
Closing carrying amount	**3,927**	**41,824**	**35,626**	**10,902**	**92,279**
At 31 December 2015					
Cost	6,728	404,721	194,740	10,902	617,092
Accumulated depreciation and impairment losses	–2,801	–362,897	–159,114	—	–524,812
Carrying amount	**3,927**	**41,824**	**35,626**	**10,902**	**92,279**

Note 21

Participations in Group companies

PARENT COMPANY	2015	2014
Accumulated cost		
At 1 January	4,059,504	4,058,468
Purchasing	69	1,036
Total	**4,059,573**	**4,059,504**
Accumulated impairment losses		
At 1 January	–177,435	—
Impairment losses for the year	—	–177,435
Total	**–177,435**	**–177,435**
Carrying amount at end of period	**3,882,138**	**3,882,069**

Purchasing for the year pertains to the new subsidiary in Canada. The impairment loss for 2014 was attributable to the Arexis AB subsidiary, since parts of the Kiobrina research project were recognised as an asset in this company.

>> Note 21, cont.

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

SUBSIDIARY/ CORP. IDENTITY NO/ DOMICILE	No. of participations	Participations in %[1]	Carrying amount
Swedish Orphan Biovitrum International AB, 556329-5624, Stockholm, Sweden	100	100	3,655,588
– 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, Turku, Finland			
– Swedish Orphan Biovitrum s.r.l., 5288990962, Parma, Italy			
– OOO Swedish Orphan Biovitrum, 5087746194520, Moscow, Russia			
– Swedish Orphan Biovitrum AS, 976313682, Trollåsen, Norway			
– Swedish Orphan Biovitrum S.L., B84710623, Madrid, Spain			
– Swedish Orphan Biovitrum Ltd, 4369760, Cambridgeshire, UK			
– Swedish Orphan Biovitrum GmbH, HRB 42329, Langen, Germany			
SOBI Middle East FZ-LLC, 91193, Dubai, United Arab Emirates	1,000	100	132
Arexis AB, 556573-5130, Stockholm, Sweden	1,000	100	225,137
Sobi, Inc. EIN 68-0682244, Delaware, USA	1,000	100	7
Swedish Orphan Biovitrum s.r.o., 28171276, Prague, Czech Republic[2]	1	1	8
BVBA Swedish Orphan Biovitrum, 0536.217.087, Brussels, Belgium	100	100	162
Swedish Orphan Biovitrum AG, 284.917.678, Luzern, Switzerland	100	100	723
Swedish Orphan Biovitrum GmbH, 416986, Vienna, Austria	100	100	313
Swedish Orphan Biovitrum (SOBI) Canada, Inc. 949375-1, Oakville, Canada	10,000	100	69
Total			3,882,138

[1] Refers to the ownership of capital, which also corresponds to the proportion of the votes.
[2] The remaining portion is owned by Swedish Orphan Biovitrum International AB.

Note 22

Financial assets

GROUP	2015	2014
Accumulated cost		
At 1 January	2,862	2,010
Divestment of Agrisera	–600	—
Financial receivables	282	810
Returned deposit	–717	—
Other	–36	42
Accumulated cost	**1,791**	**2,862**
Carrying amount at end of period	**1,791**	**2,862**

PARENT COMPANY	2015	2014
Accumulated cost		
At 1 January	621	621
Divestment of Agrisera	–600	—
Accumulated cost	**21**	**621**
Carrying amount at end of period	**21**	**621**

Note 23

Deferred tax assets and deferred tax liabilities

Recognised deferred tax assets and liabilities

GROUP 2015	Deferred tax assets	Deferred tax liabilities	Net
Stock	76,933	—	76,933
Acquired product rights	—	–328,202	–328,202
Pensions	2,500	—	2,500
Excess depreciation	—	–182,898	–182,898
Cash flow hedges, financial instruments	—	–18,125	–18,125
Other intangible fixed assets	216,700	—	216,700
Loss carry-forwards	258	—	258
Other	18,161	—	18,161
Total	**314,552**	**–529,225**	**–214,673**
Offsetting	–217,333	217,333	—
Tax assets/liabilities, net	**97,219**	**–311,892**	**–214,673**

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	—	3,251
Excess depreciation	—	–143,352	–143,352
Other	10,457	—	10,457
Other intangible fixed assets	216,700	—	216,700
Loss carry-forwards	258	—	258
Total	**307,491**	**–509,702**	**–202,211**
Offsetting	–237,538	237,538	—
Tax assets/liabilities, net	**69,953**	**–272,164**	**–202,211**

For the Parent Company, a deferred tax liability/receivable of SEK –58.6 M (19.8) remains of which the largest items relates to temporary difference reducing balances of SEK –40.7 M and cash flow hedges financial instruments of SEK –15.3 M. All loss carry-forwards are reported as deferred tax assets.

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. There are no non-capitalised loss of the Group. The value of deferred tax after year-end is calculated on a tax rate of 22 per cent (22).

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

GROUP 2015	Amount at 1 January	Recognised in profit or loss	Recorded in other comprehensive income	Translation difference	Amount 31 December
Stock	58,442	18,455	—	36	76,933
Acquired product rights	–347,967	19,765	—	—	–328,202
Pensions	3,251	–272	–479	—	2,500
Tax allocation reserves/Excess depreciation	–143,352	–39,546	—	—	–182,898
Cash flow hedges, financial instruments	—	–2,840	–15,285	—	–18,125
Other intangible fixed assets	216,700	—	—	—	216,700
Capitalised loss carry-forwards	258	—	—	—	258
Other	10,457	7,506	198	—	18,161
Total	**–202,211**	**3,068**	**–15,566**	**36**	**–214,673**

GROUP 2014	Amount at 1 January	Recognised in profit or loss	Recorded in other comprehensive income	Translation difference	Amount 31 December
Stock	18,406	40,073	—	–37	58,442
Acquired R&D	–37,900	37,900	—	—	—
Acquired product rights	–379,987	32,020	—	—	–347,967
Pensions	2,325	1,107	–181	—	3,251
Tax allocation reserves/Excess depreciation	–134,552	–8,800	—	—	–143,352
Other	5,842	3,388	1,227	—	10,457
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**

Note 24

Inventories

GROUP	2015	2014
Raw materials and consumables	14,991	10,745
Work-in-progress	316,001	401,587
Finished goods and goods for resale	444,862	351,602
Total	**775,854**	**763,935**

The cost of inventories that was expensed is included in the cost of goods sold item and amounted to SEK 914,467 K (732,822). Obsolescence cost for the year amounted to SEK 60,341 K (4,744). The increase is mainly due to an increase in inventory reserve for Kepivance because of reduced demand in Europe and various production-related costs for Kineret.

PARENT COMPANY	2015	2014
Raw materials and consumables	14,991	10,745
Work-in-progress	316,001	401,587
Finished goods and goods for resale	342,563	267,935
Total	**673,555**	**680,268**

The cost of inventories that was expensed is included in the cost of goods sold item and amounted to SEK 913,267 K (732,157). Obsolescence cost for the year amounted to SEK 60,341 K (4,744). Regarding the increase see comment in the Group.

Note 25

Accounts receivable and other receivables

GROUP	2015	2014
Accounts receivable	476,509	492,449
Minus: Provision doubtful receivables	–25,280	–12,424
Accounts receivable, net	**451,229**	**480,025**
Tax assets	20,634	19,567
Other receivables	46,942	42,283
Total other receivables	**67,576**	**61,850**
Total accounts receivable and other receivables	**518,805**	**541,875**

PARENT COMPANY	2015	2014
Accounts receivable	197,206	202,804
Minus: Provision doubtful receivables	–13,171	–8,801
Accounts receivable, net	**184,035**	**194,003**
Tax assets	16,924	17,109
Other receivables	30,699	29,605
Total other receivables	**47,623**	**46,714**
Total accounts receivable and other receivables	**231,658**	**240,717**

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

At 31 December 2015, accounts receivable amounting to SEK 127 M (148) had fallen due in the Group, whereof SEK 25 M (12) have been made for overdue accounts considered doubtful.

Changes in the provision for doubtful receivables are as follows:

Doubtful receivables

GROUP	2015	2014
At 1 January	–12,424	–10,442
Provision doubtful accounts receivable	–12,856	–3,551
Reversed provisions	—	1,569
At 31 December	**–25,280**	**–12,424**

PARENT COMPANY	2015	2014
At 1 January	–8,801	–10,370
Provision doubtful accounts receivable	–4,370	—
Reversed provisions	—	1,569
At 31 December	**–13,171**	**–8,801**

Past due accounts receivable

GROUP	2015	2014
Undue	324,199	331,560
Past due 1–30 days	68,491	69,635
Past due 31–90 days	19,346	34,327
Past due 91–120 days	12,933	7,879
Past due > 121 days	26,260	36,624
Total	**451,229**	**480,025**

PARENT COMPANY	2015	2014
Undue	176,733	181,697
Past due 1–30 days	3,390	5,974
Past due 31–90 days	1,422	3,760
Past due 91–120 days	379	648
Past due > 121 days	2,111	1,924
Total	**184,035**	**194,003**

Recognised amount per currency for accounts receivable and other receivables

GROUP	2015	2014
AUD	6,451	6,234
CHF	2,359	1,817
CZK	5,236	5,768
DKK	9,307	16,524
EUR	224,678	215,154
GBP	32,118	43,293
NOK	9,732	16,365
PLN	6,232	4,832
RON	15,201	10,685
SEK	75,555	100,392
USD	128,079	117,403
Other currencies	3,857	3,407
Total	**518,805**	**541,875**

PARENT COMPANY	2015	2014
AUD	6,451	6,234
CHF	2,359	1,722
CZK	1,440	3,365
DKK	9,188	16,346
EUR	66,093	69,973
GBP	1,568	2,878
NOK	9,232	15,897
PLN	6,232	4,832
RON	15,201	10,685
SEK	75,555	100,392
USD	35,668	4,985
Other currencies	2,671	3,407
Total	**231,658**	**240,717**

Note 26

Prepaid expenses and accrued income

GROUP	2015	2014
Accrued royalty revenues	57,844	43,277
Prepaid leasing fees	258	181
Prepaid rents	15,943	16,588
Prepaid insurance expenses	12,734	11,191
Accrued interest income	2,120	3,533
Other accrued revenues	5,552	5,481
Other prepaid expenses	23,396	30,004
Total	**117,847**	**110,255**

PARENT COMPANY	2015	2014
Accrued royalty revenues	57,844	43,277
Prepaid leasing fees	—	81
Prepaid rents	14,161	15,136
Prepaid insurance expenses	11,518	9,443
Accrued interest income	2,120	3,533
Other accrued revenues	5,526	5,461
Other prepaid expenses	18,237	23,111
Total	**109,406**	**100,042**

Note 27

Current investments and cash equivalents

	2015		2014	
GROUP	Fair value	Carrying amount	Fair value	Carrying amount
Cash and bank balances	903,660	903,660	519,147	519,147
Total	**903,660**	**903,660**	**519,147**	**519,147**

	2015		2014	
PARENT COMPANY	Fair value	Carrying amount	Fair value	Carrying amount
Cash and bank balances	750,398	750,398	392,424	392,424
Total	**750,398**	**750,398**	**392,424**	**392,424**

Note 28

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 2015				
Assets in the balance sheet				
Accounts receivable	451,229	—	—	451,229
Derivatives	—	9,255	—	9,255
Cash and cash equivalents	903,660	—	—	903,660
Total	**1,354,889**	9,255	—	**1,364,144**
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**

	Liabilities measured at fair value in profit or loss	Other financial liabilities	Liabilities held for sale	Total
31 December 2015				
Liabilities in the balance sheet				
Borrowings	—	815,158	—	815,158
Financial leasing	—	6,944	—	6,944
Accounts payable	—	183,193	—	183,193
Other liabilities	—	1,639,285	—	1,639,285
Total	—	**2,644,580**	—	**2,644,580**
31 December 2014				
Liabilities in the balance sheet				
Borrowings	—	811,775	—	811,775
Financial leasing	—	5,740	—	5,740
Derivatives	2,616	—	5,260	7,876
Accounts payable	—	235,972	—	235,972
Total	**2,616**	**1,053,487**	**5,260**	**1,061,363**

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

Note 29

Bond loan

GROUP	2015	2014
Bond loan	795,158	791,775
Total	**795,158**	**791,775**

PARENT COMPANY	2015	2014
Bond loan	795,158	791,775
Total	**795,158**	**791,775**

The bond loans are presented net of transaction costs. At 31 December 2015, the recognised value of the bond loan in the balance sheet was SEK 795 M (792). The estimated fair value is SEK 823 M (838), based on the average of the bid and ask price at the balance-sheet date.

Note 30

Other liabilities, non-current

GROUP	2015	2014
Liability to Biogen	1,179,468	—
Liabilities to credit institute	—	20,000
Other	5,178	4,036
Total	**1,184,646**	**24,036**

PARENT COMPANY	2015	2014
Liability to Biogen	1,179,468	—
Liabilities to credit institute	—	20,000
Total	**1,179,468**	**20,000**

Following the EU approval of Elocta, Sobi has acquired the right to market the product on certain markets. The cost of marketing rights corresponds to 50 per cent of Biogen's development expenses for Elocta. The nominal value amounts to USD 206 M, but since the liability will be repaid over a number of years, the discounted value of the liability is reflected in the balance sheet (USD 196 M). The right to market the product in certain markets, which is recognised as an intangible fixed asset, is recognised at the same value as the liability. The cost corresponds to an amount equal to the discounted liability, and the difference compared with the nominal value leads to deferred tax in the financial statements. The risk associated with currency effects on the liability is reduced by applying hedge accounting to the liability by hedging highly probable inflows in the future in USD via cash flow hedging, and the effect of revaluation of the liability is reflected in other comprehensive income. If full reimbursement has not been achieved within six years of Biogen's first commercial sales for the programme, Biogen is entitled to request that Sobi pay the remaining amount within 90 days from the sixth anniversary of the first commercial sales.

Liabilities to credit institute pertains to a loan of SEK 20 M from AB Svensk Exportkredit, which matures in 2016 and was therefore reclassified as a current liability in 2015.

Note 31

Other liabilities, current

GROUP	2015	2014
Liability to Biogen	459,818	—
Liabilities to credit institute	20,000	—
Non-invoiced goods received	25,501	2,074
Other	69,525	46,537
Total	**574,844**	**48,611**

PARENT COMPANY	2015	2014
Liability to Biogen	459,818	—
Liabilities to credit institute	20,000	—
Non-invoiced goods received	25,501	2,074
Other	39,888	28,793
Total	**545,207**	**30,867**

Liability to Biogen pertains to the current portion of the liability described in Note 30.

Liabilities to credit institute pertains to a loan of SEK 20 M from AB Svensk Exportkredit, which was paid in March 2016 and was therefore reclassified as a current liability in 2015.

Note 32

Post-employment benefits

Pension commitments are calculated annually, on the balance-sheet date, based on actuarial principles. Sobi has a defined-benefit 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 of selling expenses, administrative expenses and research and development expenses.

Risks

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 the employees covered by the plan will receive life-long benefits and, accordingly, the 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 and family pensions are insured through Alecta. According to the Financial Reporting Board's statement UFR 10 *Accounting for pension plans in*

ITP 2 financed through insurance with Alecta, this is a defined-benefit plan covering multiple employers. For the 2015 financial year, the company did not have access to information enabling recognition of its proportionate share of the plan's commitments, plan assets or expenses, which meant it has not been possible to recognise 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 20 M (18). 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 the 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 2015, Alecta's surplus in the form of the collective consolidation level was 153 per cent (143).

The Norwegian pension plan is subject to the Norwegian Corporate Pension Act (Foretagspenjonsloven) 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 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 2015	Present value of commitments	Fair value of plan assets	Total
At 1 January	**–41,285**	**28,371**	**–12,915**
Current service cost	–1,473	—	–1,473
Interest expense	–1,047	—	–1,047
Gains/losses on settlements	—	—	—
Revaluations:			
– Return on plan assets, excl. amounts included in interest expense	—	611	611
– Gain/loss from change in demographic assumptions	—	—	—
– Changed financial assumptions	3,924	–35	3,889
– Experience-based assumptions	–1,321	–227	–1,548
Contributions			
– employer	2,029	326	2,355
– settlements	—	–291	–291
Exchange-rate differences	1,299	–455	844
At 31 December	**–37,874**	**28,300**	**–9,576**

1 January–31 December 2014	Present value of commitments	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 expense	—	787	787
– Gain/loss from change in demographic assumptions	—	—	—
– Changed financial assumptions	–5,299	—	–5,299
– Experience-based assumptions	1,960	48	2,008
Contributions			
– employer	1,585	752	2,337
– settlements	—	–190	–190
Exchange-rate differences	65	–140	–75
At 31 December	**–41,285**	**28,371**	**–12,915**

BREAKDOWN OF THE NET OBLIGATION PER COUNTRY	2015	2014
Sweden	–1,704	–4,725
Norway	–7,872	–8,190
Total	**–9,576**	**–12,915**

>> Note 32, cont.

Actuarial assumptions on the balance-sheet date

SWEDISH PENSION PLAN	2015	2014
Discount rate, %	3.3	2.5
Expected annual inflation, %	2.0	2.0
Remaining life expectancy after retirement age, men, years	19.6	19.6
Remaining life expectancy after retirement age, women, years	22.8	22.8

NORWEGIAN PENSION PLAN	2015	2014
Discount rate, %	2.5	3.0
Expected annual inflation, %	1.5	1.5
Remaining life expectancy after retirement age, men, years	21.3	21.3
Remaining life expectancy after retirement age, women, years	24.4	24.4

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 plans, while the K2013 BE mortality table has been used for the Norwegian plan. At the balance-sheet date, Norway had seven active employees and Sweden had one active employee and one retiree. Retirement ages are set at 65 years.

Breakdown of asset class

	2015	Quoted in %	2014	Quoted in %
Shares/equity funds	9,230	100	8,710	100
Interest-bearing securities	11,913	100	12,350	100
Properties	1,070	—	905	—
Other funds	5,898	—	6,279	—
Other	189	—	127	—
Total	**28,300**		**28,371**	

Sensitivity analysis

	2015	2014
Pension commitment under current assumptions	37,874	41,285
Discount rate –0.5%	41,651	45,459
Discount rate +0.5%	34,539	37,604
Inflation +0.5%	39,265	44,374
Inflation –0.5%	34,988	39,228
Life expectancy after retirement –1 year	35,831	39,039
Life expectancy after retirement +1 year	39,344	42,910

The above sensitivity analyses are based on a change in one assumption, while all other assumptions remain constant.

In practice, this is highly unlikely to occur 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 2016 financial year, contributions to plans for remuneration after terminated employment are expected to be SEK 1,056 K (1,371) The weighted average maturity of the commitment is an estimated 36.5 years.

Note 33

Provision for pension commitments

	Group		Parent Company	
	2015	2014	2015	2014
Provision at 1 January	12,915	9,141	—	—
Redemption of defined-benefit pension plan	—	—	—	—
Payments	–984	–190	—	—
Provisions for the year	–2,355	3,964	—	—
Provisions at 31 December	**9,576**	**12,915**	—	—

See also the Consolidated statement of changes in equity, and Note 32.

	Group		Parent Company	
	2015	2014	2015	2014
Non-current	9,576	12,915	—	—
Current	—	—	—	—
Total provisions	**9,576**	**12,915**	—	—

Note 34

Accrued expenses and deferred income

GROUP	2015	2014
Provision for vacation pay and bonuses, incl. social security contributions	193,407	147,492
Accrued social security contributions	60,468	48,523
Accrued royalty expense	17,573	13,783
Discontinuation of Multiferon	9,848	17,100
Accrued manufacturing expenses	27,406	20,257
Accrued R&D expenses	18,088	41,774
Accrued interest expenses	2,561	4,494
Accrued consulting and travel expenses	15,118	7,640
Accrued discounts	148,488	96,671
Accrued expenses for audit and annual report	3,418	5,772
Other accrued expenses	53,493	47,982
Total	**549,868**	**451,488**

PARENT COMPANY	2015	2014
Provision for vacation pay and bonuses, incl. social security contributions	125,997	95,368
Accrued social security contributions	52,700	45,428
Accrued royalty expenses	16,926	11,967
Discontinuation of Multiferon	9,848	17,100
Accrued manufacturing expenses	15,887	14,016
Accrued R&D expenses	18,088	41,774
Accrued interest expenses	2,561	4,056
Accrued consulting and travel expenses	5,659	4,200
Accrued expenses for audit and annual report	1,984	3,935
Other accrued expenses	33,412	35,696
Total	**283,062**	**273,540**

Note 35

Pledged assets

GROUP	2015	2014
Contingent liabilities	200,000	200,000
Total	**200,000**	**200,000**

PARENT COMPANY	2015	2014
Contingent liabilities	200,000	200,000
Guarantee commitment	6,000	6,000
Total	**206,000**	**206,000**

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. The Parent Company has issued limited general guarantees for local credit requirements on behalf of four (four) subsidiaries.

Note 36

Tax and legal disputes

Sobi has no ongoing disputes.

Note 37

Transactions with related parties

A company related to the Chairman of the Board, Orfacare, provides consultancy regarding marketing and distribution from Sobi to Switzerland and Austria. In 2015, consultancy expenses amounted to SEK 1 M (3).

Note 38

Events after the balance-sheet date

Commercial launch of Elocta commenced in the first European countries.

Received commercialisation rights to Relistor, Deflux and Solesta from PharmaSwiss.

European patent granted for Sobi's Orfadin oral suspension.

Chief Medical Officer Birgitte Volck announced her intention to leave Sobi.

Announced clinical development programmes for acute gout and Still's disease, as well as new patent for a new pharmaceutical form of Kineret.

Bo Jesper Hansen announced his decision to step down as Chairman of the Board of Sobi at the 2016 AGM.

Sobi and Biogen received a positive CHMP opinion for Alprolix for the treatment of haemophilia B.

Adjusted purchase price for Elocta.

Refer also to the Directors' Report.

The COMP recommended that Alprolix should maintain orphan designation.

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 24 May 2016 for adoption.

Stockholm, 13 April 2016

Bo Jesper Hansen
Chairman

Matthew Gantz
Board member

Adine Grate Axén
Board member

Hans GCP Schikan
Board member

Helena Saxon
Board member

Lennart Johansson
Board member

Hans Wigzell
Board member

Annette Clancy
Board member

Catarina Larsson
Employee representative

Bo-Gunnar Rosenbrand
Employee representative

Geoffrey McDonough
Chief Executive Officer

Our audit report was submitted on 26 April 2016
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

Success built on a strong corporate culture

The launch of Elocta is a new and important milestone in the development of Sobi. We are now entering the next exciting phase of our development, with a broad and growing portfolio, and a dedicated organisation characterised by a strong corporate culture.

Sobi was founded in early 2010 through the merger of Biovitrum and Swedish Orphan. A merger that looked perfect on paper. Biovitrum's strength in research and manufacturing would be complemented by Swedish Orphan's international marketing organisation and vast business development experience. But a merger is never a simple affair. During the first few years, Sobi suffered from weak profitability and non-existent growth. A range of measures were thus required to improve efficiency and consolidate the operations, and step by step, we have gradually developed the company. The result is a leading, international specialty healthcare company, dedicated to rare diseases. One of the reasons for this success is the strong corporate culture that has emerged within the organisation; through collaboration, responsibility, respect and commitment, patients are always at the forefront of everything we do.

Corporate Governance, in close dialogue

Another success factor is the constructive and open dialogue between the Board and management. In 2015, these discussions were extra intensive, and a Board meeting was held, on average, every two weeks. Transparency and consensus in the work performed by the Board and management have strengthened Sobi in this period of rapid development. During the year, our discussions and decisions have focused on preparations for the launch of Elocta and the possible launch of Alprolix, new research projects, structural matters and the monitoring and decision of new business objectives.

Next phase

In 2015, I have had the privilege of leading a Board with the cutting-edge expertise required to continuously develop Sobi. The most important task for the Board right now is to create the right conditions for management to take Sobi into our next phase of growth. In recent years, a thorough job has been done to build up a haemophilia organisation, while successfully developing other parts of our business. We are now well-equipped to meet future challenges. Not only will Elocta be the largest-ever launch in Sobi's history, we also have the potential to create a completely new approach in the treatment of people with haemophilia. Being able to contribute to such a development is what drives us every day in our work.

The growth in Sobi's market capitalisation from SEK 5 billion at the time of the merger to about SEK 36 billion at year-end is a result of the strong culture that permeates the organisation. Only by creating real value for rare disease patients and their families will we also create shareholder value – and not the other way around.

At the 2016 Annual General Meeting, Bo Jesper Hansen will step down from Sobi's Board of Directors. The Nomination Committee proposes that Håkan Björklund be elected new Chairman of the Board.

Bo Jesper Hansen, Chairman of the Board

"Only by creating real value for raredisease patients and their families will we create shareholder value."

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 Nasdaq Stockholm. In addition to the rules stipulated by law or other statutes, Sobi applies to the Swedish Corporate Governance Code completely. This report pertains to the 2015 financial year, is 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 and the Chairman of the Board. The AGM must be held within six months of the end of the financial year in order to decide on the adoption of the income statement and balance sheet and the appropriation of profits. The AGM also elects the company's auditor. 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 or Solna. 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. Notice of the AGM is published in Post- och Inrikes Tidningar and on the company's website. An announcement that such notice has been given will be published in Svenska Dagbladet.

2015 Annual General Meeting

The 2015 AGM was held on 30 June 2015 in Stockholm. The Meeting was attended by 228 shareholders (203), in person or by proxy, representing about 63 per cent (67) of the total voting rights. Lawyer Eva Hagg was elected as Chairperson of the Meeting.

The minutes and information from the 2015 AGM are available on www.sobi.com.

2016 Annual General Meeting

The AGM will be held on Tuesday, 24 May 2016, at Wallenbergsalen at Kungliga Ingenjörsvetenskapsakademien (IVA), Stockholm, Sweden. For more information about the AGM, see page 133.

Shareholders, share capital, the share and voting rights

At year-end, Sobi's shareholders totalled 21,096 (12,955). Investor AB was the largest shareholder, with 39.6 per cent (39.7) of the share capital and 39.8 per cent (39.8) of the voting rights. The 15 largest shareholders jointly accounted for 71.7 per cent (71.6) of the share capital and 71.6 per cent (71.6) of the voting rights. No owner other than Investor AB has a direct or indirect shareholding that represents at least one-tenth of the voting rights of all shares in the company. Sobi's Articles of Association contain no restrictions on how many votes each shareholder may cast at a general meeting.

The Articles of Association do not contain any specific provisions regarding the appointment and dismissal of Board members or about amending the Articles.

Dividend policy

One of Sobi's most important business objectives is to generate long-term value for shareholders. This value may be in the form of a higher share price and/or dividend payments. When evaluating future divided payments, Sobi's board evaluates a number of factors including:

- Sustained profit trends;
- Expansion opportunities and access to capital;
- Operating risk;
- Effect of dividends on cash and cash equivalents; and
- Equity/assets ratio targets.

For 2015 the Board proposes no dividend. Short-term, the company intends to use profits to finance the continued development and expansion of its operations.

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 law
- Nasdaq Stockholm's rules and regulations
- Swedish Corporate Governance Code

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.

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 on the final banking day of August 2015, 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 observes the rules that apply to Board members' independence under the Swedish Corporate Governance Code. In 2015, the Nomination Committee held three (2014: four) meetings and also maintained contact by telephone. As a basis for its work, the Nomination Committee has taken note of the Chairman's presentation of the Board's work, including an external evaluation of the Board's performance, and a number of Board members were interviewed. The CEO was also interviewed about the development of the company's operations.

The Nomination Committee has prepared proposals to the Annual General Meeting, including proposals for Board members, remuneration to Board and Committee members, proposals for auditors and fees to the auditors and the Chairman for the AGM.

Nomination Committee prior to the 2016 AGM

Name/Represented	Share of votes 31 December 2015	Share of votes 31 August 2015
Petra Hedengren (Chairperson of the Nomination Committee) Investor AB	39.8%	39.8%
Lennart Francke Swedbank Robur Fonder AB	3.5%	3.4%
Tomas Flodén AMF Pension AB	2.2%	3.3%
Bo Jesper Hansen Chairman of Swedish Orphan Biovitrum AB (Publ)	3.3%	3.3%
Total	**48.8%**	**49.8%**

3. Board of Directors/Chairman of the Board

Sobi is a specialty pharmaceutical company, dedicated to marketing, developing and producing pharmaceutical products to treat rare diseases. The product portfolio contains products that are both marketed, and in different phases of clinical and pre-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. 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 CEO, remuneration of 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 the CEO instructions are revised and updated once a year.

Composition of the Board

The Board of the company shall comprise at least three, and not more than twelve, members. During the 2015 financial year, the Board consisted of eight members, all of whom were reelected at the AGM on 30 June 2015, as well as two employee representatives appointed by the trade unions and two deputies. Four of the members, including the employee representatives, were women. For more information about the Board, see pages 124–125.

RESOLUTIONS, 2015 AGM

The following items were resolved at the 2015 AGM:

- Reelection of all Board members
- Reelection of the Board's Chairman, Bo Jesper Hansen
- EY reelected as auditor
- Adoption of remuneration of the Board and auditor
- Approval of the proposed guidelines for remuneration of senior executives
- Discharge from liability for the Board and CEO for the 2014 financial year

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 currently (until April 2016) 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 121 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 four to six times per 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 nine meetings for 2016.

The Board's work in 2015

In 2015, the Board held a total of 24 meetings, of which nine were scheduled and 15 were extra meetings. Sobi's CEO and President, participates in Board meetings, as does Sobi's General Counsel, who has been secretary at the meetings. Other Sobi employees presented reports. The extra Board meetings were motivated by discussions

related to the preliminary and conditional non-binding proposal regarding a possible offer for the company´s shares, proposals for potential collaborations and several matters concerning commercial agreements.

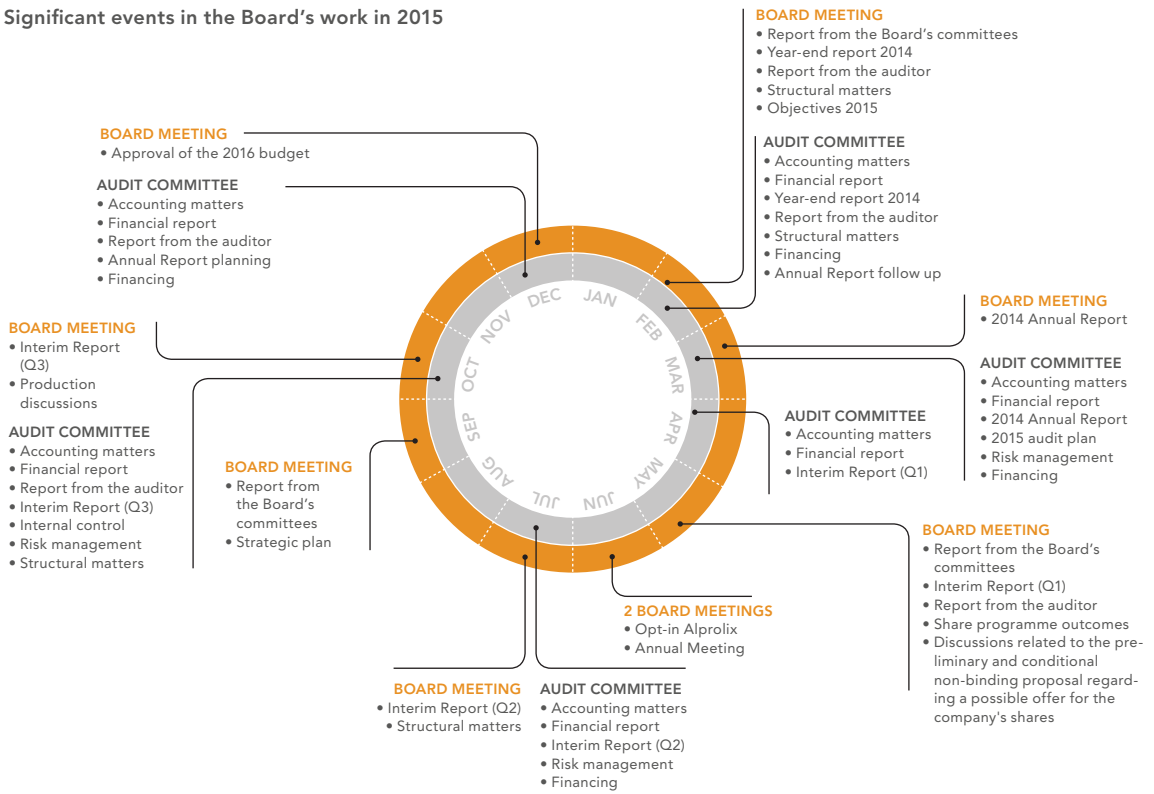
Board fees

The AGM on 30 June 2015 resolved that Board fees for the period until the next AGM would amount to a total of SEK 2,805 K, of which an amount of SEK 335 K would be paid to the AGM-elected Board members, with the exception of Chairman of the Board, who is not entitled to receive any remuneration for his work on the Board or in the Board's committees. For Audit Committee work, the Chairman would receive SEK 100 K and other members SEK 60 K each. For Compensation & Benefits Committee work, the Chairman would receive SEK 60 K, and other members SEK 30 K each. For Scientific Committee work, the Chairman would receive SEK 60 K and the other members SEK 30 K each. In 2015, Board fees totalled SEK 2,712 K,due to the Chairman of the Board not receiving any remuneration for his work in the committees. It was further decided that for each physical Board meeting, an amount of SEK 10 K would be paid to Board members residing in Europe but outside the Nordic region, and SEK 20 K to Board members residing outside Europe.

At the 2015 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, are 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 om the remuneration of Board members, see Note 12 and the table on page 121.

Significant events in the Board's work in 2015



4. Audit Committee

The Committee's main task is to address matters related to the accounting, auditing and financial reporting of the company. Sobi's Audit Committee consists of three members, all of whom are independent of management:

– Lennart Johansson (Chairman)
– Adine Grate Axén
– Helena Saxon

Sobi's CFO, is the Committee's secretary, but not a member. The Committee held six meetings during the year. Sobi's elected auditors attended four of the meetings. The agenda items are presented in the diagram on the left. The attendance and remuneration of the Board members at the Committee meetings are set out in the table on page 121.

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, a proposal for the remuneration of senior executives, and proposals for long-term incentive programmes, pension plans and other matters relating to remuneration of the company's employees. Sobi's Compensation & Benefits Committee consists of three members:

– Bo Jesper Hansen (Chairman)
– Hans GCP Schikan
– Helena Saxon

Hans GCP Schikan and Helena Saxon are independent of management. Sobi's Senior Vice President Human Resources, is the Committee's secretary, but not a member.

The Compensation & Benefits Committee held six meetings during the year. At these meetings, the Committee discussed and monitored annual salary revisions and bonus outcomes for the CEO and senior executives, and proposed guidelines and allocations for the long-term incentive programme. The proposed guidelines for remuneration of the CEO and senior executives will be presented at the AGM in May 2016 for adoption by the shareholders. The Board members' atten-

dance at the Committee meetings is presented in the table below.

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

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. The Scientific Committee consists of four members, three of whom are independent of management:

– Hans Wigzell (Chairman)
– Hans GCP Schikan
– Annette Clancy
– Bo Jesper Hansen

The fourth member, Bo Jesper Hansen, is not independent of management. Sobi's Head of Drug Design and Development, is the Committee's secretary, but not a member. In 2015, the Committee's work involved a strategic review of the company's projects and activities related to lysosomal storage diseases and the company's plans for further development activities around Kineret. The Committee held two meetings in 2015, and all members were present.

7. CEO/Leadership Team

Sobi is organised along a functional organisation and the Leadership Team consists of the CEO and the heads of the most important functions. The Leadership Team is composed of individuals with a broad range of expertise, as well as deep and extensive experience in both research and development, and the production and sales of pharmaceuticals. Members of the Leadership Team also possess the requisite expertise in finance, law, human resources and communication. As of 1 January 2015, the Leadership Team has consisted of ten members, including the CEO. Each year, the Board determines the division of duties between the Board, the Chairman of the Board, and the CEO. 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 CFO, General Counsel and other senior executives present information on matters that require the attention of the Board.

In 2015, the Leadership Team held one meeting every month.

For more information about the Leadership Team, refer to pages 126–127.

Remuneration of senior executives

To attract and retain competent employees, Sobi has established long-term incentive programmes. All employees receive a fixed salary plus 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 000s)						Attendance[1]			
	Independence	Fixed salary/ fees	Audit Committee	Compensation & Benefits Committee	Scientific Committee	Other	Total	Board of Directors	Audit Committee	Compensation & Benefits Committee	Scientific Committee
Bo Jesper Hansen	[2]	—	—	—	—	—	—	19/24	—	6/6	2/2
Hans Wigzell	•	304	—	—	56	—	360	20/24	—	—	2/2
Lennart Johansson	[3]	304	93	—	—	—	398	21/24	6/6	—	—
Helena Saxon	[3]	304	56	28	—	—	388	21/24	6/6	6/6	—
Adine Grate Axén[4]	•	304	56	—	—	50	410	22/24	6/6	—	—
Hans GCP Schikan	•	304	—	28	28	50	410	23/24	—	6/6	2/2
Matthew Gantz	•	304	—	—	—	60	364	22/24	—	—	—
Annette Clancy	•	304	—	—	28	50	382	21/24	—	—	2/2
Catarina Larsson	[5]	—	—	—	—	—	—	24/24	—	—	—
Bo-Gunnar Rosenbrand	[5]	—	—	—	—	—	—	24/24	—	—	—

[1] The figures in the table show total attendance/meetings. In 2015, the Board held a total of 24 meetings, of which nine were scheduled and 15 were extra meetings.
[2] Board member does not qualify as independent to the company and its management.
[3] Board member does not qualify as independent to larger shareholders.
[4] The fee includes Board fees excluding social security contributions. Gross payment to Board member´s company amounted to SEK 539 K, which included remuneration for social security contributions.
[5] Employee representative.

8. Auditors

Sobi's auditor is the auditing firm EY, with Authorised Public Accountant Björn Ohlsson as auditor in charge. EY has been Sobi's auditor since the 2014 AGM, and was elected as auditor until the end of the 2016 AGM. The external auditors discuss the external audit plan and risk management with the Audit Committee. The auditors perform a review of the interim report for the third quarter, and audit the annual accounts and consolidated financial statements. The auditors also express an opinion on whether this Corporate Governance Report has been prepared in accordance with, and whether certain disclosures herein are consistent with, the annual accounts and consolidated financial statements. The auditors report the results of their audit of the annual accounts and consolidated financial statements, their review of the Corporate Governance Report in the auditor's report, and a separate opinion on the Corporate Governance Report, in a presentation to the AGM. In addition, the auditors present detailed findings from their reviews to the Audit Committee three times per year, and to the Board in its entirety once per year.

For information regarding fees for the company's auditors, see Note 13.

Björn Ohlsson
Authorised Public Accountant, EY

Internal control and risk management systems in relation to the financial reporting process

The Board is responsible for internal control in accordance with the Swedish Companies Act and the Swedish Corporate Governance Code. The Board presents the most important elements of Sobi's internal control and risk management systems in relation to the financial reporting process below. In 2015, efforts to streamline and develop procedures in the finance department continued.

The internal control environment at Sobi follows the established COSO Framework, comprising the following five components:

1. Control environment
2. Risk assessment
3. Control activities
4. Information and communication
5. Monitoring activities

1. Control environment

The control environment constitutes the basis of Sobi's internal control. The control environment mainly comprises the culture that defines the tone of the work and communication of the Board and management. 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 the financial reporting process consists of a clear organisational structure, decision-making processes, powers 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 business model, vision, strategies, objectives and values.
- Sobi Code of Conduct & Ethics.
- Organisational structure and descriptions of positions.
- Administrative processes, guidelines and instructions such as powers, authorisation instructions, risk management policy, purchasing and investment policy, security policy, and accounting and reporting instructions.
- Information about the company's ethics and core values, expertise issues and the regulatory 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 possible to;

- Identify and create action plans for risks that may impact the defined objectives in relation to the financial reporting process.
- 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 2015 included monitoring the units' work with process-based control, monitoring and reporting on internal governance and control. Risk management is reported quarterly to the 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 aim of the control activities is to prevent and detect errors and irregularities, and to propose subsequent corrective actions should any such irregularities occur. 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 on 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 information services relating to financial reporting. Effective communication is important for all employees in the company. 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 communication of important information to the market, a Disclosure Committee has been established, comprising the CEO, CFO, COO, General Counsel, Chief Patient Access Officer and Head of Communications.

Financial information is presented regularly in the form of:

- Full-year and interim reports;
- The Annual Report;
- Press releases about important news and events that could significantly affect the valuation of the company and the share price;
- Presentations and teleconferences for financial analysts, investors and the media on the day of publication of full-year and interim reports, and in conjunction with the publication 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. Monitoring activities

The Board and the Audit Committee decide on the forms of monitoring activities 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.

Activities 2015

– Update of current ERP system in the Parent Company.
– Introduction of the same ERP system in all subsidiaries.
– Centralisation of bank administration powers and reduction in the number of banks.

Activities in focus in 2016

– ERP system follow-up.
– Working plan for internal control.

Breaches

The company has not breached any of the regulations on the stock exchange on which its shares are traded, or acted contrary to generally accepted practices on the stock market.

Auditors' report on the Corporate Governance Statement

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

Engagement and responsibility

We have examined the Corporate Governance Report for 2015 on pages 118–123. The Board of Directors is responsible for the Corporate Governance Report and that it is prepared in accordance with the Swedish 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 the RevU 16 auditing standard, The auditors' examination of the Corporate Governance Report. That means 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 Report has been prepared and is consistent with the annual accounts and the consolidated accounts.

Stockholm, 26 April 2016
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

Board of Directors

BO JESPER HANSEN

Born 1958.
Chairman and Board member since 2010.
MD with a PhD from Copenhagen University.

Other assignments: Board member of GenSpera, Inc., Newron Pharmaceuticals SpA, Orphazyme ApS, CMC AB, Azanta A/S, Karolinska Development AB and Ablynx NV.

Previous assignments: Various positions in Swedish Orphan International AB since 1993, including CEO. 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 from Princeton University and MBA from Harvard Business School.

Other assignments: Executive Vice President of BTG.

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

Shares: 0

ADINE GRATE AXÉN

Born 1961.
Board member since 2010.
MBA, Stockholm School of Economics. Harvard AMP.

Other assignments: Board member of Sky 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.

Shares: 32,000

LENNART JOHANSSON

Born 1955.
Board member since 2010.
MBA, Stockholm School of Economics.

Other assignments: Member of the management team and Senior Advisor in Patricia Industries (a division of Investor AB). Board member of Hi3G, Chairman of the Board of Vectura AB and deputy Board member of Mölnlycke Health Care.

Previous assignments: CEO of b-business partners and Emerging Technologies AB. Board member of SAAB AB, IBX Group AB, Gambro Holding AB. Member of Investor AB management team.

Shares: 20,000

HELENA SAXON

Born 1970.
Board member since 2011.
MBA, Stockholm School of Economics.

Other assignments: CFO of Investor AB.

Previous assignments: CFO of Hallvarsson & Halvarsson, Vice President of Investor AB and financial analyst at Goldman Sachs. Board member of Aleris, Gambro and Mölnlycke Health Care.

Shares: 15,500

HANS GCP SCHIKAN

Born 1958.
Board member since 2011.
PharmD, Utrecht University.

Other assignments: Chairman of the Board of Asceneuron in Switzerland, InteRNA in the Netherlands and Complix in Belgium. Board member of Hansa Medical and Wilson Therapeutics in Sweden, and the Dutch Top Sector Life Sciences & Health in the Netherlands. Advisor to various organisations in the Life Science sector.

Previous assignments: CEO of Prosensa and member of Prosensa's Supervisory Board. Board member of Top Institute Pharma. Chairman of Nefarma, the association for innovative medicines in the Netherlands, and a number of senior positions in the former Organon and Genzyme.

Shares: 4,000

HANS WIGZELL

Born 1938.
Board member since 2005.
MD and Professor emeritus of immunology.

Other assignments: Chairman of the Board of Rhenman & Partners Asset Management AB and Cadila Pharmaceuticals Svenska AB. Board member of Karolinska Development AB (publ), RaySearch Laboratories AB (publ), Valneva SE (publ), Sarepta Therapeutics, Inc. (publ) and AB Wigzellproduktion. Member of the Royal Swedish Academy of Sciences, and the Royal Swedish Academy of Engineering Sciences.

Previous 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.
BSc Pharmacology from Bath University, UK.

Other assignments: Chairman and Board member of three private European biotechnology companies; Genable SA, Obseva SA and 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.

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: 1,561

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: 4,986[1]

BJÖRN OHLSSON

Authorised Public Accountant
Ernst & Young AB

[1] Includes shareholdings of related physical and legal entities.

Executive Leadership Team

GEOFFREY MCDONOUGH

Born 1970.

Chief Executive Officer.

Employed since 2011.

MD, Harvard Medical School, US, BSc Biology and BA Philosophy from University of North Carolina, US.

Other assignments: Board member of Zafgen and PTC Therapeutics.

Previous positions: Senior positions in Genzyme Corporation since 2002, most recently as the CEO for Europe, Middle East and Africa. SVP and General Manager, Personalized Genetic Health, Global Business Leader, LSD Therapeutics, US. Prior to Genzyme, he also worked as an internist and paediatrician in the US.

Shares: 774,923

MATS-OLOF WALLIN

Born 1951.

Senior Vice President, Chief Financial Officer.

Employed since 2013.

BSc from Uppsala University, Sweden.

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.

Shares: 20,945

ALAN RAFFENSPERGER

Born 1960.

Senior Vice President, Chief Operating Officer.

Employed since 2012.

BSc 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, General Manager of the Nordic and Baltic Region at Amgen. Sales and Marketing Director at Roche Pharmaceuticals, Sweden, Vice President, Global Marketing Diabetes Care at Roche Diagnostics. Business Director Europe, Diabetes Care at Boehringer Mannheim. Senior positions at Pharmacia in Sweden and the US.

Shares: 105,002

WILLS HUGHES-WILSON

Born 1971.

Senior Vice President, Chief Patient Access Officer.

Employed since 2012.

LLB (Hons) from the University of Durham, UK.

Previous positions: Vice President Health/Market Access Policy EMEA at Genzyme Corporation. 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 association, and Ernst & Young Consulting.

Shares: 74,675[1]

BIRGITTE VOLCK

Born 1962.

Senior Vice President, Chief Medical Officer.

Employed since 2012.

MD, PhD, University of Copenhagen, Denmark.

Previous positions: Various senior positions at Amgen, most recently as Executive Development Director of Bone, Neuroscience & Inflammation, International R&D at Amgen Limited in Uxbridge, UK. Nordic Medical Director & Project Director at Genzyme A/S in Denmark, and Vice President, Clinical Development & Medical Affairs at Pharmexa A/S in Denmark. Prior to this, a number of clinical and scientific positions at Copenhagen University Hospital.

Shares: 109,159

DENNIS SCHMIDT 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. Leading positions in international companies including Genzyme, Ferring Pharmaceuticals and A.P. Møller-Mærsk.

Shares: 8,018

STEFAN FRAENKEL

Born 1972.

Senior Vice President, Head of Corporate Development

Employed since 2009.

PhD in International Accounting and Management, MBA from the Copenhagen Business School, Denmark and an engineering degree from Chalmers University of Technology, Sweden.

Other assignments: Board member of Akinion Pharmaceuticals.

Previous positions: Business development at Wyeth. Prior to this, he worked as a management consultant.

Shares: 15,263[1]

FREDRIK BERG

Born 1955.

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

Employed since 2001.

LLM from Stockholm University, Sweden.

Previous positions: Head of Legal/Intellectual Property at Pharmacia AB and General Counsel for Pharmacia Europe, Middle East and Africa. Law firm Lindahl. Legal Counsel and various management positions in the legal departments of KabiVitrum, Procordia, Kabi Pharmacia and Pharmacia & Upjohn. Law firm Tisell & Co.

Shares: 22,661

STEPHEN JAMES

Born 1966.

Vice President, Head of Drug Design & Development

Employed since 2001.

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

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

Shares: 15,524

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.

Other assignments: Board member of Processindustriell IT and Automation (PiiA).

Previous positions: Factory Director, Biologics Manufacturing, Managing Director at Pfizer Health AB and Board member of Pfizer Health AB. Director of Quality Operations, Pfizer, AstraZeneca.

Shares: 1,292

[1] Includes shareholdings of related physical and legal entities.

Auditors' report

To the annual meeting 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 2015. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 64–116.

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 judgment, 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 the accounting policies used and the reasonableness of the 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 2015 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 2015 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.

We therefore recommend that the Annual General Meeting adopt the income statement of the Parent Company, the statement of comprehensive income of the Group and the balance sheets of the Parent Company and the Group.

Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the CEO of Swedish Orphan Biovitrum AB (publ) for 2015.

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, 26 April 2016
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

Global Reporting Initiative Index 2015

Specific disclosures – 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 its sustainability efforts on an annual basis, as part of the Annual Report. Sobi prepares its Sustainability Report in accordance with the Core option of the latest GRI sustainability reporting guidelines, G4. The indicators below have been selected on the basis of a materiality analysis, which is further described on pages 22–23 of the Annual Report. The indicator overview above lists the GRI indicators that have been applied to reflect the aspects and topics considered most significant for Sobi. All page references below refer to pages in Sobi's 2015 Annual Report or at www.sobi.com

● = Fully reported ◐ = Partially reported

Standard disclosures		Page references	Reported	Comment
Strategy and analysis				
G4-1	CEO's statement	8–9, www.sobi.com	●	
G4-2	A description of key impacts, risks and opportunities	28–29, 70–72	●	
Organisational profile				
G4-3	Name of the organisation	83	●	
G4-4	Primary brands, products and services	2–3, 30–31	●	
G4-5	Location of organisation's headquarters	83		
G4-6	Countries where the organisation operates	3, 20–21, 95, 108	●	
G4-7	Nature of ownership and legal form	56–58, 83	●	
G4-8	Markets served	2–3, 5, 12–15, 20–21	●	
G4-9	Scale of the organisation	69, 73–74, 95	●	
G4-10	Total workforce by employment type, contract, region and gender	95	●	
G4-11	Percentage of employees covered by collective bargaining agreements		●	All employees in the Swedish operations (representing approximately 57 per cent of Sobi's employees) are covered by collective bargaining agreements.
G4-12	Describe the organisations' supply chain	24	●	
G4-13	Significant changes during the reporting period	6–7	●	
G4-14	Whether and how the precautionary approach is applied	28–29, 70–72	●	Risk management is integrated into all strategic and operational work. There is a special procedure for the handling of hazardous chemicals, which describes the risks are identified, assessed and managed, including how the precautionary principle should be addressed.
G4-15	Endorsement of external charters, principles or initiatives	22–24, 70–72	●	Sobi complies with the new European requirements on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and organisations. Sobi's clinical programmes and testing follow the ethical principles of the Declaration of Helsinki, the PhRMA & EFPIA's "Principles for Responsible Clinical Trial Data Sharing" and the EMA Policy on publication of clinical data, which entered into force on 1 January 2015. Sobi applies industry-specific codes of conduct (LIF and EFPIA).
G4-16	Memberships in associations	www.sobi.com	●	
Identified material aspects and boundaries				
G4-17	Organisational structure	118, 124–127	●	
G4-18	Process for defining report content	22–24	●	

Standard disclosures		Page references	Reported	Comments
G4-19	Material aspects identified in the process for defining report content	22–24	●	
G4-20	Aspect Boundaries within the organisation		●	Indicators cover all of Sobi's operations.
G4-21	Aspect Boundaries outside the organisation	22–24	●	
G4-22	Explanation of the effect of any re-statements of information provided in previous reports		●	There have been no re-statements of information since previous reports.
G4-23	Significant changes from previous reporting periods in the Scope and Aspect Boundaries		●	There have been no relevant changes in the Scope and Aspect Boundaries since previous reporting periods.
Stakeholder engagement				
G4-24	List of stakeholder groups	12–14	●	
G4-25	Basis for identification and selection of stakeholders with whom to engage	12–14, 22–24	●	
G4-26	Approach to stakeholder engagement	12–13, 22–24	●	
G4-27	Key topics and concerns raised through stakeholder engagement	12–13, 22–24, 25, 39	●	
Report profile				
G4-28	Reporting period		●	Calendar year 2015
G4-29	Date of most recent previous report		●	April 2014
G4-30	Reporting cycle		●	Annually
G4-31	Contact point for questions regarding the report		●	Oskar Bosson, Head of Communications, oskar.bosson@sobi.com

Standard disclosures		Page references	Reported	Comments
G4-32	Table showing where information about all parts of the Standard Disclosures can be found	129–132	●	
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.
Governance				
G4-34	Governance structure	118	●	
Ethics and integrity				
G4-56	Values, principles, standards and norms of behaviour	16, 18–19, 22–29, 69 www.sobi.com	●	Sobi's Code of Conduct and Ethics is available on www.sobi.com.

Indicators related to material aspects		Page references	Reported	Comments
ECONOMIC				
Indirect economic impacts				
Management approach		22–24, www.sobi.com	◐	
G4-EC8	Significant indirect economic impacts	14, 23, 25, 70–72, 88–90	●	Donation to the World Federation of Hemophilia
SOCIAL				
LABOUR PRACTICES AND WORKING CONDITIONS				
Employment				
Management approach		26–29, 70–72	●	
G4-LA1	Rate of employee turnover by age group, gender and region	95	◐	

Indicators related to material aspects		Page references	Reported	Comments
Occupational health and safety				
Management approach		28–29, 70–72	●	
G4-LA6	Rates of injury, occupational diseases, lost days, absenteeism and total number of work-related fatalities, by region and by gender			In 2015, fifteen incidents were reported, none of which led to sick leave.
Training and education				
Management approach		26–27	●	
G4-LA11	Employees receiving regular performance and career development reviews, by region and by gender	26–27	●	
Diversity and equal opportunity				
Management approach		26–27	◐	
G4-LA12	Composition of governance bodies and employees according to diversity indicators	27, 95, 124–127	◐	
SOCIETY				
Anti-corruption				
Management approach		24 www.sobi.com	●	
G4-SO4	Communication and training on anti-corruption policies and procedures	24, 122–123	●	Issues related to anti-corruption are regulated in Sobi's Code of Conduct and Ethics and Global Policy on Anti-corruption. In Sweden, Sobi is a member of the Swedish Association of the Pharmaceutical Industry (LIF), and follows their "Ethical Rules for the Pharmaceutical Industry." These guidelines include specific rules 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 Pharmaceutical Marketing. 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		●	In 2014, no cases of corruption involving Sobi or Sobi's employees were brought to the attention of the company's management.
Compliance				
Management approach		22–24, www.sobi.com	●	
G4-SO8	Significant fines and total number of non-monetary sanctions for non compliance with laws and regulations		●	During 2014 Sobi has not identified any non-compliance with laws and regulations, which possibly could have led to fines or non-monetary sanctions.

Indicators related to material aspects		Page references	Reported	Comments
PRODUCT RESPONSIBILITY				
Customer health and safety				
Management approach		12–13, 22–29 www.sobi.com	●	
G4-PR1	Percentage of significant product and service categories for which health and safety impacts are assessed for improvement	12–13, 16, 32–35	●	
G4-PR2	Incidents of non-compliance with regulations concerning health and safety impacts of products		●	In 2015, Sobi did not identify any non-compliance with laws, regulations or voluntary codes concerning the health and safety impacts of its products.
Products and services labeling				
Management approach		22–24, www.sobi.com	●	
G4-PR4	Incidents of non-compliance with regulations and voluntary codes concerning product and service information and labeling		●	In 2015, Sobi did not identify 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 budget holders, 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 related to material aspects		Page references	Reported	Comments
Marketing communications				
Management approach		22–24, www.sobi.com	●	
G4-PR7	Incidents of non-compliance with regulations and voluntary codes concerning marketing communications, including advertising, promotion, and sponsorship		●	In 2015, Sobi did not identify any non-compliance with laws, regulations or voluntary codes concerning promotion of its products.
Compliance				
Management approach		22–24, www.sobi.com	●	
G4-PR9	Significant fines for non-compliance with laws and regulations concerning the provision and use of products and services		●	In 2015, Sobi did not identify any non-compliance with laws, regulations or voluntary codes concerning the provision and use of its products.

2016 Annual General Meeting

2016 Annual General Meeting

Swedish Orphan Biovitrum AB (publ) will hold its Annual General Meeting on Tuesday, 24 May 2016 in Wallenbergsalen at Kungliga Ingenjörsvetenskapsakademien (IVA), Grev Turegatan 16, Stockholm, Sweden.

To participate

Shareholders who wish to participate in the Meeting must be recorded in the share register maintained by Euroclear Sweden AB on Wednesday, 18 May 2016. Shareholders must notify the company of their intention to participate no later than Wednesday, 18 May 2016 in one of the following ways:

- Visiting Sobi's website: www.sobi.com
- By phone: +46 (0)8-697 34 27
- By mail: Swedish Orphan Biovitrum AB (publ), Annual General Meeting, SE-112 76 Stockholm, Sweden

The notification should include the shareholder's:

- Name
- Personal/corporate identity
- 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 Annual 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, 18 May 2016. 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.

Proxy

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 2016

January–March Interim Report	27 April 2016
Annual General Meeting	24 May 2016
January–June Interim Report	15 July 2016
January–September Interim Report	27 October 2016

The Annual Report can be downloaded in PDF format from www.sobi.com, as well as previous annual reports, interim reports and press releases.

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Definitions

Capital employed
Total assets less non-interest-bearing liabilities.

Cash flow per share
Changes in cash and cash equivalents divided by the weighted average number of outstanding shares.

Debt-to equity ratio
Relative proportion of shareholders equity and debt used to finance the company's assets.

Earnings per share
Profit/loss divided by the average number of shares.

EBIT
Earnings before interest and tax (Operating income).

EBITA
Earnings before interest, tax and amortisation.

EBITDA
Earnings before interest, tax, depreciation and amortisation.

Equity per share
Equity divided by the number of shares.

Equity ratio
Total assets divided by equity.

Full-time equivalent (FTE)
A unit that indicates the number of hours worked by an employee on a full-time basis, used to make workloads comparable across various contexts.

Gross margin
Gross profit as a percentage of sales.

Gross profit
Operating revenues less cost of goods and services sold.

Net debt
Interest-bearing non-current and short-term liabilities minus cash and bank balances.

Non-recurring items
Non-recurring items are defined as transactions of a non-recurring nature.

Profit/loss
Profit/loss for the period.

Return on capital employed
Earnings Before Interest and Tax (EBIT)/Capital Employed.

Return on equity
Profit/loss after tax as a percentage of average equity.

Return on total capital
Profit/loss after financial items plus financial expenses as a percentage of average total assets.

Glossary

Alprolix
Alprolix (eftrenonacog alfa) is a recombinant, extended half-life clotting factor therapy under development for people with haemophilia B. Alprolix is the first recombinant, clotting factor therapy with prolonged circulation in the body, that has been approved for adults and children with haemophilia B in the US, Canada, Australia, New Zealand and Japan. A marketing authorisation application for Alprolix in EU was submitted to the EMA in June 2015.

Biopharmaceutical
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 (EMA).

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.

EHL
Extended half-life.

EHC
European Haemophilia Consortium, a non-profit organisation representing national patient organisations of people with rare bleeding disorders in Europe.

Elocta
Elocta (efmoroctocog alfa) is the first recombinant, clotting factor VIII therapy with prolonged circulation in the body. The product is approved in the EU for the treatment and prophylaxis of bleeding episodes in patients with haemophilia A (factor VIII deficiency) and can be used by people of all ages.

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 rare, genetic disorder in which the ability of a person's blood to clot is impaired. Haemophilia A occurs in about one in 5,000 male births annually, and haemophilia B occurs in about one in 25,000 male births annually. Both occur more rarely in females. People with haemophilia experience bleeding episodes that may cause pain, irreversible joint damage and life-threatening haemorrhages.

HT-1
Hereditary tyrosinaemia type 1 (HT-1) is a rare genetic disorder that can cause liver failure, kidney dysfunction and neurological problems and can be fatal if left untreated.

HTA
Health technology assessment is the systematic evaluation of the properties and effects of a health technology.

IFRIC
International Financial Reporting Interpretations Committé.

IL-1
Interleukin-1 (IL-1) is a key mediator of inflammation and driver of autoinflammatory diseases.

Kineret
Kineret (Anakinra) is a drug used to treat inflammatory diseases.

MAA
Marketing authorisation application, an EU-application for approval to market a medical product.

MAH
Marketing authorisation holder, the company in whose name the marketing authorisation has been granted and who is responsible for all aspects of the product.

MPS IIIA
Sanfilippo syndrome (MPS IIIA) is a genetic disorder that belongs to a group of metabolic disorders known as mucopolysaccharidoses (MPS diseases). These are rare metabolic disorders caused by the absence of various lysosomal enzymes, which are needed to break down various molecules in the body. MPS IIIA causes the substance sulfamidase that is normally broken down by the enzyme to accumulate in the body and damage the organs. MPS IIIA can be fatal.

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. A request for treatment intended for patients with a life threatening, chronic or seriously debilitating disease, where there is no other satisfactory treatment option with medicinal products authorised in their country.

Orfadin
Orfadin (nitisinone) is a drug used to treat hereditary tyrosinaemia type 1 (HT1-).

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.

Still's disease
Still's disease is an autoinflammatory disease that affects both children and adults, and is characterised by persistent high spiking fevers, recurring rashes and arthritis. Still's disease is also known as systemic-onset juvenile idiopathic arthritis (SJIA) or adult-onset Still's disease (AOSD).

UCD
Urea cycle disorders are 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.

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.

WFH
World Federation of Hemophilia, an international not-for-profit organisation.

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